Virginia Department of Agriculture and Consumer Services

Food Safety Program

FIELD OPERATIONS MANUAL

Table of Contents

SECTION I. **ADMINISTRATIVE**

Procedure Number	**Procedure Name**	**Date**
Procedure I-00	Compliance and Enforcement & Inspection Classification	Revised 11/15/16
Procedure I-01	Inspector Safety	Revised 1/19/16
Procedure I-02	Transition from FSS to FSS Senior	New 7/21/16
Procedure I-03	Use of Official State Credentials	Revised 7/1/99
Procedure I-04	Refusal to Permit Entry, Inspection, or Sampling	Revised 5/1/09
Procedure I-05	State Cell Phone	Revised 7/15/10
Procedure I-06	Computer Software and Paperwork Submission Criteria	Revised 7/25/17
Procedure I-07	Use of the Inspection Report	Revised 12/13/99
Procedure I-08	Records Necessary for Ownership Changes	Revised 8/22/02
Procedure I-09	Digital Camera—Use & Mounting of Photographs	Revised 3/19/14
Procedure I-10	Computer Care and Maintenance	Revised 1/19/16
Procedure I-11	Farmers Markets	Revised 6/15/06
Procedure I-12	Dress Code	Revised 12/2/15
Procedure I-13	Email use and Etiquette	Revised 1/19/00
Procedure I-14	Inclement Weather Policy	Revised 3/5/15
Procedure I-15	OPEN-RESERVED FOR FUTURE USE	
Procedure I-16	Work Schedule	Revised 5/1/09
Procedure I-17	Timesheet Instructions	Revised 3/05/15
Procedure I-18	Preparation for Court	New 2/9/01
Procedure I-19	Operation of a State Vehicle	Revised 6/11/14
Procedure I-20	Employee Conduct	New 8/1/01
Procedure I-21	Contact with the Media	Revised 3/11/16
Procedure I-22	OPEN-RESERVED FOR FUTURE USE	
Procedure I-23	VDACS Food Safety Program Training Manual	Revised 8/4/17
Procedure I-24	Continuing Education	New 2/12/15
Procedure I-25	Work Day Standard	Revised 4/22/14
Procedure I-26	OPEN-RESERVED FOR FUTURE USE	
Procedure I-27	Expense Reimbursement Vouchers	Revised 11/20/14
Procedure I-28	OPEN-RESERVED FOR FUTURE USE	
Procedure I-29	OPEN-RESERVED FOR FUTURE USE	

SECTION II. **RAPID RESPONSE TEAM**

Procedure Number	Procedure Name	Date
Procedure II-01	Foodborne Illness Complaint Investigations	Revised 6/22/16
Procedure II-02	Suspected Tampering & Bioterrorism Investigations	Revised 3/13/15
Procedure II-03	Guide to Conducting GMP Inspection Audits	New 10/1/15
Procedure II-04	OPEN-RESERVED FOR FUTURE USE	
Procedure II-05	Equipment Verification/Calibration	New 3/12/15
Procedure II-06	Product Recall	New 3/11/15
Procedure II-07	Recall Audit Check	Revised 12/29/16
Procedure II-08	Traceback/Traceforward Investigation	Revised 12/29/16
Procedure II-09	Communications Plan	Revised 4/30/15
Procedure II-10	After Action Report/Improvement Plan	New 11/18/14
Procedure II-11	RRT Media Policy	New 4/29/16
Procedure II-12	OPEN-RESERVED FOR FUTURE USE	
Procedure II-13	OPEN-RESERVED FOR FUTURE USE	
Procedure II-14	OPEN-RESERVED FOR FUTURE USE	
Procedure II-15	OPEN-RESERVED FOR FUTURE USE	

SECTION III. **INSPECTIONS & INVESTIGATIONS**

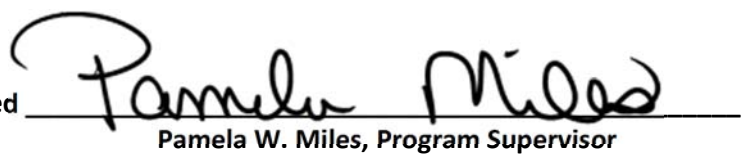
Procedure Number	Procedure Name	Date
Procedure III-01	Seafood HACCP Inspections	Revised 7/23/10
Procedure III-02	In Home Food Manufacturing Operations	Revised 3/7/02
Procedure III-03	Seafood Peddlers	Revised 12/6/10
Procedure III-04	Swollen Cans	Revised 11/17/99
Procedure III-05	Retail Store Inspection Criteria	Revised 11/17/99
Procedure III-06	Vacuum Packaging Systems in Retail Establishments	Revised 12/2/05
Procedure III-07	Retail Apple Inspection	Revised 4/5/00
Procedure III-08	Hot and Cold Holding Temperatures	Revised 8/19/10
Procedure III-09	Self-Serve Potentially Hazardous Foods	Revised 7/3/03
Procedure III-10	Mushrooms, Cultivated and Wild Harvested	New 7/21/16
Procedure III-11	Risk-Based Approach to Territory Management	Revised 9/7/17
Procedure III-12	Foods, Including Pies, Acceptable for Unrefrigerated Display	Revised 1/31/00
Procedure III-13	Expiration Dates	Revised 6/15/12
Procedure III-14	Retail Egg Inspection	Revised 5-15-02
Procedure III-15	Game Animals & Non Amenable Species	New 3/30/15
Procedure III-16	Preliminary Inspections of Proposed Water Bottling Sites	Revised 9/25/07
Procedure III-17	Seizure and Release Forms	Revised 6/2/14
Procedure III-18	Inspections of Firms Handling Allergenic Ingredients	New 3/7/02
Procedure III-19	Food Labeling Guide	New 3/7/02

Procedure III-20	Nutritional Labeling (NLEA) Guide	New 3/7/02
Procedure III-21	Food Manufacturing Inspection Procedures	Revised 12/30/16
Procedure III-22	Inspection of Sprout Processors	New 7/2/03
Procedure III-23	Dietary Supplements	New 7/18/03
Procedure III-24	Nonprofit Organizations Holding One Day Food Sales	Revised 11/30/04
Procedure III-25	Use of the Blacklight in Identifying Rodent Activity	New 6/2/04
Procedure III-26	Pre-packaged Food Exemption	New 11/2/04
Procedure III-27	Jurisdictional Issues	Revised 5/10/12
Procedure III-28	Inspection of Community Canneries	New 7/18/05
Procedure III-29	Home Kitchen Exemption	New 7/8/08
Procedure III-30	Employee Health Policy	New 9/22/08
Procedure III-31	Demonstration of Knowledge (Retail Establishment PIC)	Revised 6/10/16
Procedure III-32	Equipment Sink Requirements	New 1/1/09
Procedure III-33	Smoking Restrictions in Retail Food Stores	New 12/1/09
Procedure III-34	Variance Procedures	Revised 6/2/14
Procedure III-35	On-Site Corrections in Retail Establishments	Revised 9/7/17
Procedure III-36	Long Term Compliance in Retail Food Establishments	New 6/2/14
Procedure III-37	Initial Validation of a HACCP Plan	New 6/2/14
Procedure III-38	On-Site Verification of HACCP Plans	New 6/2/14
Procedure III-39	Consumer Complaint Investigations (general guidelines)	Revised 4/3/15
Procedure III-40	Food Service Inspections of Wineries Meaderies Cideries	New 12/15/15
Procedure III-41	Food Service Inspections of Breweries and Distilleries	New 12/11/15
Procedure III-42	Inspection of Community Kitchens	Revised 7/12/16
Procedure III-43	OPEN-RESERVED FOR FUTURE USE	
Procedure III-44	OPEN-RESERVED FOR FUTURE USE	
Procedure III-45	OPEN-RESERVED FOR FUTURE USE	

SECTION IV. **SAMPLING**

Procedure Number	**Procedure Name**	**Date**
Procedure IV-01	VDACS Sampling Procedures	Revised 8/22/17
Procedure IV-02	OPEN-RESERVED FOR FUTURE USE	

The procedures in this manual are provided to insure consistency and guidance throughout the Commonwealth of Virginia in our Food Safety Program. Additional memorandums and notices (emails) may be inserted in the section pertaining to the subject until such time the specific procedure is modified or added. This manual is subject to change and input from field personnel is strongly encouraged. By my signature below I certify that all procedures are current.

Approved  **Date:** 9/22/17

Pamela W. Miles, Program Supervisor

3

Procedure I-00: Compliance and Enforcement & Inspection Classification

The Food Safety program is charged with ensuring the food supply is safe and wholesome. The program accomplishes its goal through a risk-based inspection of retail food stores, food and dietary supplement manufacturers, and warehouses. The program partners with industry with the expectation that compliance will be accomplished voluntarily. To facilitate this effort, an inspection classification system is used to indicate the food safety condition and degree of compliance for each establishment. These classifications, explained below, are used to determine the need for regulatory action. The classification system is supported by four pillars: 1) Virginia Law (the Virginia Food Laws); 2) Adopted Federal Regulations (21 CFR Parts 100-190); 3) The Retail Food Establishment Regulations (based on the FDA model Food Code); and 4) The professional training and standardization of Food Safety Specialists (FSS). Three basic classifications are used to identify the food safety condition of food establishments, they are NAI (no action indicated), VAI (voluntary action indicated), and OAI (official action indicated).

Inspection classification criteria are numerous and may be broad in scope. The major factors taken into consideration when determining inspection classifications are:

- Risk assessments
- Number of violations
- Type of violations
- Public health significance of violations
- Compliance history

NAI- NO ACTION INDICATED - Establishment has violations that do not require a physical follow up inspection by the FSS. The firm is considered by the Inspector to be in **substantial compliance** with the Virginia Food Laws and applicable regulations. Next routine inspection: 6-36 months, based on risk. Routine Letters of Information may be recommended by the FSS. Exhibits of routine correspondence are included in the appendix.

VAI - VOLUNTARY ACTION INDICATED – Violations were found during the inspection that may support official action. Regulatory action may result if conditions are not resolved. This is a **monitoring status**. A follow up inspection is performed within 90 calendar days of the date of the inspection or sooner, based on risk. VIPRS automatically calculates the date of the follow up inspection as 90 calendar days after the date of the inspection however the Food Safety Specialist may change the date to earlier than 90 calendar days if they believe the conditions at the firm warrant a follow up inspection sooner. The Regional Manager also has the authority to change the follow up date if they feel a follow up inspection should be conducted sooner. The follow up inspection must be completed on or prior to the date scheduled in VIPRS. If the follow up date occurs on a weekend or holiday, the follow up must be completed prior to the date scheduled in VIPRS. Routine Letters of Information may be recommended by the FSS.

OAI - OFFICIAL ACTION INDICATED – Violations are critical and/or pose an immediate public health risk. Conditions may support criminal charges. A follow up inspection is performed within 42 calendar days of the date of the inspection or sooner, based on risk. VIPRS automatically calculates the date of the follow up inspection as 42 calendar days after the date of the inspection however the Food Safety Specialist may change the date to earlier than 42 calendar days if they believe the conditions at the firm warrant a follow up inspection sooner. The Regional Manager also has the authority to change the follow up date if they feel a follow up inspection should be conducted sooner. The follow up inspection must be completed on or prior to the date scheduled in VIPRS. If the follow up date occurs on a weekend or holiday, the follow up must be completed prior to the date scheduled in VIPRS. Letters of Warning or formal hearings may be recommended by the FSS.

Letters of Information. These letters have been developed as a means of educating firms on specific topics relevant to food safety when inspectional findings indicate violations that do not pose an immediate public health risk. They may be used to: 1) assist otherwise compliant firms to come into voluntary compliance on a specific issue of public health interest; 2) inform chronic violators of measures needed to maintain an acceptable compliance history; and/or 3) to provide a record of interaction for further compliance and enforcement actions. The issuance of a Letter of Information is recommended by the FSS by selecting the requested letter in the inspection screen in VIPRS. This request is approved by the Regional Manager when they review the inspection in VIPRS. All letters are sent to the firm by the Regional Office (the Regional Manager, designee, or Administrative Assistant). The Regional Office (either the Regional Manager, designee, or Administrative Assistant) shall send a scanned copy of the letter via email to the Food Safety Specialist on the day the letter is mailed and a copy shall be placed in the appropriate folder on the LAN. Informational letters shall be sent to the firm within 10 working days of the inspection being reviewed by the manager.

Letter of Warning. An initial OAI inspection classification usually results in the firm being sent a Letter of Warning. The issuance of a Letter of Warning is recommended by the FSS by selecting the requested letter in the inspection screen in VIPRS. This request is approved by the Regional Manager when they review the inspection in VIPRS. All letters are sent to the firm by the Regional Office (the Regional Manager, designee, or Administrative Assistant). The Regional Office (either the Regional Manager, designee, or Administrative Assistant) shall send a scanned copy of the letter via email to the Food Safety Specialist on the day the letter is mailed and a copy shall be placed in the appropriate place on the LAN. A Regional Manager may forego sending a Letter of Warning for OAI inspection findings when correction of the violative condition is expected expeditiously as documented by the FSS. However a follow up inspection shall still be conducted within 42 calendar days of the date of the inspection as stated above. Letters of warning shall be sent to the firm within 5 working days of the inspection being reviewed by the manager.

Field Hearings. Should follow inspection of an OAI-classified firm note a lack of substantial improvement, the Regional Manager may opt to send a *Field Hearing, 10-day Written Response Required* letter to the firm that requests documentary evidence of the firm's plan to correct violative conditions and a record of measures taken. When the Regional Manager opts not to send a *Field Hearing, 10-day Response Required* the firm will be scheduled for an *On-Site Field Hearing*. Ideally, the on-site field hearing is held at the firm and attended by the owner(s) and/or management of the firm, the FSS and a Field Supervisor, or Regional Manager. The hearing officer leads the hearing by reviewing inspectional history, referencing the applicable sections of the Virginia

Retail Food Establishment Regulations, adopted federal regulations, and the Virginia Food Laws including penalties. The firm is then given the opportunity to explain any steps they have taken to correct the violations. The responses of the firm will be documented for the record and uploaded to the LAN. Every effort should be made to schedule the on-site field hearing as soon as possible after the inspection that initiated the compliance action. As stated above an inspection is performed *within* 42 calendar days of the inspection that initiated the compliance letter. At the discretion of the inspector, the follow up inspection may be performed on the same day as the on-site field hearing. The issuance of a Field Hearing Letter or an On-Site Field Hearing Letter is recommended by the FSS by selecting the requested letter in the inspection screen in VIPRS. This request is approved by the Regional Manager when they review the inspection in VIPRS. All letters are sent to the firm by the Regional Office (the Regional Manager, designee, or Administrative Assistant). The Regional Office (either the Regional Manager, designee, or Administrative Assistant) shall send a scanned copy of the letter via email to the Food Safety Specialist on the day the letter is mailed and a copy shall be placed in the appropriate place on the LAN. Field Hearing letters (either 10-day response or on-site) shall be sent to the firm within 5 working days of the inspection being reviewed by the manager.

Administrative "Show Cause" Hearing. Should the second follow up inspection of an OAI-classified firm note a lack of substantial improvement, the Regional Manager will schedule an *Administrative ("show cause") Hearing*. To facilitate the Administrative Hearing, the firm will be sent a letter identifying the date, time, and location of the hearing *within 5 working days* of the third consecutive OAI inspection being reviewed by the manager. Every effort should be made to schedule the Administrative Hearing as soon as possible after the inspection that initiated the compliance action. The issuance of an Administrative Hearing letter is recommended by the FSS by selecting the requested letter in the inspection screen in VIPRS. This request is approved by the Regional Manager when they review the inspection in VIPRS. All letters are sent to the firm by the Regional Office (the Regional Manager, designee, or Administrative Assistant). The Regional Office (either the Regional Manager, designee, or Administrative Assistant) shall send a scanned copy of the letter via email to the Food Safety Specialist on the day the letter is mailed and a copy shall be placed in the appropriate place on the LAN.

At the *Administrative Hearing*, the firm owner(s) and/or management are given an opportunity to present their views either orally or in writing, in person or by attorney in accordance with Section 3.2-5128 of the Virginia Food Laws. When in person, the administrative hearing is presided over by the Regional Manager at a VDACS office. The Regional Manager, Field Supervisor and the FSS may also attend pursuant to the details of the case. Upon convening, the Regional Manager will state the reason for the hearing, identify it as a *show-cause* hearing, and will stress the need for the firm's representatives to detail specific improvements made or planned to correct the violative conditions at issue. The Regional Manager will also review pertinent inspectional findings ending with the most recent inspection, which will be discussed in detail. The firm's representatives will then be given the opportunity to explain corrective measures. At the conclusion of the *Administrative Hearing*, the firm's representatives will be advised that a decision will be made, based on their input, whether to give them an additional opportunity to comply.

The Regional Manager will provide a detailed summary of the hearing and a recommendation for further compliance and enforcement action to the Program Supervisor. Summaries of Administrative Hearings will be placed on the LAN. Should the Program Supervisor determine that an additional opportunity to comply is warranted, the firm will be notified *within* 5 working days of the hearing via letter sent by certified mail that the

Agency will withhold further regulatory action pending compliance with the Virginia Food Laws. Included in this letter will be a notice and warning to place the premises in a sanitary condition pursuant to section 3.2-5132 of the Code of Virginia. If further regulatory action is withheld a follow up inspection will be performed *within* 42 calendar days of the inspection that initiated the compliance action as previously stated. If the Program Supervisor determines that the facts of the case warrant referral to the jurisdictional Commonwealth's Attorney, the case will be recommended to the Program Manager for review and concurrence.

Should the follow up inspection results indicate a continuation of the violative conditions, or if the results of the Administrative Hearing warrant prosecution in the opinion of the Program Manager, the case file will be referred to the Commonwealth's Attorney for criminal prosecution as follows:

- A case folder is developed establishing a history of the violations, including copies of inspection reports, sample reports and analysis results, pictures, memos and any other pertinent evidence to support the charges made.

- Proposed charges are identified.

- An appointment with the jurisdictional Commonwealth's Attorney or designee is set.

- The Regional Manager and FSS attend the meeting with the Commonwealth's Attorney.

- The Regional Manager explains the nature of the visit, the Food Safety Program, the voluntary compliance approach, the violative history of the firm, and the applicable penalty sections of the law. The Commonwealth's Attorney then decides what approach they will take, generally bringing criminal charges against the firm managers and/or owners.

- Charges that are supported by the evidence are identified and agreed upon.

- The Regional Manager and the inspector proceed to the magistrate's office to attest to the charges.

- The magistrate records the charges and issues summonses to the violative firm with orders to appear in court at the specified location, date, and time.*

* The prosecution process may vary from county to county

If at any time a firm undergoing compliance actions undergoes a follow up inspection that indicates significant improvement, the inspection classification may be downgraded to VAI or NAI, at the professional discretion of the FSS, with the concurrence of the Regional Manager.

In addition, there may be circumstances where the follow up inspection cannot be conducted in the normal timeframes as stated above. For example the inspector may visit the firm and the firm may be closed or another agency's involvement may extend the follow up inspection date. In these circumstances a "No Inspection" will be added to the firm's inspections in VIPRS to document why the follow up inspection was not conducted in the normal timeframes. There may also be instances where a firm does not follow the normal compliance process of OAI, Letter of Warning; OAI, Field Hearing; OAI, Administrative Hearing; OAI, Prosecution. For example, the Regional Manager may elect to send a Letter of Warning – 10 Day Reply after the initial OAI inspection even

though a Standard Letter of Warning has already been sent. There may also be cases where the conditions at the firm warrant a Field Hearing or Administrative Hearing prior to the letter of warning. The compliance process that the firm follows is at the discretion of the Regional Manager reviewing the inspection reports.

GENERAL GUIDELINES FOR DETERMINING VARIOUS INSPECTIONAL CLASSIFICATIONS

NAI - NO ACTION INDICATED

RODENT ACTIVITY – A firm must have very minimal rodent activity (e.g. a few mouse droppings on the floor along the back stockroom wall, or very minor activity in a processing area with otherwise good overall sanitary conditions). Rodent defiled foods must not be present. An effective and ongoing rodent exclusion and control program exists and is followed.

INSECT ACTIVITY - A firm must have very minimal insect activity (e.g. few dead roaches on the floor along the back stockroom wall). Insect infested foods must be non-existent or minimal and isolated to a single product. An effective and ongoing insect exclusion and control program exists and is followed.

FOOD TEMPERATURES – Evidence of temperature abuse in a food firm is minimal or can be corrected onsite. Very minimal or no time/temperature abuse of time/temperature control for safety (TCS) foods. An effective temperature management and date marking system exists and is followed.

UNCLEAN FOOD PROCESSING EQUIPMENT, UTENSILS, AND MACHINERY - A firm cleans and sanitizes all of its equipment on a daily basis, or more often as necessary. Unsanitary conditions with regard to processing equipment, utensils, including food-contact surfaces, are minimal. An effective cleaning and sanitizing program exists and is followed.

PROPER PLUMBING AND RESTROOM FACILITIES - The firm is plumbed according to the requirements of the Virginia Food Laws, the Virginia Retail Food Regulations, and/or 21CFR Part 110 (GMPs), and has fully operational restroom facilities. For further clarification on this category, please see the Commonwealth of Virginia Plumbing Code (current revision).

EMPLOYEE PRACTICES - A firm where employees demonstrate proper and careful sanitary controls and habits. Potential cross-contamination of foods resulting due to improper sanitary controls and/or habits must not be evident.

CLEANLINESS OF FLOORS, WALLS AND CEILINGS - Firms maintain floors, walls and ceilings in a clean and sanitary manner. The lack of proper attention to discrete areas does not alone constitute the basis for a violative classification unless a risk of adulteration is present. An effective and ongoing cleaning program exists and is followed.

VAI - VOLUNTARY ACTION INDICATED

RODENT ACTIVITY – The firm has evidence of active rodent activity that may include portions of the food processing area but appears to be controlled. There is no rodent activity on food contact surfaces and there are no rodent defiled foods on display. An effective and ongoing rodent exclusion and control program exists, but may not be followed.

INSECT ACTIVITY – The firm has evidence of active insect activity that may include portions of the food processing area but appears to be controlled. There does not appear to be insect activity on food contact surfaces. Insect-infested foods are somewhat significant, but isolated. An effective and ongoing insect exclusion and control program exists, but may not be effective.

FOOD TEMPERATURES - Some time/temperature abuse of TCS foods exists, however, gross time/temperature abuse of numerous foods does not exist. Also essential in determining the severity of the violation is whether the food is being offered for sale in the raw or ready to eat form. An effective temperature management and date marking system exists, but may not be followed.

UNCLEAN FOOD PROCESSING EQUIPMENT, UTENSILS, AND MACHINERY - The firm fails to thoroughly clean food processing equipment, including food contact surfaces, on a daily basis or more often if necessary. Although gross unsanitary conditions do not exist with respect to cleanliness, conditions necessitate monitoring by the FSS. An effective and ongoing cleaning and sanitizing program exists, but may not be followed.

PROPER PLUMBING AND RESTROOM FACILITIES – There are violations of the Virginia Food Laws, 21 CFR 110 (GMPs), and/or the Virginia Retail Food Establishment Regulations, (e.g., lack of a required multiple-compartment sink, the firm lacks hot water in isolated areas such as one sink, or there is standing water due to plumbing deficiencies). For further clarification on this category, please see the Commonwealth of Virginia Plumbing Code (current revision).

EMPLOYEE PRACTICES – A firm where employees demonstrate inconsistent sanitary controls and habits resulting in numerous violations. Cross-contamination of foods appears likely. Numerous employee-practice violations are present including but not limited to: 1) Bare hand contact with ready-to-eat foods; 2) PIC food safety training is fair as evidenced by incorrect correct responses to DOK questions (Retail only): 3) Personnel responsible for identifying sanitation failures or food contamination lack the background of education or experience for the production of clean and safe food (GMP only); 4) An employee health policy is in place but may not be properly communicated to employees.

CLEANLINESS OF FLOORS, WALLS AND CEILINGS – Firm does not maintain floors, walls and ceilings in a clean and sanitary manner. A risk for adulteration is present. An effective and ongoing cleaning program exists but may not be followed.

OAI - OFFICIAL ACTION INDICATED

RODENT ACTIVITY – Live rodents and/or numerous dead, decomposing rodents are present. Rodent droppings or urine stains on food contact surfaces and packaging, rodent-gnawed packaging. Rodent defiled foods being offered for sale. A rodent exclusion and control program does not exist or is not being followed.

INSECT ACTIVITY - Extensive, ongoing, and/or widespread insect infestation involving multiple foods are noted and/or insects are present where foods are unprotected, such as delicatessens, salad bars or meat processing rooms is present. An insect exclusion and control program does not exist or is not being followed.

FOOD TEMPERATURES – Extensive time/temperature abuse of TCS foods. A temperature management and date marking system does not exist or is not being followed.

UNCLEAN FOOD PROCESSING EQUIPMENT, UTENSILS, AND MACHINERY – Apparent disregard for the cleaning of food processing equipment, including food contact surfaces. Gross unsanitary conditions exist, particularly for the processing of TCS ready-to-eat foods. A cleaning and sanitizing program does not exist.

PROPER PLUMBING AND RESTROOM FACILITIES – Improperly plumbed sanitary devices, restroom facilities, and/or septic systems (e.g., the lack of water, the lack hot water under pressure throughout the firm, lack of dedicated hand sink, lack of a multiple-compartment equipment sink after follow-up inspections, or a failing drainage or sewage system). Significant violations of the Virginia Food Laws, the Retail Food Establishment Regulations, and/or 21CFR Part 110 (GMPs). For further clarification on this category see the Commonwealth of Virginia Plumbing Code (current revision).

EMPLOYEE PRACTICES – Apparent disregard for sanitary controls and habits by food workers such that food contamination is likely. Excessive employee-practice violations are present including, but not limited to: 1) Handwashing is not occurring; 2) Bare hand contact with ready-to-eat foods is usual practice; 3) PIC food safety training is poor to non-existent as evidenced by incorrect correct responses to DOK questions (Retail only) 4) Personnel responsible for identifying sanitation failures or food contamination do not have a background of education or experience for the production of clean and safe food (GMP only); 5) Employees demonstrating signs of illness are engaged in food-handling.

CLEANLINESS OF FLOORS, WALLS AND CEILINGS – Firm does not maintain floors, walls and ceilings in a clean and sanitary manner. Adulteration is observed by the FSS. A cleaning program is not in place or is not being followed.

OTHER FACTORS TO CONSIDER

An inspection may be classified VAI or OAI based on such a single violation, depending on the risk categorization of the firm. Inspection classifications of VAI or OAI may also result from violations in combination with one another. For example, an inspection may reveal evidence of: 1) rodent activity; and 2) unsanitary conditions involving a non-food-contact surface of a delicatessen processing area. These violations, if considered alone, may lead to a classification of NAI or VAI, however, the violations in combination with one another may lead to a classification of VAI or OAI. The context of the inspection, the risk posed by the firm's operations, and the risk associated with the individual violations, when combined, will indicate the overall inspection action indicator/classification. Therefore, when classifying an inspection where multiple violations are found, all violations and an analysis of risk must be considered.

VAI Inspections. Many inspection classifications will be obvious; the vast majority fall into the NAI category, and most OAI classifications are easily determined because of the types of violations, or number of violations found. The VAI category should be used for the following reasons:

- The firm needs to be followed up more quickly, but not within 42 calendar days (as is the case with an OAI inspection).
- The firm needs to be sent a Letter of Information.
- Significant, but not severe, plumbing violations that need time to be resolved.
- Any reason that would justify a faster follow-up than a routine inspection.

VAI follow up inspections must be completed by the FSS by the date scheduled in VIPRS as previously stated. Follow up inspection may result in continued VAI classification, up-classification to OAI, or down-classification to NAI as follows:

• A firm may be re-classified as VAI following an initial VAI inspection when the firm appears to be taking action to correct the violation(s) at issue. The FSS may recommend correspondence be sent to the firm and may allow additional time to complete corrective actions.

• A firm may be up-classified to OAI following an initial VAI inspection if the firm fails to take action to correct the violation(s) at issue or if additional violations are found. The FSS will recommend a Letter of Warning be sent to the firm and will conduct a follow up inspection at the firm within 42 calendar days of the date of the inspection.

• A firm will be down-classified to NAI following an initial VAI inspection when actions to correct the violation(s) at issue have been completed and approved by the FSS. The firm's inspection schedule will resume routine, periodic, status based on risk.

"Virtual" Re-inspection

"Virtual" follow up inspection is a process by which a violative firm may mail, email, or fax evidence of violation corrections to VDACS without having to undergo a physical re-inspection by a FSS. Firms may be virtually re-inspected *with prior approval of the Regional Manager* if:

- The inspection is VAI (OAI in very rare cases);
- The inspectional history is satisfactory;
- The firm's risk profile is up-to-date;
- VDACS's professional relationship with the firm is good;
- The FSS has reason to believe that correction is *imminent*; and,
- Interim measures are taken to ensure that public health will not be adversely impacted by the decision

Virtual inspection encounters will be documented in the inspectional database. The virtual inspection will be documented by adding a "No Inspection" to the firm's inspections in VIPRS to document why a virtual inspection was done. In no case does this option preclude the FSS from returning to the firm for follow up inspection as indicated by the firm's response, or other factors.

Chronic Violators and Critical Violations – GMP Inspections Only

For manufacturing and warehouse operations, a chronic violator is defined as a firm that has 3 VAI or 2 OAI inspections within one calendar year or 5 VAI or 4 OAI inspections within 3 calendar years. Chronic violators will be tracked using VIPRS by the MFRPS Coordinator or designee. Chronic violations are defined as repeat violations (designated as R on the inspection report). Critical violations are defined in accordance with Procedure III-21 Manufacturing Inspection Procedures. Critical violations are automatically captured by VIPRS based on the specific violation code chosen. Depending on the specific violations observed this may also cause the classification of the inspection to be VAI or OAI. The MFRPS Coordinator will track critical and chronic violations and violators and will determine appropriate steps to take based on what the data shows.

Ceasing Foodservice/Manufacturing Operations

A FSS may request the temporary cessation of foodservice/manufacturing operations and/or the sale of food products to the public in extreme circumstances demonstrated by blatant disregard for food safety laws and regulations that when combined with risk, pose an imminent health hazard to the public. Violations that may prompt a FSS to recommend ceasing foodservice/manufacturing operations may include but are not limited to: 1) raw sewage on the premises; 2) grossly-infested or visibly contaminated foods; 3) service of foods from unapproved sources, including uninspected salvage operations and non-amenable species; 4) epidemiological

evidence of a foodborne illness originating at the firm; 5) evidence of metal shavings in finished product; 6) misbranded foods representing an immediate public health hazard; 7) lack of hot water in the firm or 8) repeated production of foods without a variance and/or HACCP plan.

The FSS should contact the Regional Manager prior to requesting a firm voluntarily cease operations. The firm will be instructed to notify the FSS when the violative condition has been resolved at which time the FSS should promptly validate the compliance status of the firm. When the violative issue is resolved to the satisfaction of the FSS pursuant to the Virginia Food Laws, the firm may resume foodservice/manufacturing operations and/or the sale of food products immediately.

Notice of Seizure

The Food Safety Program does not normally remove a suspected food product from a firm's physical location. In Virginia the term "seizure" indicates that the food product is in the custody of the Commonwealth and may not be removed, sold, or otherwise disposed of, even though it may remain on the firm's property pending legal disposition.

Seizure notices should be issued by a FSS in order to hold a suspect food product from sale to the public pending further investigation. Justifications for seizure other than for suspicion of adulteration or misbranding include:

- Seizure authority may be used to hold food on behalf of other agencies pending further enforcement action.
- Seizure authority may be used to hold food that has been in a disaster until it can be salvaged or destroyed.
- Large quantities of food damaged in non-disaster situation may also be seized pending appropriate dispositions as warranted by the specific situation.

Samples for laboratory analysis may be required when products are seized by VDACS Investigators.

When a seized product is sampled, the sample number(s) shall be listed in the remarks section of the Seizure Notice. In addition type "PRODUCT UNDER SEIZURE" in the "Customer Notes" section of the Sample Collection Report. The original copy of the seizure should be left with person in charge of the operation. A copy should be saved electronically on the LAN and a copy should be kept by the FSS for his/her files. Inspection Reports must indicate when products are seized/released, including the reason for seizure/release, a thorough description of each product, including the amount.

If the product is to be released, a "Release" form will be filled out. This form is similar to the "Seizure" form and both forms should be filled out according to Procedure 111-17 Seizure Notice. The "Reason" section should state the reason for the release. (Example: Laboratory analysis reveals that the product complies with the Virginia Food Laws. This product is released from seizure.)

If the products seized are found to be in violation of the Virginia Food Laws they must be destroyed or denatured. In this case an Inspection Report or destruction form will be filled out stating that the products were voluntarily destroyed or denatured. A Notice of Release need not be filled out as the Inspection Report or destruction form serves as the release.

When the product is seized on behalf of other agencies and laboratory analysis or other information reveals that the product complies with the Virginia Food Laws, the Regional Manager should contact representatives from the other agency to determine disposition as Virginia law does not permit VDACS to retain custody of the product. If the product is found to be adulterated, Virginia law requires that it be voluntarily destroyed/denatured by the firm, or that they are forfeited to the Commonwealth for final disposition. If the seizure is made on behalf of another agency the product may be held on the basis of documentary evidence of adulteration pursuant to §3.2-5126 of the Virginia Food Laws. In the absence of such documentary evidence, the food products may be released at the discretion of the Program Supervisor or the Program Manager.

The power to seize food products without recourse to the courts is unusual therefore, FSS's should exercise this option judiciously. If there is any question about whether or not to seize food products, FSS's should contact their Regional Manager. A thorough understanding of the Virginia Food Laws is essential in developing justification for seizure action.

Court Injunction

The Food Safety Program may request the court of jurisdiction to issue a temporary or permanent injunction restraining a firm from committing acts prohibited in section 5126 of the Virginia Food Laws regardless of whether a legal remedy is available to the firm. This action is used as a last resort, when all other compliance and enforcement measures available to the Program have failed, or are inappropriate to the degree of risk posed by the violation(s).

Communication of Compliance and Enforcement Policy and Guidance

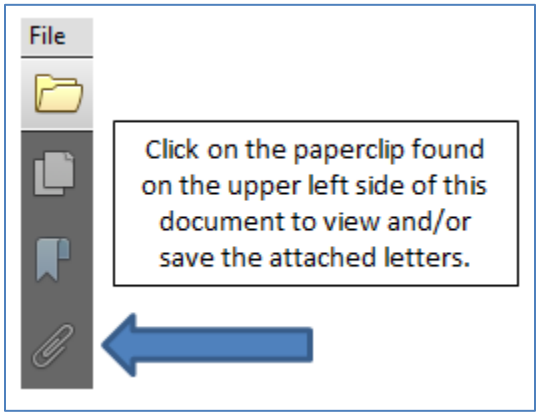
The Food Safety Leadership Team (Program Supervisor, Regional Managers, and Field Supervisors) meet on a regular basis to discuss the formulation and administration of needed policies and procedures including those involving compliance and enforcement. New or revised policy is disseminated to the field staff via email and documented in the VDACS Field Operations Manual.

Additionally, compliance policy and guidance is routinely discussed at quarterly regional meetings as well as at an annual state-wide meeting of staff during which time policy changes, the rationale for the changes, lessons learned and timelines for implementation are reviewed, discussed and improved. Guidance may also be provided by email from time to time as needed.

In addition to written policy and guidance, field staff members are provided cell phones to facilitate effective communication with the office. If necessary, both Regional Managers and Field Supervisors are available to provide clarification on compliance and enforcement issues.

List of Letters

(Letters are attached)



ROUTINE LETTERS OF INFORMATION
- Birds-In-Store Info Letter
- Date Marking Info
- Demonstration of Knowledge Info Letter
- Equipment Sink Info Letter
- Equipment Sink Info Letter When a 2 Compartment Sink Will Suffice Info Letter
- Handwashing Sink Info Letter
- Raw Foods of Animal Origin Info Letter
- Sanitizing Info Letter
- Temperature Info Letter
- Thawing Information Letter

LETTERS OF WARNING (LOW)
- Uninspected Low Acid Acidified Foods LOW
- Birds-In-Store LOW
- Hazardous Food Temp LOW
- Outdated Infant Formula LOW
- Plumbing LOW
- Plumbing LOW with Reply Requested
- Standard Letter of Warning
- Standard LOW with Reply Requested
- Violative Sample Result
- Water Coliform 3
- Water Fecal Coliform 3

WELL WATER CONTAMINATION
- Water-Coliform 1
- Water-Coliform 2
- Water-Fecal Coliform 1
- Water-Fecal Coliform 2

VARIANCE and HACCP
- Acidified Rice Variance with HACCP Info Letter
- Game Processing Variance Approval
- Meat Smoking & Curing Variance with HACCP Info Letter
- Meat Curing & ROP Variance with HACCP Info Letter
- ROP HACCP Only Info Letter
- ROP Variance with HACCP Info Letter

FIELD HEARING
- Field Hearing Letter – Onsite
- Field Hearing Letter – 10 Day Reply

ADMINISTRATIVE HEARING
- Administrative Hearing Letter 1
- Administrative Hearing Letter 2
- Administrative Hearing Letter 3

NOTICE and WARNING

NOTICE and WARNING, ACTION DEFERRED

COMPLIANCE ACTION - NOTICE OF SEIZURE

COMPLIANCE ACTION LETTER - NOTICE OF RELEASE

Procedure I-01: Inspector Safety

The safety of Food Safety Specialists (FSS) who have establishments perceived to be in a high crime or unsafe areas are of paramount importance to all concerned. Also, serious consideration must be given to the safety of the FSS conducting home operation inspections/visits. This FOM is to provide guidance and requirements for conducting inspection work in the aforementioned situations. This FOM is not intended to replace the use of common sense and sound personal judgement nor is it to suggest that these firms are to be excluded from services provided by this agency.

POLICY

The following basic policy will be followed. Any questions or deviations concerning this issue should be immediately directed to your Regional Manager or Field Supervisor, if the manager is unavailable, or the Central Office, if your Regional or Supervisor, is unavailable.

1. Be alert and fully aware of your surroundings in the establishment and the area outside the firm. This also applies to home operation inspections/visits. All Food Safety Specialists are to dress appropriately so as not to draw undue attention to them.
2. When visiting establishments and it is perceived as being unsafe for whatever reason, an inspection will not be conducted at that time. An Inspection Report will be completed at a later time indicating that you attempted an inspection/visit. The Inspection Report will contain the statement "Firm appears to be unsafe at this time. Inspection will be rescheduled." It is suggested that firms, which appear to be unsafe, be rescheduled for the morning hours or rainy days. After two (2) attempted inspections, you will contact your Regional Manager and request that an inspector be assigned to accompany you on the inspection. In the event that the situation is still unsafe, the matter will be referred to your Regional Manager for disposition on a case by case basis. Firms perceived to be in a unsafe areas are not to be excluded in any way from the services provided by this agency. Every reasonable effort will be made to provide services to these communities.
3. At no time will a FSS carry any firearm during an inspection/visit or in their state vehicle unless the individual has a permit to carry a concealed firearm; has specific approval from the Commissioner of Agriculture or his designated representative; and meets all legal requirements and any training VDACS deems necessary.
4. If at any time you have concerns about safety or allegations of sexual harassment, leave immediately and document situation. Contact your Regional Manager to determine the appropriate response.

HOSTILE SITUATIONS

Physical resistance to VDACS inspections and threats to, or assaults on, VDACS employees engaged in their work are extremely rare. More often than not, investigations and/or inspections are conducted in a professional and reasonable manner. However, there will be times when you are confronted by unfriendly or hostile persons.

It is important to distinguish between a hostile individual and someone who is unfriendly. An inherent part of being a FSS is dealing with people who are not happy to see you. From time to time, you are going to encounter situations where store owners/employees will say things that are going to make you feel uncomfortable. As an inspector, you need to develop a "thick skin" and continue to do your job.

Your activities must always be conducted with tact, honesty, diplomacy, and persuasiveness. Even though you must, at times, adopt a firm stance, you must not resort to threats, intimidation, or strong-arm tactics.

Many times a hostile or uncooperative attitude results from fear, timidity, or previously bad encounters with government personnel. In most cases, a calm, understanding, and persuasive attitude on your part will overcome the person's reluctance or hostility. Often just letting the person "vent" will calm them down and make them receptive to inspectional activities.

If you are physically threatened, or if you sense the real possibility of an assault, get out of the confrontation, get to safety, and call your Regional Manager (alternatively Field Supervisor or Central Office) immediately. Make careful and exact notes of who said what to whom, who did what, and whether someone tried or succeeded in threatening, assaulting, or taking information, equipment, or samples from you. Forward your notes to your Regional Manager in the form of an e-mail or memo.

In summary, if you find yourself in a situation where you perceive violence is imminent, stop the inspection and leave. Immediately report the facts to your supervisor. Food Safety Specialists are not to call the police on their own accord. The Regional Manager will discuss the issues with the Program Supervisor before contacting the local authorities. Your supervisor can summon the local police to accompany a Food Safety Specialist if there is a reasonable fear of danger to the inspector. However, normally we want to contact the establishment owner/manager to try and resolve the problem before going to the police.

Procedure I-02: Transition from Food Safety Specialist to Food Safety Specialist Senior

This procedure outlines the assessment criteria used by the Regional Manager to Transition a Food Safety Specialist to the Food Safety Specialist Senior level.

Assessment Tool #1 – Completion of Retail Training

In order to progress to the FSSSr level, a developing FSS must complete his or her retail training. There are two aspects of retail training that must be completed – Field Training and Coursework.

Fieldwork Overview

For Retail Food Inspection Training this is achieved by completing a minimum of 25 joint field training inspections or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSS has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments. A sufficient number of field training inspections led by the trainee are to be conducted to allow the demonstration of all competencies identified in the training plan (See the VDACS Training Manual). Upon completion of the field training process, the FSS should have successfully demonstrated all competencies in the training plan and be ready to conduct independent inspections of retail food and/or food service facilities.

Coursework Overview

The Conference of Food Protection (CFP) has worked with the FDA to identify a prerequisite curriculum designed to provide a FSS with a solid understanding of essential food safety and public health principles needed to conduct effective retail food safety inspections. A list of these courses can be found in the training plan. The FSS shall complete the prerequisite coursework ***prior*** to conducting independent inspections and before transitioning to the FSSSr level.

Documentation Used to Establish Completion of Retail Training

- The *VDACS Retail Field Training Worksheet will be used to* track the FSS's progress in successfully demonstrating specific performance elements and competencies.
- VIPRS *will be used* to track the number and type of establishments within which training has been conducted.
- Appendix 2.2 Individual Training Record will be used to track the coursework successfully completed by the FSS.

Assessment Tool #2 - Manufacturing Training Completion

In order to progress to the FSSSr level, a developing FSS must complete his or her manufacturing training. There are two aspects of manufacturing training that must be completed – Field Training and Coursework.

Field Training Overview

For Basic Food Inspection Training this is achieved by participating in a minimum of ten (10) joint trainee-led inspections with a qualified trainer and receiving a minimum of two (2) "Acceptable" ratings. An "Acceptable" rating is defined as a trainee-led inspection in which the trainee demonstrates the knowledge, skills, and abilities necessary to perform basic and advanced wholesale food inspections. Upon completion of the field training process, the FSS should have successfully demonstrated all competencies in the training plan and be ready to conduct independent inspections of food manufacturers as well as food warehouses.

Coursework Overview

The FDA Manufactured Food Regulatory Program Standards has identified a curriculum designed to provide a FSS with a solid understanding of essential food safety and public health principles needed to conduct effective wholesale food safety inspections. A list of these courses can be found in the training plan. The FSS shall complete the prerequisite coursework ***prior*** to conducting independent inspections and before transitioning to the FSSSr level.

Documentation Used to Establish Completion of Manufacturing Training

- The *VDACS Wholesale Field Training Worksheet* will be used to track the FSS's progress in successfully demonstrating specific performance elements and competencies as they relate to food manufacturers or food warehouses
- VIPRS will *be used* to track the number and type of establishments within which training has been conducted and the overall rating of the FSS during a trainee-led inspection of a specific firm.
- Appendix 2.2 Individual Training Record will be used to track the coursework successfully completed by the FSS.

Assessment Tool #3 –Specific Coursework

In order to progress to the FSSSr level, a developing FSS must successfully complete the following courses:

- **FD180 Food Good Manufacturing Practices**
- **FD152 Food Processing and Technology**
- **FD202 Conducting Acidified Food Inspections**
- **Any additional courses that may be required to meet the needs of consumer protection and industry changes**

Documentation Used to Establish Completion

Successful completion of any required educational coursework will be determined via an examination of any and all coursework completion documents by the FSS's Regional Manager.

Assessment Tool #4 - Meeting the Core Responsibilities and Agency/Departmental Objectives as Outlined in the EWP

Documentation Used to Determine if the FSS has Met the Core Responsibilities and Agency/Departmental Objectives as Outlined in the EWP

The FSS's most recent Performance Evaluation will be used to determine if the FSS has met the core responsibilities as outlined in their EWP. A minimum rating of "Meets Expectations" must be achieved in each category of the EWP in order for the developing FSS to transition to the FSSSr level.

Assessment Tool #5 – Retail Standardization

In order to move to the FSSSr level, the Food Safety Specialist must be Standardized by a Field Supervisor/Standardization Officer.

Final Assessment

Subsequent to completion of all required criteria, the FSS's Regional Manager will complete an updated PAF with supporting documentation, if required. Copies of said documentation will be provided to the Program Supervisor. If a PAF is not required, the Regional Manager will provide the documentation showing the criteria above have been met. The Program Supervisor and the FSS's Regional Manager will collectively determine whether to elevate the FSS to the FSSSr level. If the FSS has requested to work an alternate work schedule, the Regional Manager will approve and submit form VDACS Work Schedule and submit to the Program Supervisor. The Alternate Work Schedule Form will then be submitted to HR.

Procedure I-03: Use of Official State Credentials

The credentials you have been issued consist of a leather case marked with the Seal of the Commonwealth and the name of the Department, a picture identification card and a badge identifying you as a State Food Inspector. They are distinctive and unique in the Department.

Their use requires a certain amount of responsibility on your part so that it reflects in a positive manner on you, your office and your Department. Remember, you are not a policeman. Do not display your credentials in an overt or aggressive manner. To do so would, invariably, bring criticism on all of us. Your credentials are merely a distinctive method of identification. Display them in the same manner you would any other form of identification, friendly and low key. It is permissible, when working with police, fire and other emergency agencies, to remove the badge from the case and attach it to your clothing if you need to cross fire lines, etc., and be readily identifiable to emergency personnel. Only do this in exceptional circumstances.

The loss of state credentials must be reported to your Regional Manager or the Central Office IMMEDIATELY.

You are responsible for these credentials. They identify you as an official agent of the state. Do not allow them to get out of your possession. In the wrong hands they can cause considerable damage to the image we wish to project.

Procedure I-04: Refusal to Permit Entry, Inspection, or Sampling

During the course of your work, an occasion might arise when you are refused entry into a firm or refused the right to make an inspection. In that event you should explain that you have the right to inspect the firm pursuant to state law. If that approach fails, you should get a copy of the Virginia Food Laws and read section 3.2-5102 to the person refusing your request. Section 3.2-5126(A)5) should then be read to the individual, followed by the penalty section 3.2-5126(B). If you are still refused entry after properly identifying yourself and after reading the above sections of the law, you should telephone your Regional Manager immediately. This procedure also applies to the refusal to permit the collection of a sample.

FIELD OPERATIONS MANUAL

PROCEDURE I-05
Revised

State Blackberry Cell Phone

In your position as a Food Safety Specialist, the State has provided you with a Blackberry cell phone to facilitate efficient communication. In an effort to promote quality customer services in a timely manner, the office will provide your cell phone number to appropriate parties when necessary.

The position of Food Safety Specialist requires you to be available when necessary to respond to emergency situations. Therefore, you are to carry your Blackberry on flex days and weekends (days and evenings) in order to facilitate a rapid response to any disaster and/or emergency situation that may occur. *Please note that the only time that you are not required to carry your Blackberry with you is when you are on leave and/or when you are at home where you can be reached by telephone.*

Currently, the state is utilizing Verizon Blackberry cell phones. All employees are expected to read the associated instruction manuals to familiarize themselves with the equipment. Any problems with the phone should immediately be brought to the attention of your Regional Manager for necessary repairs.

Usage policy

- The phone is to be used for state business only.
- The phone is not to be used while operating a vehicle. Vehicles should be parked prior to using the Blackberry.
- Each phone has been allocated 600 anytime minutes, 500 mobile to mobile minutes and 1000 night/weekend minutes. It is imperative that calls be kept to a minimum to avoid excess charges.

VOICEMAIL

Part of your responsibility in having a Blackberry is to check your messages regularly. You should check your voice mail every day, including flex days and weekends. Weekend message retrieval is very important in the event that an emergency has occurred and the Fire Department or other such agency has tried to contact you about an

emergency situation involving food. *You are required to answer your Blackberry during working hours and respond to voice mail in a timely manner.*

Messages are to be responded to as quickly as possible but should not exceed 30 minutes unless there are extenuating circumstances (i.e. in a training class, inspecting a facility that does not allow a cell phone, etc).

NOTE: All cell phone calls will be answered, regardless of whether the number is known (i.e. a number other than the office), according to established timeframes.

In conjunction with checking your messages regularly, you should also make use of a standard professional recording on your voice mail that indicates your position, who you work for, and in the event of an emergency, your pager number. Your recording should mirror the following example:

Hello. You have reached (your name), Food Safety Specialist for the Virginia Department of Agriculture's Food Safety & Security Program. Please leave me a message with your name, telephone number, the best time to reach you at that number, and a brief description of why you are calling, and I will return your call at my earliest convenience. If this is an emergency and you need immediate assistance, you may call the (Richmond, Roanoke, or Tidewater) office at (office phone number).

Additionally, you may want to modify your greeting when you know you are going to be on vacation or out of the office for a particular amount of time, indicating the days that you will be "out of the office" and when you will be returning. This way, your customers will be aware of your schedule and will know to expect a delay in you returning their call or can contact the appropriate office for assistance if needed. Such a modified greeting might be as follows:

Hello. You have reached (your name), Food Safety Specialist for the Virginia Department of Agriculture's Food Safety & Security Program. I will be out of the office June 15-18th. If you wish to leave a message, please indicate your name, telephone number, the best time to reach you at that number, and a brief description of why you are calling, and I will return your call when I return to the office at my earliest convenience. If you need immediate assistance, you may contact the (Richmond, Roanoke, or Tidewater) office at (office phone number).

TETHERING APPLICATION

Blackberries can be tethered to your laptop computers. This application allows your laptop computer to access the internet anywhere there is cellular coverage from your Blackberry.

TECHNICAL SUPPORT

All requests for assistance with your blackberry should be directed to the Virginia Information Technologies Agency (VITA) Customer Care Center. You will need to create a "ticket" to get the device corrected. The Customer Care Center operates 24 hours a day/7 days per week.

To access eSupport: http://esupport.cov.virginia.gov

Toll free phone: 1-866-637-8482 (VITA)

Individual field personnel WILL not attempt to obtain support services outside of VITA. Such action could result in disciplinary action.

Revised July 2010

Procedure I-06: Computer Software (VIPRS) and Paperwork Submission Criteria

When submitting your required forms the following guidelines should be followed:

A. The following submission criteria is to be followed in regards to Inspections in the VIPRS computer software program:
- Inspections should be completed using the Offline or Live Site of the VIPRS inspection software
- Bring your computer into the firm. The most responsible person in charge of the firm at the time of the inspection shall sign electronically on your tablet computer in the designated signature blocks in the VIPRS system.
- The inspection report may be printed or if the firm agrees, a copy may be emailed. After the inspection report is printed or emailed to the firm, the inspectional data is to be **submitted** (via VIPRS) immediately following the completion of the inspection in order to finalize and "lock down" the report.
    - To email the report, using chrome, click print and change the destination to PDF. This will save the report as a PDF document. Save the document as the name of the firm and the date of the inspection.
- If the firm is able to sign electronically, the inspection report does not need to be uploaded to the LAN. However, if the signature was unable to be attained electronically, the hard copy needs to be uploaded to the LAN.
- The VIPRS Offline Client shall be synchronized TWICE DAILY – at the beginning of each work day and at the end of each work day

B. The following submission criteria is to be followed in regards to Samples in the Offline VIPRS computer software program:
- Every effort shall be made to ship samples the same day they are collected
    - If this is not possible, TCS samples must be shipped the next day. Non-TCS samples must be shipped within two (2) working days from the date of collection
    - Special circumstances can be discussed with your Regional Manager
- Samples shall not be shipped to the lab until the sample has been submitted (and synchronized if using the Offline VIPRS client) in VIPRS
- See FOM Procedure IV-01 VDACS Sampling Procedures for additional information

The following submission criteria is to be followed regarding the placement of other documents on the LAN:

- All other correspondence (complaints, home operations, FDA contract documents, time and activity, vehicular incidents, etc.) shall be scanned and saved to the LAN within 2 working days of the completion date.

If you cannot access the VIPRS computer software system at the time of inspection the following steps are to be followed:
- Use the "PDF" document version of the needed report to conduct the inspection. Secure a hard copy signature and scan/save an electronic version of the signed report to the LAN (as a PDF document). *NOTE: When saving documents on the LAN, access the ODF drive – (Food Inspect) folder and save in the designated folder.*

- Process ("key") the information into VIPRS within 2 working days following the completion of the inspection.

C. Expense vouchers should be submitted on a monthly basis, however, when overnight travel is involved, expense vouchers should be submitted within 5 working days after completion of the trip. Personnel in training status should submit their vouchers on a weekly basis.

D. Monthly mileage reports should be submitted promptly on the last work day of every month but no later than the 5th of the next month to Annie McCullough (annie.mccullough@vdacs.virginia.gov).

E. Timesheets and leave requests are to be submitted in TAL (Time Attendance and Leave). Timesheets are to be submitted no later than the Monday following the completion of the workweek. Leave requests should be submitted in advance or on the day you return to work from an unexpected absence.

F. Weekly reports summarizing significant activities in your territory are to be submitted the last day of the work week.

G. Photographs taken in preparation for additional regulatory action must be submitted in accordance with FOM I-09.

H. A daily "calendar" or log **WILL** be maintained in the agency furnished "date book". In this book you will record your daily activities, e.g. inspections, complaints, visits, meetings, etc.

Any unusual circumstances concerning submission of correspondence should be discussed with your Regional Manager.

FIELD OPERATIONS MANUAL

PROCEDURE 1-07
Formerly 029

USE OF THE INSPECTION REPORT

The inspection report was designed to be a multi-use form to help streamline some of the paperwork that Inspectors must complete.

Only factual statements are appropriate for the inspection report. You will NOT "editorialize" at any time. "The facts ... Nothing but the facts".

For example:

An accumulation of old food product was found on the floor in the walk in cooler. Only prepacked food products are kept in this cooler.

This firm is on a private well and the waste is discharged to the public sewage system.

The firm is permitted by the Northampton District Health Department under permit number 12345.

The functions of the inspection report are: reporting inspectional violations, recording data entry information, documentation of voluntary destructions, recording **factual** information pertaining to visit, documentation of sample collection, and the writing of memos. In consideration of its many uses, following are instructions for the proper completion of this form.

WHEN USED TO REPORT INSPECTIONAL VIOLATIONS

Observations should be reported in a narrative format and in the order of relative importance. However, any food products found in violation of the laws and related regulations that will require additional regulatory action (i.e. destruction, seizure, sampling, etc.) will need to be itemized on the inspection report. **THE DISPOSITION OF THESE FOODS (DESTRUCTIONS, REMOVALS FROM SALE, REHEATING,**

CHILLING, REFRIGERATION, etc.) ARE NOT TO BE LISTED ON THE INSPECTION REPORT. The inspection report when used to report inspectional violations is to be used to document objectionable conditions only. The disposition of foods and other comments will be included on the data entry section of the report. When products are destroyed the number of the observation should be listed in the space provided at the end of the report next to the phrase "The adulterated food items listed in observations ___ were destroyed with my consent."

The following is an example:

Inspection Report left with Mr. Nicky Icky, Owner by Mr. F. B Goodguy Inspector # 007

_____ **Adulterated food items listed in observations #3 were destroyed with my consent**.
_____ Witnessed the collecting, marking, or sealing of samples _____

WHEN USED AS A MEMO FOR VISITS

When this form is used as a memo for a visit, fill the top part of the form out as usual. In the area where it says "During an inspection of" write VISIT. Again, only factual statements will be made.

In the narrative part of the form write your memo, purpose for the visit (i.e. sampling, complaint, out of business, etc.).

Following are examples:

1. During today's complaint investigation the following products were found insect infested:
   a. 6/12 oz. Hershey's candy bars
   b. 15/1 lb. bags of Jimbo Jumbo's peanuts

2. Today's visit revealed this firm to be out of business.

3. During today's visit samples were collected.

4. I received a phone call from the fire department notifying me of a fire at this firm today. I found about 200 pounds of various food products damaged due to the fire. These products were buried at the county landfill.

5. I visited this firm today to destroy 200/16 oz. bottles of Sandy's ginger ale that were under seizure. Laboratory analysis of the samples revealed that the products were adulterated with mold.

When food products have been destroyed the inspection report needs to be signed and initialed in two places. The first signature indicates that they have received the original sheet and the second initial indicates that the food products listed were destroyed with their consent. In the space at the bottom of the sheet where you list the observation numbers for the food products destroyed type in the word *ABOVE* since there are no numbered observations.

Revised December 13, 1999

FIELD OPERATIONS MANUAL

PROCEDURE I-08
Formerly 035

RECORDS NECESSARY FOR OWNERSHIP CHANGES

The inspection fee legislation effective July 1, 2002 has made it necessary to alter the way we document ownership changes. In order to ensure that the correct owner is billed the following procedure has been developed. **This procedure will be applicable regardless of whether the firm name changes.**

1. An inspection report will be filled out with the CFN and the previous owner's information. In the body of the inspection report indicate that the firm is out-of-business due to an ownership change.
2. A second inspection report will be filled out for the new owner. The CFN should be listed as "New firm". Please remember to also indicate the type of establishment and the location code.
3. The CFN on the new owner will be different from the previous owner.

Revised August 2002

Procedure II-01: Digital Camera—Use & Mounting of Photographs

Use and Photograph Composition

The camera is an important and useful piece of inspectional equipment available to an inspector. Photographs provide an effective form of evidence collection in documenting unsanitary conditions encountered during an inspection. The camera, used by a competent photographer, can tell the complete story of the conditions in an establishment. The quality, sequence, and composition of photographs can make or break a case.

It has been said that one picture is worth a thousand words. It can likewise be said that a poor picture can be worse than no picture at all. It is imperative that Inspectors become familiar with their camera. Food Safety Specialists should know how to manipulate all the controls of their camera and have some feeling for the limitations of their camera, what it can and cannot do. Once a Food Safety Specialist learns these things he/she should begin to develop an eye for picture composition and sequencing shots. Remember, not only are you depicting unsanitary conditions but you are telling a story as well. You want the story to lead the viewer to the conclusion that the conditions you have encountered are serious, they violate the law, and they can or do contaminate the product(s). You want the conditions you depict to hold the viewer's attention. For example, suppose you observed grain beetles in the flour dusting hopper of a roll machine. A simple picture of the insects would suffice. However, think of how much better two shots would be. One photo could show the roll conveyor in relationship to the other machines in the bakery with the flour dusting hopper on top of the machine and rolls traveling along the conveyor. The second shot would be a close-up showing the insects in the dusting flour. The conclusion reached by the average viewer would be that the insects in the dusting flour could very easily and most probably do fall onto the rolls. This is only one example of the importance of photograph composition and proper sequencing. There are many others. As you gain experience in photography you will be able to recognize these opportunities with greater ease. The important thing is to remember that each inspection constitutes a photographic story. What you need to do is think about the best way to tell that story and proceed from there.

There are a few items in the simple mechanics of taking photographs that need to be mentioned.

First, HAVE YOUR CAMERA AND SMARTPHONE CHARGED AT ALL TIMES!

Second, if you have an issued Canon PowerShot D20 Digital Cameras, these cameras are relatively simple to operate and are capable of excellent photographs.
In addition to the cameras, Food Safety Specialists may use their Smart Phones to document adverse conditions, capture food product labels and other situations of interest & concerns.

Third, all photographs should be related to the objectionable conditions listed in the inspection report. This does not mean that each photo is a different objectionable condition. You may take several pictures of the same condition for clarity or emphasis, or you may take an overview photo before zooming in for a close-up shot of a condition that was found in the area. What we want to avoid is having a photo of an objectionable condition and then not being able to find the condition on the inspection report.

Fourth, try to have the ID card in each picture. The ID card should have the name and address of the firm, the date, and the Food Safety Specialist's initials printed on it. The purpose of this card is to identify each photo as to location, date, and photographer. Identification is useful in court actions when giving testimony about photos. We realize that you may not be able to get the ID card into all photos. When you "zoom in" for a close-up shot, the ID card may be too large to include. Don't worry about it. There are exceptions to everything. If the

majority of your photos are well-identified you should have no trouble getting those exceptions introduced. What you need to remember is that the ID card is important and should be used wherever possible. When using the ID card, try not to contaminate food contact surfaces with it. In other words, don't pick up the card from a dirty floor and set it on the bandsaw; use another ID card if necessary. Be sure to include a photo of your ID card when posting your photographic evidence on the LAN/APEX. In addition, the identification card used in the photos should be mailed to the office to be included as part of the overall photographic evidence.

Finally, to stay familiar with the camera, you should take pictures at least quarterly. If you do not have situations that require photographs during an inspection then take some practice pictures of situations that might occur.

If management objects to the taking of photographs due to "legal" considerations, explain that photos are an integral part of an inspection and present an accurate picture of firm conditions. Advise management that the Courts have held that photographs may lawfully be taken as part of an inspection. If management still refuses, contact your Regional Manager or Field Supervisor for appropriate guidance.

Mounting of Photographs

The presentation of photographic evidence, either in court or at hearings, generally has a very positive effect on getting the job done. Therefore, the proper mounting of photographs is most important.

All photographs should be mounted in the same visual plane. That is, when you look at the page you should be able to tell what each photo represents. You should not have to turn the page on its side, etc.

Each page of photographs should have the name and address of the firm, the date the photos were taken and your initials across the top as well as the page number.

Each photograph should have a caption describing what is seen in the photo followed by the violation number in parenthesis.

All photos should be mounted in sequential order according to the violation listing on the Inspection Report.

Photographs must be submitted within seven (7) calendar days from the inspection.

Procedures Transferring Photos from Camera to Computer and Mounting

Inspectors need to be able to manipulate and transfer the pictures from their camera to their computer. Pictures will be printed out at the respective Regional Office to be used in regulatory actions/court for evidence. The following procedures should be followed in preparing pictures for submission:

TRANSFERRING PICTURES TO COMPUTER:

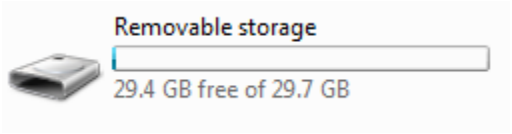
- Right click on the Desktop, select "New" then "Folder".
- Rename your new folder with the appropriate information (firm name, date etc).
- Folder may be placed later to "My Pictures" if it is not done automatically by your laptop.

OPTION A:
From your Smartphone, email the pictures to yourself; then drag the pictures from your Outlook mailbox to the new folder on the Desktop.

OPTION B:

- From your Canon, connect the camera to the computer via the USB cable.
- Turn the camera "On".
- Double click on the "Windows" button on the menu bar

- Select "Computer" then double click on the Camera device (Canon PowerShot D20)
- Double click on the image:



- Double click on the DCIM Folder
- Select the desired pictures and drag them to the new folder on the Desktop.
- Turn camera off once done and disconnect it from your computer.

MOUNTING THE PICTURES INTO A WORD DOCUMENT:

- On the attached Picture template.dot, enter the firm's information, date, your initials and page # on the top.
- Hit "Enter"
- Drag & drop the desired picture to the Picture template.dot
- Hit "Enter"
- Write picture description below the picture.
- Repeat steps as necessary.
- You could save your work as you go to be as one continuous document or save pages individually back into the new folder on the Desktop.
- Be sure to save the original pictures.

Procedure I-10: Computer Care and Maintenance

Computers and printers are a very important resource. Their importance will increase as we develop and improve the program. In addition to simply compiling reports, the system is an extremely important communication and information gathering tool. It is of the utmost importance that each person fully understands that they are responsible for the proper care and maintenance of their assigned equipment.

All computer operators are **required** to review the Virginia Department of Agriculture and Consumer Services Policy and Procedure Manual Number 10.1, Ethical use of Agency Information Resources. This policy sets forth guidelines for ethical and appropriate use of VDACS information and computing resources and for preventing security compromises to those two resources. All employees are required to sign an acknowledgment form which states you have read and understood the policy as well as an IT Security Agreement which certifies you understand the terms and accept the responsibility for adhering to the same. (NOTE: VDACS Policies and Procedures can be accessed from the VDACS intranet home page). Also, each computer and printer came with manuals. These manuals provide the novice and accomplished computer user the BASIC information they need. Although the information is basic, all field computer users are required to have reviewed the manuals and they must be kept readily available as reference material.

Care of the Hardware

First and foremost, read your manuals and follow their instructions. Often times they will provide simple solution to routine problems and how to operate the equipment efficiently and safely. Take care of the equipment like it was your personal property.

Always consider the environmental factor you are faced with in you territory. Do not, under any circumstances, leave the computer or printer in your car overnight. During the day, take steps to protect the computer and printer from temperature extremes. Simple steps like keeping the equipment covered with a light colored towel to reflect the heat in the car will provide a significant degree of protection for your computer. Try to park in the shade to reduce heat accumulation in the summer or in the sun in the winter. In the event you are required to be involved in a lengthy visit at an establishment (an all-day inspection for example). it may be necessary to bring your computer in from the car to avoid damage from extremes of heat and cold. Of course, when this is done, you must insure that you leave the computer in a secure area of the firm. Make sure your equipment is on a stable surface to prevent accidental falls; do not expose the equipment to magnets; do not allow the equipment to get wet (drinking beverages over the equipment is not a good idea).

Security

The laptop computer assigned to you has been identified as containing sensitive data. Encryption software has been added to your laptop, however, it is imperative that you take all steps necessary to safeguard both the physical device and the data which is contained on it. Do not invite theft or assault. Common sense goes a long way in this area. There are situations where using the computer would not be a good choice and handwriting

the Inspection Report to expedite the visit is a wise choice. Consult with your regional manager for guidance in providing services in dangerous locations.

Passwords

The passwords have to meet the following criteria:

Length will be 9 characters minimum

Passwords will have to be mixed letters and numbers

Passwords will expire every 90 days

When your password is getting ready to expire, you will receive a warning if you login anytime on the last 2 days prior to expiration. You will have 3 grace logins after the password expires but please change it when first notified to prevent getting locked out.

The following procedure should be followed in changing your password:

When you are prompted that your password is going to expire and asked to change the password, press "No" and let the computer finish opening up.

Sign into the VPN as you would normally do.

Press the keys Ctrl + Alt + Del, and select “Change Password”.

Complete all of the information blocks to change your password (enter your old password, your new password, and confirm your new password).

Once you have done all of the above, your password will be changed and you will have the same password for your computer, the VDACS intranet, and for Outlook email.

Special Note: All requests for access or password resets must still be submitted through the VDACS Access Request System (this link can be found on the VDACS intranet home page). These items SHOULD NOT be submitted through VCCC.

Computer Technical Support

All requests for assistance with your computer will be directed to the Virginia Information Technologies Agency (VITA) Customer Care Center for assistance with computer-related issues. The Customer Care Center, otherwise known as the Enterprise Helpdesk, operates 24 hours a day/7 days per week.

Individual field personnel WILL not attempt to obtain computer support services outside of VITA. Such action could result in disciplinary action.

To request assistance on IT issues individuals can reach the Enterprise Helpdesk at:

Toll free phone: 1-866-637-8482 (VITA)

Email: vccc@vita.virginia.gov

Administrative procedures

The help desk will validate your identity using a PIN number and secret word. Once your identity is validated, the Helpdesk will log your call and route the "ticket" to the appropriate infrastructure technician, engineer, application developer or database administrator. Once the call is logged, you will receive several emails. The first will indicate the ticket number and will validate that the call was logged. Additional emails will be sent to you each time the ticket is updated by the technician and once it is resolved.

Additionally, you are expected to keep your regional manager informed that you are having difficulty and have contacted the Helpdesk.

FIELD OPERATIONS MANUAL

Procedure I-11

FARMERS MARKETS

The following administrative procedures will be used when conducting and reporting inspections of farmers markets. In all situations, the Food Safety Specialist should encourage the market vendor to carry documentation of their home inspection with them to the various farmers markets they attend. This will help Inspectors identify who is and who is not under inspection should the vendor travel out of their "home" area to sell their products. Farmer's Markets should be inspected one to two times annually unless otherwise instructed. The overall market and each **food service** vendor will be charged an annual inspection fee.

THE MARKET

A. The overall market will be assigned a CFN.

B. An Inspection Report will be issued to the manager covering the overall condition of the market. If there is not an on-site manager, determine who the responsible person is and present or mail a copy of the report to that person.

C. The inspection report should include the following information:

1. The name of the market manager or most responsible person.

2. The phone number and address of the Farmers Market and the mailing address and phone number for the person in charge (if different from the market).

3. The date the market first opens for the season.

4. The date the market closes for the season.

5. Hours of operation (i.e. 8-5 weekdays, weekends, etc.)

FOOD SALES BOOTHS (ALL BOOTHS EXCEPT FOOD SERVICE VENDORS)

A. Only the actual Farmers Market will be assigned a CFN. Each individual food booth will **no longer** be assigned a CFN unless the inspection for the booth receives an OAI classification.

B. You will need to inspect each food booth during your inspection of the market.

C. Any objectionable conditions found at a vendor's booth will be listed on the actual farmer's market inspection report beneath the name of the vendor for all NAI and VAI inspections. Please note that you will only discuss your inspectional findings with these vendors. No report will be issued to these establishments.

D. Food Sales Booths receiving an OAI/30 day classification will need to be issued a separate inspection report. These booths will receive a letter of warning so you will need to document on the report the name and mailing address of the owner. These inspectional findings will also need to be placed on the Farmers Market Report. The OAI classification will also include vendors selling uninspected food products. In regards to uninspected food manufacturers, unless otherwise notified that the manufacturing location has been placed under inspection, an onsite f/u inspection will need to be conducted at the market.

E. Any vendors that were previously assigned a CFN number should be removed from your inventory by submitting an Inspection Report classifying the firm OOB, even though 'technically' they are an active business.

UNINSPECTED FOOD PROCESSING OPERATIONS

A. If you encounter booths offering their products for sale where the processing or packaging location is not under inspection, the following protocol is to be followed:

1. Document on the inspection report for the farmers market that uninspected food products are being offered for sale.

a. Include the name of the vendor, actual (physical) location of the manufacturing site, phone number and types pf products being offered for sale.

2. If there are concerns about product safety (i.e. whether the product is low acid or acidified), then contact your Regional Manager or Field Supervisor for guidance as to whether the product in question should be "pulled" from sale and/or sampled.

B. If there is a question as to whether or not the manufacturing site may be under inspection in another Food Safety Specialist's (FSS) territory, the following protocol is to be followed:

1. If you are unsure if the manufacturing site is under inspection, notify the appropriate FSS for that territory and their manager.

2. The notified FSS shall provide you a response via e-mail when the firm has been placed under inspection or if the firm is already under inspection.

3. Do not document on the inspection report if you are unsure as to whether the manufacturing site is under inspection.

.

FOOD SERVICE VENDORS

Food service operations at Farmers Markets (that are run by **governmental entities)** will now be inspected by VDACS. Typically, these operations are of a temporary nature and are conducted in an "outdoor" setting. You will need to fill out an inspection report for each of these vendors. All of these vendors will be assigned a CFN. Additionally, any objectionable conditions will need to be documented on the overall market report. Include on the inspection report:

- Name of Firm
- Owner/Operator of Firm
- Home Address
- Home Phone Number
- Description of food service operation
- Where foods are being prepared (Processing locations must be under inspection, i.e. approved source)

The Va. Department of Health will continue to inspect all Food Service Operations at Farmers Markets run by private individuals/organizations. Additionally, conventional restaurants at all Farmer's Markets (both government and private) will be inspected by the health department.

See attached requirements for Food Service Vendors at Farmer's Markets.

Requirements for Food Service Vendors at Farmer's Markets.

Regulatory Authority: Virginia Food Laws, Code of Federal Regulations (110).

Structural Components for Outdoor Cooking

- **Floors**

  Floor surfaces in a permanent outdoor cooking operation will be in accordance with the requirements for temporary food establishments. Floor must be of a suitable construction that controls dust, dirt and other similar contaminants.

  (1) If graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other suitable approved materials that are effectively treated to control dust and mud.

- **Walls**

  It will not be necessary to install walls in an outdoor temporary food operation. However, if conditions warrant installation of walls may be necessary.

- **Overhead Protection**

  Overhead protection for each temporary food establishment must be provided. Examples of acceptable overhead protection are tent, canopy, awning, table-type umbrella, or a permanent structure. The presence of overhead protection such as a tent or canopy does not preclude circumstances in which protection of individual food containers is also required, such as placement of food near a warewashing operation (potential splash contamination.)

- **Ventilation and Fire Protection**

Local regulations shall govern ventilation and fire protection requirements at outdoor cooking sites.

Equipment / Food Contact Surfaces

- **Food Contact and Equipment Surfaces**

  Construction, maintenance, and cleaning of all equipment pieces shall be in accordance with applicable laws and regulations. All food contact surfaces used in an outdoor cooking operation shall be designed, constructed, and maintained in accordance with applicable laws and regulations. Surfaces shall be smooth, easily cleaned, free of rust, dents or pitting, and durable under normal outdoor use conditions.

- **Cooking / Hot Holding Equipment**

  Hot foods should be held at 140°F or above. A continuous heat source such as electric or gas is preferred, however the use of sterno, wood, or charcoal is acceptable if consistent temperatures are achieved and/or maintained.

- **Cold Holding Equipment**

  Cold foods should be held at 45°F or below. Ice or electrical/gas powered equipment may be used provided acceptable temperatures are achieved.

- **Plumbing / Water / Sewer (Wastewater) Facilities**

  Potable water must be provided for all temporary food service facilities. Water and sewer may be permanently plumbed or supplied via portable tanks. Food grade water hoses are acceptable to transport water to the facility as long as backflow prevention devices are provided. The use of a garden hose to convey water is prohibited.

  If not plumbed, the sizes of the tanks shall be in accordance with any applicable laws and regulations for mobile food units. The quantity of tanks provided shall be sufficient to fully accommodate the needs of the operation.

  Handwash facilities must be conveniently located in all food processing and preparation areas. Heated water (90°F minimum) must be provided for handwashing. An insulated water cooler or electric coffee/tea urn with a spigot is the preferred method if a mobile hot water sink is not available.

Suitable containers must be provided for the collection of both solid and liquid waste.

Toilet facilities for employees must be convenient and easily accessible.

- **Food Storage and Display**

  Open or uncovered containers of food are not allowed -- except working containers. Foods may remain uncovered during preparation, cooking, and serving for short periods of time if circumstances permit.

  All food shall be protected from customer handling, coughing, sneezing, or other contamination by wrapping, the use food shields, or other effective barriers.

  Condiments must be dispensed in single-service type packaging, in pump style containers, or in protected squeeze bottles, shakers, or similar dispensers which minimize contamination of food items by food workers, patrons, vermin, environmental conditions, or other sources. Self service containers of non-potentially hazardous condiments such as minced onions, relish, and the like shall be acceptable so long as the foods are adequately protected from contamination.

Equipment, Utensil, and Warewashing

A properly plumbed three compartment sink with hot and cold running water or three containers of adequate size shall be provided for washing, rinsing, and sanitizing food contact surfaces of utensils and equipment. Adequate quantities of hot wash water (should be at least 110 F), liquid detergent, and sanitizer must be provided onsite for equipment and utensil washing.

Procedure I-12: Dress Code

As an employee of the Virginia Department of Agriculture, you are expected to project a professional image in all public situations. How you are dressed is an important part of your public image. Good public relations and practicality require you to dress appropriately for the activity in which you are engaged. A Food Safety Specialist will be neat, clean and well-groomed. Dress appropriately for the task or occasion, giving thought to the usual attire of the individuals in whose company you will be. Our agency dress code includes guidelines for dressing appropriately while working or meeting with the public. Those guidelines, together with our Food Safety Program guidelines, include the following information:

Slacks/Pants/Jeans
Slacks that are similar to "Dockers" (khakis), wool pants, dressy capris, and other nice looking casual pants are acceptable. In some situations (see examples in the "Additional Clarifying Points" section), jeans are acceptable as long as they are in good condition, not ripped, faded, or torn, and clean. Inappropriate pants include sweatpants, exercise pants, Bermuda shorts, pajama pants, shorts, overalls, leggings, jeggings, and any spandex or other form-fitting pants such as those worn for athletic wear.

Skirts, Dresses, and Skirted Suits
Casual dresses and skirts, and skirts that are split at or below the knee are acceptable. Dress and skirt length should be at a length at which you can sit comfortably in public. Short, tight skirts or dresses are inappropriate for work. Mini-skirts, skorts, sun dresses, beach dresses, and spaghetti-strap dresses are inappropriate. An otherwise bare-shouldered dress is acceptable only if worn with a cover-up such as a cardigan, jacket or another top.

Shirts, Tops, Blouses, and Jackets
Casual shirts, blouses and tops, dress shirts, sweaters, button-downs, oxfords, golf-type shirts, and turtlenecks, and the like, are acceptable attire for work. Inappropriate attire for work includes tank tops; sweatshirts; midriff tops; shirts with potentially offensive words, terms, logos (except for university, college or agency logo), pictures, cartoons, or slogans; halter-tops; tops with bare shoulders; and t-shirts unless worn under another blouse, shirt, jacket, or dress.

Shoes and Footwear
Loafers, oxfords, clogs, boots, flats, dress heels, and deck-type shoes (i.e. "top-siders") are acceptable for work as is comfort style shoes. Wearing no stockings or socks is acceptable in warm weather if the shoe style permits. Flip-flops, bedroom shoes and slippers are not acceptable; some work situations may require steel-toe shoes or boots for safety. Closed toe shoes may be required in certain situations where safety is a concern.

Jewelry, Makeup, Perfume, and Cologne
These items should be in good taste, with limited visible body piercing. Remember, that some people are allergic to the chemicals in perfumes, so wear these substances with restraint. Some jewelry may need to be covered, secured, or removed during the inspection of some food establishments.

Additionally, as reflected in FOM 1-01 Inspector Safety, when working in unsafe areas you are to dress appropriately so as not to draw undue attention to yourself.

Protective clothing

The office provides smocks (and coveralls) for this purpose. Smocks, as well as hair restraints, are to be worn whenever you are in a processing environment whether it is a large manufacturer, convenience store with a food service, or a home baking operation-they are all processing/preparation environments.

You do not need to wear a smock in non-processing areas as long as you are wearing a name tag (ie: identification tag) indicating you are a Food Safety Specialist. You are responsible for keeping your smock clean and in good condition. Only clean smocks are to worn during firm inspections. Wash and press them as needed; alternatively, the Food Safety Program will reimburse you for laundering costs of the smock (up to $8.00) if you choose to use a cleaning service. You may also request reimbursement for up to $100.00 for the purchase of a pair of steel toe shoes.

If a firm requires their employees to wear additional protective clothing, such as beard guards, hard hats, safety glasses, ear plugs, safety vests, steel toe shoes, etc., then you are expected to dress like-wise. If you do not have the specific safety gear needed, request it through your regional office. In most cases, the firm will provide it as a courtesy if you do not have the specific safety gear needed.

Additional Clarifying Points:

- All clothing should be clean, wrinkle free and not worn-out, torn, frayed, stained, dirty, faded, discolored, patched, ripped, or missing buttons.
- Clothes with offensive slogans or pictures, e.g. profanity and nude or semi-nude pictures, offensive gestures, suggestive cartoons are not acceptable.
- Camouflage and athletic apparel including, but not limited to, hunting clothes, spandex and lycra garments such as biking shorts, warm-up or athletic pants, sweatpants, sweatshirts, jogging or track suits, or athletic apparel with team logos are never acceptable.
- Clothing must not create a distraction. All clothing, especially jeans, must be consistent with the expectations for a business casual environment and not attract undue attention or serve as a distraction to others. It must also be appropriate to type of work being performed and take into account the expectations of any customers served.
- Individuals serving on an interview panel need to dress in a professional manner that is a step above the standard “business casual”. Men: a suit, or sport coat and slacks; Women: a dress, skirt and blouse, dress slacks and blouse, or a suit.
- ***More guidance on jeans – Generally, employees meeting with clients should dress using the same dress code standard (or better) as the client with whom they are meeting. <u>As professionals, we should never be dressed more casually than the individuals we are meeting with or regulating.</u> A few examples:***
    - ***If khakis and a polo shirt are standard wear at an establishment being inspected, VDACS employees should not wear jeans (e.g. chain grocery stores).***
    - ***If jeans are standard attire at an establishment, jeans may be appropriate in some instances (e.g. a warehouse where jeans are standard attire).***
    - ***Jeans may be appropriate for disaster work.***
    - ***Jeans should not be worn if the standard attire of an establishment is not known.***
    - ***In any non-routine situations, consult with your Regional Manager about the appropriateness of wearing jeans.***

FIELD OPERATIONS MANUAL

PROCEDURE I-13
New

EMAIL USE AND ETIQUETTE

Electronic mail, commonly referred to as "email", has become a necessary and effective communication tool to exchange information between the offices, the field, our clients and each other.

In order to increase the efficiency of email, all field and office personnel will check and respond to their email on a DAILY basis.

All email that you receive and/or generate on your agency computer is for official use only and may be subject to a "freedom of information" (FOI) request. Simply deleting an email from your computer, does not prevent it from being recovered.

EMAIL DO'S AND DON'TS:

DO Keep email short. Be concise.

DO respond to your mail as soon as possible.

DO NOT send inflammatory comments. Be official and factual.

January 19, 2000

Procedure I-14
Revised

INCLEMENT WEATHER

The following procedure outlines the protocol that will be followed during inclement weather conditions. This protocol is fully compliant with all HRO policies and directives relating to inclement weather. Please remember that conditions vary widely across the state and may even vary within a region.

If weather conditions, such as snow and/or ice storms, hurricanes, severe rain storms etc., are such that the field Food Safety Specialist (FSS) does not feel that he or she can perform field work **safely,** they should contact their Regional Manager to discuss the situation.

It is important for an employee to communicate with their supervisor if weather is going to impact their ability to perform their job duties. Subsequent to discussing the situation with your Regional Manager, you and the Manager should collectively determine whether or not you should stay at home or perform field work. In determining whether conditions are suitable for working at home, the FSS should utilize information from the following sources, but not limited to:

- Consult the National Weather Service website or local news sources for current weather and future conditions
- Review if other organizations or events are closing. Local government closings can be a good indicator of travel conditions in an area. School closing probably should not be used because they consider different factors for bus and student safety.
- The VDOT website or calling 511 will provide road condition reports

Criteria, such as the general condition of roads, streets and highways in the FSS's **immediate** vicinity, the availability of work in their immediate vicinity and/or contiguous areas, terrain (i.e. steep hills that must be navigated in close proximity to residence) etc. should be utilized. Another critical factor is your ability and/or experience in driving in severe weather, e.g. snow and ice.

If **weather conditions improve** at some point in time during the workday the FSS should **resume his or her normal field duties** when and where possible.

Note: The FSS can also contact their Field Supervisor for a determination as to how to deal with inclement weather situations. Once a determination has been made the Field Supervisor should provide that information to the Regional Manager.

Mobile Workers

Food Safety Specialists are considered to be 'mobile workers'. A mobile worker is defined as an employee who works a clear majority of their planned schedule in a mobile mode away from agency offices/facilities out in the 'field'.

Weather related State Office closings, delayed openings, etc do not affect mobile workers. Mobile workers are expected to continue working during Agency or Regional Office emergency closings unless it is not possible due to power outages or other conditions that prevent them from working. Additionally, mobile workers who do work during an authorized closing would not receive compensatory time.

In instances where it is impossible to perform field work then work related activities should be performed at the FSS's home office when possible (ORA-U courses, administrative work, food safety research, returning phone calls, review of Laws and/or Regulations, etc.).

Timesheet/Leave Slip Issues

If weather conditions are such that field work is not possible and work is conducted from home the FSS would record the number of hours worked in the home office on their timesheet.

If a Food Safety Specialist is able to work at home and they chose not to work, they must use leave.

If field work is not possible and home office work has been completed/finished then the timesheet should show "Emergency Closing" for the remainder of that particular day (choose emergency closing from the "Type" dropdown menu) and indicate the number of hours in which work was not performed.

Also, if home office work is not possible to due to unforeseen circumstances such as a power outage then the timesheet should show "Emergency Closing" for that particular day and the Inspector should provide a brief statement on their particular situation in the "comments" section of the timesheet

See FOM Procedure I-17 Timesheet Instructions for more information how timesheets and leave should be handled during inclement weather situations.

****SAFETY FIRST!****

YOU MUST RECORD, IN YOUR DAILY CALENDER, THE FACT THAT YOU WORKED AT HOME DUE TO WEATHER CONDITIONS AND WHO YOU INFORMED. THIS IS FOR YOUR PROTECTION!

Revised March 2015

Procedure I-16: Work Schedule

Background and Policy

The Department of Personnel and Training (DPT) has authorized Alternate Work Schedules (AWS) since 1993. However, in order to avoid misuse, clarification is needed. The Food Safety Program is responsible for ensuring adequate coverage to all areas Monday through Friday from 8:15 a.m. through 5:00 p.m. Full service must be available to our consumers throughout those hours. Additionally, the AWS is a privilege, and not a right.

New Food Safety Specialists (FSS employed for less than one year), are not permitted to work an alternate work schedule. Generally, once personnel advance to the "Senior" level they can be eligible, but the eligibility for the AWS is at the sole discretion of the Regional Manager.

New personnel in "training" will follow the instructor's working hours at all times.

Options

The following are the only options available to field personnel (Food Safety Specialists):

- Ten (10) hour days, four (4) days per week
- Eight (8) hour days, five (5) days per week
- Ten (10) hour days, four (4) days per week

Employees electing to work four (4) day weeks must schedule those days with their supervisors. Starting hours are between 6:30 a.m. and 7:30 a.m. and ending times are between 5:15 p.m. and 6:30 p.m.

When employees are sick or on annual leave, ten (10) hours will be charged each day. Time off for the holidays will for eight (8) hours only. Employees scheduled to work 10-hour days on holidays must charge two (2) hours to leave. No employee is authorized to work for the two (2) hours at "home". OR, the employee can revert to the regular eight (8) hour days for the week in which a holiday occurs.

Without exception, for the holidays of Thanksgiving, Christmas and New Year's, employees **must** revert to the eight (8) hours/five (5) days work schedule.

You **must** obtain pre-approval from your Regional Manager before working the AWS, and before making any changes in your work schedule. Additionally, you may be required to submit your "days off" schedule in a format and frequency designated by your Regional Manager, for their review and approval.

Eight (8) hour days, Five (5) days per week

Employees who elect to work a five (5) day week must schedule work hours with their supervisor. Flexible hours for five (5) day work weeks are from 7:00 a.m. to 6:00 p.m. Employee leave balances will be charged eight (8) hours per day when sick or annual leave is taken. Employees take holidays as scheduled.

Inclement Weather

During periods of inclement weather, Field Operations Manual Procedure I-14 Inclement Weather applies. Your activity during inclement weather work hours is subject to verification by your Regional Manager.

Procedure I-17: Timesheet Instructions

It is the policy of the Virginia Department of Agriculture and Consumer Services to follow the Federal Fair Labor Standards Act (FLSA) as directed by the Virginia Department of Personnel and Training and the U.S. Department of Labor. All field employees in the Food Safety Program are considered "non-exempt", meaning they are subject to all minimum wage and overtime provisions of FLSA.

Therefore, in accordance with FLSA, the Department has required that all non-exempt personnel submit an accurate VDACS Timesheet via the web-based time, attendance and leave (TAL) system.

TAL - FREQUENTLY ASKED QUESTIONS (FAQs):

- Employees must use EmployeeDirect to access TAL. If you do not have an EmployeeDirect user name and password, you must go to https://edirect.virginia.gov/ and select "Register Now" under the header "Not Registered?"
- You must complete both the leave request and the timesheet. The leave request is your prior approval for leave and the timesheet serves as the legal requirement for the Fair Labor Standards Act (FLSA). You will need to record all hours worked and leave taken on the timesheet. TAL will pull the leave used from the timesheet only and deduct it from your balances. If you do not complete the timesheet, your balances will not be accurate.
- Timesheets should be submitted in TAL the day following the end of the work week. TAL provides a notification to employees that a timesheet is due. If you do not heed the notification and complete the timesheet, you may not be paid.
- You need to enter your start and end times in the comment field as well as the amount of time taken for your lunch break. This is the only way Payroll can verify the total hours you enter for the day is accurate.

OVERTIME and COMPENSATORY LEAVE:

- Overtime leave earned is automatically calculated in TAL and employees do not need to take any other action to receive credit for overtime leave. Overtime is earned when you physically work more than 40 hours in a work week.
- Compensatory time earned is not calculated automatically. Employees who earn compensatory leave, must enter a Type of "Compensatory Earned" on their TAL timesheet. Compensatory leave is earned when an employee works more than their scheduled hours, but physically works less than 40 hours. This can occur when an employee works a holiday or takes personal leave and works more than their scheduled hours.

Compensatory time earned and overtime earned **must have supervisory approval** and should be reserved for emergency or extraordinary work on weekends, holidays and evenings after your normal work day. Emergency situations like fires, floods and truck wrecks, will continue to have priority and approval in these situations may have to be secured after the fact. However, other extra work, which must be conducted on holidays, or on the

weekends, like the inspection of farmers markets or other situations where inspections must occur in off-hours, should be approved in advance by your supervisor.

Approval process:

- Food Safety Specialists will need to submit an email to their manager with a brief explanation as to why they need to work over 40 hours (ie. earn compensatory or overtime leave).
- The manager will respond back either approving or denying the request.

Under normal circumstances, employees shall not work more than forty (40) hours in any work week. Employees are to "**schedule adjust**" at the end of their work week to avoid exceeding 40 hours.

STATE OFFICE EMERGENCY CLOSING

Food Safety Specialists are considered to be "Mobile Workers". Weather related State Office closings, delayed openings, etc .do not affect mobile workers and you are expected to continue working during an Agency or Regional Office emergency closing unless it is not possible due to power outages or other conditions that prevent them from working safely.

- In situations where the employee is working from home during inclement weather and they have completed/finished all their work then the timesheet should show "Emergency Closing" for the remainder of that particular day and indicate the number of hours in which work was not performed.
- When home office work is not possible to due to unforeseen circumstances such as a power outage then the timesheet should show "Emergency Closing" for that particular day and the Inspector should provide a brief statement on their particular situation in the "comments" section of the timesheet.

Procedure I-18: Preparation for Court

If it is necessary to initiate legal action against a firm, the food safety specialist must be a well prepared witness. Prior to the trial date, he/she should be sure that his/her files are up to date and in chronological order according to dates of inspection, etc. The Food Safety Specialist should review his/her files and notes and become very familiar with the facts in the case. The Food Safety Specialist's file and other pertinent information should be available at the trail.

When testifying, the Food Safety Specialist should always direct his/her testimony to the judge or jurors in case of a jury trial. It is important to remember that the judge or the jury will make the final decision.

The Food Safety Specialist should give clear, distinct, concise, and positive answers on the witness stand. You should never be evasive when answering questions. You should answer the specific question asked by the court and no more. If you do not understand a question asked by the court, then you should ask for the question to be repeated.

Special Note: When testifying in court, there may be situations where the Food Safety Specialist may only be allowed to refer to his/her notes taken during the inspection and not the Inspection Report. Therefore, when performing inspections of establishments that may result in legal/court action, place the notes of the objectionable conditions you have taken during the inspection into the firm folder. Make sure that these notes are available for reference purposes when you are called upon to testify.

The following listed items are what one Virginia circuit court judge says are important in presenting a case:

1. Tell the truth.
2. Have confidence in your case.
3. Give positive answers.
4. Witness must be informed and prepared.
5. Witness must listen to the questions.
6. If you do not know the answer, say "I do not know"
7. Never get angry on the stand.
8. Must be able to prove there has been a violation through facts.
9. Impression made on the witness stand is very important.
10. Be neatly dressed.
11. Be courteous.

Procedure I-19: Operation of a State Vehicle

Assignment of Vehicle

- The vehicle is assigned to you for the purpose of performing your regular duties and special assignments in your assigned territory and other points in Virginia. Passengers, except those directly related to the purpose of the official State business or travel, are forbidden; also any other individual shall not be permitted to operate the assigned vehicle.
- The use of a state owned vehicle for purposes other than those specified above shall be only with the consent of your immediate supervisor.

Maintenance and Service of Vehicle

- Drivers must call Vehicle Management Control Center (VMCC)/TechCom Inc. 1-866-857-6866 for routine maintenance, repair or roadside assistance. Select Option # 1 to reach an operator.
- All vehicles should be kept in their original working condition as much as possible in order to prevent premature failure and personal injury. If a problem exists that you are aware of, do not neglect to get it fixed.
- Arrangements should be made with your Regional Manager to look into the feasibility of obtaining a 'loaner' vehicle if your state car will be out of service for an extended period of time.

Monthly Mileage Reports and Gas Receipts

- All operators of State vehicles are required to submit a monthly mileage report on forms furnished for this purpose to the Department. You will need to submit the mileage form along with original gas receipts to Annie McCullough no later than the 5th of the following month (Annie.McCullough@vdacs.virginia.gov). The report and gas receipts can be sent to by e-mail if you have the ability to scan your gas receipts, if not then you will need to mail the mileage report and gas receipts on the 1st of the month to make sure that they are received by the deadline. Instructions for completing the mileage report are stated on the form.

Accidents

- All accidents involving any State-owned, leased, or rented vehicle must be reported immediately to the Vehicle Management Control Center (VMCC) at 866-857-6866, available 24 hrs/day 7 days/week. VMCC will coordinate a response to the accident and call the State Police, wrecker service and any other necessary party and report the accident to Risk Management
- The driver will need to complete an Auto Loss Notice Report and send it to the Office of Fleet Management Services (OFMS) and to the agency Vehicle Transportation Officer (ATO) which is John Lawton.
- The accident report will be reviewed by a Safety Committee set up by the Governor of Virginia. If this Committee decides that the accident resulted from speeding, careless or reckless driving, or any other

fault of the driver, then the Department will be held liable for repairs and other damages, and the driver will be subject to penalty.

- Each operator of a State vehicle should thoroughly acquaint himself with instructions pertaining to the operation of such vehicles and the procedure for reporting accidents. These instructions are placed in each vehicle as well as forms for reporting accidents.

Traffic citations (Speeding tickets, etc)

- If you are issued a ticket you will need to notify the office promptly. The driver should pay the ticket as soon as possible and provide the office a copy of the paid ticket receipt.

Safety

- Safety first - it pays! Make it a point to drive carefully and observe all traffic laws including the wearing of seat belts.
- Vehicles are to be kept locked at all times.
- Cell phone usage is prohibited while driving. Park the car when on the phone.

Appearance of State Owned Vehicle

- It is essential that we exercise proper care to keep the vehicle we operate clean and neat at all times. We realize that at times weather conditions make it quite impossible to keep your car clean, but there is need for realization of the importance of this matter.
- No smoking is allowed in a state car. Eating is prohibited while driving.

POLICIES AND PROCEDURES FOR FUEL PROGRAM

Mansfield/Voyager Fuel Cards are to be used for either regular unleaded gasoline or E85 (Flex-Fuel vehicles) if the vehicle is capable of using E85. This includes all Enterprise Rent-A-Cars. We do not have high performance vehicles that require premium or Mid-grade fuel.

Fuel for vehicles is to be obtained from the OFMS facility, a VDOT facility, or a Voyager accepted commercial station. A directory of VDOT motor vehicle service facilities is located in the glove compartment of each vehicle. The normal hours of operation of these facilities, unless otherwise noted in the directory, is 8:00 a.m. to 4:30 p.m., Monday-Friday excluding state holidays. A directory of Voyager locations can be found at http://www.usbank.com/voyagerfleet/search.jsp.

Use only unleaded regular fuel in gasoline powered CoVA vehicles. Mid-grade or premium blends are only to be used when regular is not available. E85 fuel is to be used in Flex-Fuel vehicles where available. A list of E85 locations and approved vehicles can be found at http://www.e85refueling.com/. Operators are expected to use self-service pumps at commercial stations, since this option is normally more economical.

Operators MUST enter correct odometer readings, no tenths, into the card readers at all VDOT and commercial self-service fueling sites. The Vehicle Management Control Center will run daily fueling reports and will contact

all Agency Transportation Officers and drivers who consistently fail to enter correct odometer readings. Correct odometer readings are critical to the fleet management system, and this requirement will be strictly enforced.

Finally, it is important to realized that the unauthorized use of and/or negligence when operating a State-owned, leased, or rented vehicle may result in disciplinary action, up to and including dismissal. Employees guilty of misuse may also lose their privilege to operate a State-owned, leased, or rented vehicle.

Procedure I-20: Employee Conduct

Field personnel are the first line of public contact (and in most cases the only contact) for the Department. Your actions will be the basis from which they judge the Food Safety Program. The public, as well as this Department, expect and deserve exemplary behavior and conduct. Be cognizant that the public, as well as the regulated industry, are quick to point out deficiencies in our performance.

Integrity

You are entrusted with equipment and field duties under minimal supervision. You have an inherent responsibility to protect and conserve all government property including equipment and supplies. Employees may not use or permit others to use official information not available to general public for personal gain or to advance a private interest. You are expected to conduct yourself in a professional manner so that the work of the Food Safety Program is effectively accomplished. Your job is to gather and present the facts. Accurate and objective observations are mandatory.

Attitude

You must be dignified, tactful, courteous and diplomatic. At no time will you display strong-arm tactics, an air of superiority, or an over-bearing nature. Demeaning comments and/or intimidation tactics toward a firm or their employees will not be tolerated or defended.

Ethics

Employees shall not, directly or indirectly, solicit or accept a gift. Generally speaking, an employee shall avoid any action that might result in or create the appearance of:

1. Holding a conflicting financial interest.
2. Loss of impartiality in performing official duties.
3. Using public office for private gain.

If an employee violates this policy, he or she may be subject to disciplinary action under the Standards of Conduct and Performance, up to and including termination.

Procedure I-21: Contact with the Media

Over the years, the inspectional and investigational activities of the Food Safety Program have received coverage in the electronic and print media. On occasion, you may be approached by the media to comment or provide information regarding your inspectional activities. If media representatives contact you, do not state you have "no comment", instead tell them to contact your Regional Manager and provide them with their contact information. You may be permitted to appear on camera or be interviewed, but authorization must be gained in advance. Do not solicit media interviews or on-camera appearances unless you are authorized.

There may be occasions when representatives from the news media will be present during your inspection and request to film or interview you. When this occurs, you are to immediately contact your Regional Manager to make them aware of the situation before proceeding with your inspection. The Regional Manager must then contact the Program Supervisor/Manager and Communications Office for guidance on how to respond. If you are given permission by management, you should continue to conduct the inspection as you normally would. The presence of these individuals should have no impact on the manner in which the inspection progresses with the exception that you will need to take precautions to preserve the confidentiality of any information you may have obtained.

In summary, whenever the media approaches you, be courteous and helpful but refer any request to be interviewed or filmed to your Regional Manager.

Procedure I-23: VDACS Food Safety Program Training Manual

Table of Contents

I. Introduction ---------- 2

II. Retail Training Program Overview ---------- 2

A. Prerequisite Curriculum ---------- 4

B. The VDACS Retail Field Training Worksheet ---------- 6

C. The Retail Establishment Log ---------- 10

D. Preparing for Joint Retail Field Training Inspections --------- 10

E. Conducting Retail Field Training Inspections ---------- 11

F. Release from Training ---------- 18

G. Continuing Training ---------- 18

H. Veteran Inspectors ---------- 20

III. Manufacturing Training Program Overview ---------- 20

A. Field Training Overview ---------- 21

B. Coursework ---------- 21

C. The VDACS Wholesale Field Training Worksheet ---------- 25

D. The Wholesale Establishment Log ---------- 25

E. Preparing for Joint Wholesale Field Training Inspections --- 26

F. Conducting Wholesale Field Training Inspections ---------- 27

G. Release from Training for Basic GMP Inspections ---------- 27

H. Advanced Food Inspection Training ---------- 27

I. Continuing Education ---------- 28

J. Veteran Inspectors ---------- 28

IV. Field Operations Manual ---------- 29

Attachment A – VDACS Retail Field Training Worksheet ---------- 29

Attachment B – VDACS Wholesale Field Training Worksheet ---------- 29

I. Introduction

The purpose of this Training Manual is to promote uniformity in the training of VDACS Food Safety Specialists (FSS). This manual describes procedures to accomplish an effective and meaningful training experience to fully prepare the FSS to conduct food safety inspections of Retail and Manufacturing operations. The criteria in this training manual are based on the requirements of the FDA's Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) and FDA's Manufactured Food Regulatory Program Standards (MFRPS) regarding training (Standard 2). This Training Manual focuses on two components of the multi-tiered approach contained in Standard 2 - coursework (online and classroom) and the field training model for preparing all Food Safety Specialists (FSS) to conduct independent food safety inspections. The instructions and worksheets provided in this manual constitute a training process, rather than a certification or audit process. While this manual shall be used as a guide in determining what to cover during training, the trainer may deviate from it to expose a trainee to unusual situations that will warrant their attention.

The training program and this manual are designed to prepare new hires to effectively apply the appropriate laws and regulations in the performance of their duties, as well as to help ensure effective on-going training of trained FSS. This training will emphasize that the FSS is not just an inspector who identifies, and reports food safety violations, but a SPECIALIST who can base decisions not only on what is in the "book", but also on sound scientific food safety principles. Additionally, they will develop the ability to offer constructive corrective recommendations, based on the aforementioned, to the establishments under our jurisdiction. Every effort will be made to insure that the new FSS is exposed to the widest range of activities and scope of our responsibilities. With the knowledge and skills obtained through this comprehensive training program, the VDACS Food Safety Program Food Safety Specialists become exceptionally well prepared to help protect consumers from foodborne illness and to support the food industry in their effort to comply with food safety laws and regulations.

Goals of the Training Program

1. To develop the ability to interpret and apply applicable laws and regulations in diverse situations.
2. To develop the ability to make autonomous decisions and to take appropriate actions in diverse circumstances and environments.
3. To develop the ability to effectively communicate, both orally and written.
4. To develop the ability to provide quality customer service.
5. To develop the ability to use computerized equipment and applications.
6. To develop a thorough knowledge of the Virginia Food Laws (VFL) and related laws/regulations.
7. To develop a thorough knowledge of Food Law inspectional and enforcement procedures.
8. To develop a thorough knowledge of food safety practices and principals.
9. To develop a thorough knowledge of food processing theory and practice.

II. Retail Training Program Overview

The VDACS retail training program consists of the completion of a set of online training courses (the retail prerequisite curriculum), immediately followed by field training. During this time, the new FSS will work with various Food Safety Specialists, who are considered qualified trainers, throughout the state on a weekly basis. Qualified trainer is defined as an individual who has successfully completed the training elements as outlined in Steps 1 through 3 of Standard 2 of the Voluntary National Retail Food Regulatory Program Standards (see below), and is recognized by the Training Coordinator (a Regional Manager assigned by the Program Supervisor to coordinate, track, and maintain documentation of the training process) as having the field experience and

communication skills necessary to train new employees. Veteran inspectors, defined later in this document, will also be considered qualified trainers.

Description of Steps 1 through 3 of Standard 2

1. Satisfactory completion of the prerequisite curriculum as defined in Section A below.
2. Completion of a field training process as defined below.
3. Completion of a minimum of twenty-five (25) independent inspections and completion of the post course curriculum as defined in Section F (Additional Food Safety Courses) below.

The Training Coordinator or designee will set up monthly training schedules and distribute them to all parties involved in advance so that all necessary arrangements (meeting time and place, hotel accommodations, etc.) can be made.

Initially, the newly hired FSS will spend one or two days in the Richmond office for orientation purposes and for receiving supplies needed for conducting inspections and for working from a home office. The rest of the week will be spent working with the Training Coordinator to become familiar with the Virginia Food Laws (VFL) and related regulations enforced by the Food Safety Program. Additionally, time will be spent going over pertinent Department and Agency Policies and Procedures, various forms of paperwork, and beginning the prerequisite courses. The following week the new FSS will work to complete the prerequisite courses. Once the prerequisite courses are complete (or very nearly complete), the trainee will begin Retail inspection field training with a qualified trainer, per the training schedule issued by the Training Coordinator or designee. During this time, the trainers will be explaining the various operations, the conditions observed and how these conditions relate to the VFL and related regulations.

As the new FSS becomes familiar with these activities, they will begin to handle portions of the inspection and paperwork on their own under the supervision of the qualified trainer. At this time the trainee FSS begins to move into the next stage of their training. During this period, the trainee FSS will be working alongside and comparing notes concerning the observed objectionable conditions with the trainer FSS. The trainee FSS should also be composing the majority of the paperwork at this stage with some assistance from the qualified trainer. At this stage in training, the trainee will become more comfortable with conducting inspections, filling out paperwork, and with understanding how objectionable conditions observed in the firm relate to the VFL.

During the ending stages of training, the new FSS will be handling all aspects of the inspection, including discussions with management, with little or no assistance from the trainer. The trainer, however, will be observing the actions, techniques and knowledge developed by the new FSS in order to help determine when they will be ready to be released from training and able to assume his or her own territory. At the end of the first phase of training, the new FSS will be familiar with inspecting retail firms. Inspections of manufacturing operations will not be conducted at this time. If a new manufacturing facility, like a home-op, is opening in their territory, the new FSS must request assistance from a FSS trained in manufacturing inspections. Until manufacturing training has been completed, the new FSS cannot do these inspections independently.

The new FSS will also tour the laboratory operated by the Division of Consolidated Laboratory Services (DCLS). The trainee will be required to attend the next CASA meeting held at DCLS, which will take place about every two years. This will be an opportunity to observe what goes on in the analysis of a food sample as well as meeting some of the scientists involved in the work.

Field Training Overview

All trainers should emphasize quality rather than quantity during the workweek. This should not be a rushed week. There should be ample time allowed in each processing area and part of the inspection for questions and discussion. Take the time to explain and see that the trainee understands what they see and what or why something is being done. In order to expose the trainee to all aspects of a firm's operation, comprehensive firm inspections that focus on foodborne illness risk factors should be performed.

The main focus during firm inspections will be to identify potential food safety issues that may arise and the measures needed to prevent and control those hazards. It is very important for the trainer to place emphasis on those risk factors that could contribute to a foodborne illness. Those risk factors include: improper holding temperature, inadequate cooking, contaminated equipment, unsafe food sources, and poor personal hygiene.

In the case that all the prerequisite courses have not been completed by the trainee prior to entering field training, time should be allotted in the workweek by the trainer for finishing these courses. The FSS can participate in conducting joint field training inspections while they are in the process of completing the prerequisite coursework.

A. Prerequisite Curriculum

PREREQUISITE COURSES

The Conference for Food Protection (CFP) worked with the FDA to identify a prerequisite curriculum designed to provide a FSS with a solid understanding of essential food safety and public health principles needed to conduct effective retail food safety inspections. The FSS should complete the prerequisite coursework during their first **FOUR** weeks of employment. The required courses are listed below.

Course Name	Course Number	Course Provider	Course Type	Web Link
Public Health Principles	FDA36	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basic Food Law for State Regulators	FDA35	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basic of Inspection: Beginning Inspection	FDA38	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basic of Inspection: Issues & Observations	FDA39	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Introduction to Food Security Awareness	FD251A	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Introduction to Food Security Awareness Exam	FD251	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Code Chapter 1: Purpose and Definitions	FDAFC02	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Code Chapter 2: Supervision	FDAFC07	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Code Chapter 3: Part I	FDAFC03	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Code Chapter 3: Part II	FDAFC05	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Code Chapter 3: Part III	FDAFC06	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Code Chapter 4: Part I	FDAFC08	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Code Chapter 4: Part II	FDAFC10	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Code Chapter 5: Water, Plumbing, and Waste	FDAFC04	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)

Course Name	Course Number	Course Provider	Course Type	Web Link
Food Code Chapter 6	FDAFC09	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Code Chapter 7: Poisonous and Toxic Materials	FDAFC01	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Code Chapter 8: Enforcement and Annex 1	FDAFC11	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Communication Skills for Regulators	None	IFPTI	Online	IFPTI Training
Food Microbiological Control 1: Overview of Microbiology	MIC01	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 2A: Gram-Negative Rods	MIC02	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 2B: Gram-Positive Rods and Cocci	MIC03	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 3: Food borne Viruses	MIC04	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 4: Food borne Parasites	MIC05	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control: Mid-Series Exam	MIC16	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 5: Controlling Growth Factors	MIC06	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 6: Control by Refrigeration and Freezing	MIC07	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 7A: Control by Thermal Processing	MIC08	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 7B: Control by Pasteurization	MIC09	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 10: Aseptic Sampling	MIC13	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 12 : Cleaning and Sanitizing	MIC15	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Introduction to Incident Command System, ICS100	IS-100.b	FEMA (Federal Emergency Management Agency)	Online	FEMA
ICS for Single Resources and Initial Action Incident, ICS-200	IS-200.b	FEMA (Federal Emergency Management Agency)	Online	FEMA
National Incident Management System (NIMS) An Introduction	IS-700.a	FEMA (Federal Emergency Management Agency)	Online	FEMA
National Response Framework, An Introduction	IS-800.b	FEMA (Federal Emergency Management Agency)	Online	FEMA

ComplianceWire FDA ORAU Self Registration: http://www.compliancewire.com/secure/custom/FDAORAUSelfReg.asp
ComplianceWire FDA ORAU website: https://www.compliancewire.com/Net/Secure/login.aspx
IFPTI website: https://ifpti.absorbtraining.com/
FEMA website: http://training.fema.gov/is/nims.aspx

New FSS will obtain the necessary ORAU login information from the Training Coordinator. The time needed to complete the prerequisite courses will vary from one trainee to another. If the prerequisite courses are not completed during the first two weeks of employment, the new FSS must notify the Training Coordinator of the need for more time. While it is not mandatory that the prerequisite courses be completed prior to starting field

training it is highly encouraged. However, the prerequisite courses **must** be completed prior to the new FSS being released from Retail Training and conducting independent inspections.

B. The VDACS Retail Field Training Worksheet

VDACS RETAIL FIELD TRAINING WORKSHEET

The *VDACS Retail Field Training Worksheet* (see Attachment A), which is used for retail field training only, provides a structured approach for tracking the FSS progress in successfully demonstrating specific performance elements and competencies. The Retail Field Training Worksheet should be reviewed prior to training so the trainer knows what they will be looking for during the training process. The trainer should review with the trainee the competencies that will be included as part of the field training inspections.

The *VDACS Retail Field Training Worksheet* provides areas for documenting:

- Trainee and Trainer information;
- Whether or not there was an opportunity to demonstrate a competency; and
- When a FSS consistently demonstrates a competency correctly.

INSPECTION TRAINING AREAS

The *VDACS Retail Field Training Worksheet* is divided into seven (7) inspection training areas:

I. Pre-Inspection
II. Inspection Observations and Performance
III. Oral Communication
IV. Written Communication
V. Professionalism
VI. Sampling
VII. Complaint Investigations

PERFORMANCE ELEMENTS

The *VDACS Retail Field Training Worksheet* contains a total of 24 “performance elements” within the seven (7) inspection training areas.

I. Pre-Inspection – (2 Performance Elements)
   1. Has the required equipment and forms to conduct the inspection.
   2. Reviews the establishment file for previous inspection reports, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance.

II. Inspection Observation and Performance – (7 Performance Elements)
   1. Provides identification as a regulatory official to the person in charge, confirming agency authority for the inspection and stating the purpose of the visit.
   2. Has knowledge of VDACS laws, rules, and regulations required for conducting retail food/foodservice inspections.

3. Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.
4. Obtains immediate corrective action for out of compliance employee practices and management procedures essential to the safe storage, preparation and service of food.
5. Correctly assesses the compliance status of other regulations that are included in VDACS prevailing statutes, **and/or regulations** (e.g. Infant Formula, Apple Marking, Ground Beef, etc).
6. Verifies correction of out of compliance observations identified during the previous inspection.
7. Correctly uses inspection equipment during the joint inspection.

III. Oral Communication – (6 Performance Elements)
1. Asks questions and engages in a dialogue with the person in charge/employees to obtain information relevant to the inspection.
2. Provides the person in charge/employees with accurate answers to inspection-related questions or admits not knowing the answer.
3. Uses available means (e.g., interpreter, drawings, demonstrations, diagrams, international food safety icons) to overcome language or communication barriers.
4. Follows VDACS policy in regard to disclosure of confidential information.
5. Uses effective communication and conflict resolution techniques to overcome inspection barriers.
6. Conducts the exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.

IV. Written Communication – (3 Performance Elements)
1. Completes inspection form per VDACS administrative procedures (e.g., observations, corrective actions, public health reasons, applicable code references, compliance dates).
2. Includes with the inspection report any compliance or regulatory documents identified or cross-referenced in written statements (e.g., exhibits, attachments, sample forms, seizure forms, destruction forms).
3. Presents the inspection report, and when necessary cross-referenced documents, to the person in charge.

V. Professionalism – (3 Performance Elements)
1. Maintains a professional appearance consistent with VDACS policy (e.g., clean outer clothing, hair restraint).
2. Demonstrates proper sanitary practices as expected from a food service employee.
3. Only reports substantiated findings as violations.

VI. Sampling – (2 Performance Elements)
1. Uses an aseptic food sample collection method consistent with criteria established by laboratory serving VDACS (e.g. DCLS, FDA Regional Laboratory).
2. Uses an aseptic water sample collection method consistent with criteria established by laboratory serving VDACS (e.g. DCLS)

VII. Complaint Investigations – (1 Performance Element)
1. Thoroughly investigates consumer complaints.

COMPLETING THE RETAIL FIELD TRAINING WORKSHEET

STEP 1 – DETERMINE PERFORMANCE ELEMENTS TO BE INCLUDED

Performance elements appear in the **shaded areas** of the *VDACS Retail Field Training Worksheet.* The trainer should review the performance elements contained in the *VDACS Retail Field Training Worksheet*. An "X" has been placed in the box adjacent to each performance element that is included in the VDACS training plan.

STEP 2 – DETERMINE COMPETENCIES FOR EACH SELECTED PERFORMANCE ELEMENT

The *VDACS Retail Field Training Worksheet* provides a list of competencies (job tasks) under each performance element. These competencies are intended to serve as examples of job related tasks that a FSS will be expected to successfully demonstrate during field training inspections.

An "X" has been placed in the box for each of the competencies that are part of the FSS's job responsibilities.

Some of the competencies listed for a performance element may not be applicable. For example, currently data loggers and light meters are not part of the standard issued equipment for inspection staff. The FSS would not be responsible for using this type of equipment. Since this is the case, the boxes adjacent to these competencies are left blank as they would not be included in the training plan.

STEP 3 – RECORDING OBSERVATIONS

☒	**III. Oral Communication** **3. Uses available means (e.g., interpreter, drawings, diagrams, demonstrations, international food safety icons) to overcome language or communication barriers.**	**Opportunity occurred for FSS to demonstrate competency during joint field training inspection**		**Competency demonstrated during joint field training inspection**	
		YES	**NO**	**YES**	**NO**
☒	Avoided using jargon and acronyms, without explanation.	☒	☐	☒	☐
☒	Used interpreter, drawings, demonstrations, or diagrams to overcome language or communication barriers.	☐	☒	☐	☐
☒	Checked the person in charge's understanding of information/instructions by asking the operator to paraphrase or demonstrate the information/instructions.	☒	☐	☐	☒

Comments: Reviewed techniques with the FSS for asking open-ended questions when checking food employees understanding of information presented during the inspection. Discussed the importance of demonstrating, when possible, a specific procedure when it appears that management or food employees may not clearly understand a verbal explanation. For example, setting up the wash, rinse, and sanitize bins of a 3 compartment sink, then checking for understanding by having the food employees demonstrate the procedure. The FSS should continue to work on this competency during the field training inspections scheduled for next week.

The *VDACS Retail Field Training Worksheet* contains two major columns for recording observations:

- *Opportunity occurred for FSS to demonstrate competency during joint field training inspection.*

YES – An "X" is placed in this box if the trainee had an opportunity to successfully demonstrate the listed competency during the inspection. In the graphic above, the trainee had the opportunity to demonstrate competencies pertaining to "avoid the use of acronyms/jargon" and "check the person in charge's understanding of information/instructions."

NO – An "X" is placed in this box if the inspection environment did not require or present an opportunity for the trainee to successfully demonstrate the competency. Using the graphic above, an opportunity did not occur during the field training for the trainee to demonstrate "the use of interpreters/drawings/demonstrations to overcome language or communication barriers." For example, employees in the firm may have spoken English and were able to communicate effectively with the inspectors. If an "X" is placed under NO in this column then the *Competency demonstrated* column does not need to be filled out.

- *Competency demonstrated during field training inspections.*

YES – An "X" is placed in this box if the trainee successfully demonstrates the competency during the inspection. When possible, a trainer should observe a trainee demonstrating a competency several times. In the graphic displayed on the previous page, the trainer has indicated that the trainee has successfully demonstrated the ability to avoid acronyms/jargon when providing explanations to food employees during inspections.

NO - An "X" is placed in this box if the trainee has an opportunity to demonstrate a competency during the inspection but does not do so correctly or does not act correctly in the inspection situation. It is important to emphasize that a "NO" determination for the competency does ***not*** *in any way* denote or indicate that the trainee has failed. It is simply part of the continuous learning process and is intended to identify areas where additional training is needed. When a "NO" determination is made regarding a specific competency, the trainer should take immediate steps to review or demonstrate the correct procedure or protocol with the trainee. In the graphic on the previous page, the trainer has indicated that the trainee needs additional training related to communication techniques for determining the person in charge's level of understanding for the information presented during the inspection.

Comments - The trainer can provide detailed descriptions of observations made during joint training inspections in the "comments" section at the bottom of each performance element table, as well as additional training provided and future training objectives. In the example used for this discussion, the trainer has provided the following statements in the comment section:

Reviewed techniques with the FSS for asking open-ended questions when checking food employees understanding of information presented during the inspection. Discussed the importance of demonstrating, when possible, a specific procedure when it appears that management or food employees may not clearly understand a verbal explanation. For example, setting up the wash, rinse, and sanitize bins of a 3 compartment sink, then checking for understanding by having the food employees demonstrate the procedure. The FSS should continue to work on this competency during the field training inspections scheduled for next week.

Only one (1) *VDACS Retail Field Training Worksheet* will be filled out at the end of the week when training is complete. When the worksheet is complete, a copy is emailed to the Training Coordinator by COB Tuesday of the following week. The Training Coordinator will review the worksheet and place it on the LAN in a restricted folder viewable only by management. The form does not need to be printed.

C. The Retail Establishment Log

The *Individual FSS Training Log* provides a method of documenting the number and type of establishments within which training has been conducted. A "Risk Category" column provides a quick reference as to the complexity of food preparation processes that have been included in the FSS's training and assists in determining what types of establishments to include in future field training inspections. The retail establishment fieldwork section of the log provides a quick method for distinguishing trainer-led (demonstration) inspections from those that are trainee-led. The information used to fill in this chart is pulled out of VIPRS by the Training Coordinator. In VIPRS, if the trainee's name is listed under the Secondary Inspector column, this indicates the inspection was trainer-led. If the trainee's name is listed under the Inspector column, this indicates the inspection was trainee-led. In order to be released to conduct independent inspections, the trainee must complete a minimum of twenty-five (25) joint field training inspections or a sufficient number of joint inspections determined by the training coordinator and verified through written documentation that the FSS has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments. Joint training inspections may be trainee or trainer-led inspections.

D. Preparing for Joint Retail Field Training Inspections

STEP 1 – IDENTIFY SOURCE DOCUMENTS FOR ORIENTATION

Information that a trainer should review as part of the FSS's orientation to the retail food protection program includes but is not limited to:

- The *VDACS Retail Field Training Worksheet* that identifies the specific performance element competencies that a FSS will need to successfully demonstrate during joint field training inspections;
- The current Retail Food Establishment Regulations for the Enforcement of the Virginia Food Laws and the Virginia Food Laws;
- The Field Operations Manual (FOM) Procedures;
- The inspection form;
- Any instructions that assist trainees with documenting inspection findings;
- The prerequisite curriculum posted on FDA's ORA U web site and the web address for obtaining an access password; and
- Other documents specific to VDACS that the trainer has determined are integral to the retail food protection training program.

The inclusion of the above list of source documents is not meant to imply that all material must be reviewed during a single dedicated FSS orientation session. The documents are included here to provide a starting point for a checklist of materials a trainer will likely need to review with the FSS during the first weeks of employment.

STEP 2– REVIEW TRAINING PLAN WITH TRAINEE

A review of the VDACS retail food protection training plan should include a discussion of:

- The performance elements, how they were determined, and their impact on conducting effective food safety inspections;
- The specific competencies that comprise each performance element so the trainee has a clear understanding of what job tasks they will be expected to successfully demonstrate during the course of the field training process;
- Training methods and approaches that will be offered to facilitate a trainee's demonstration of the competencies;
- How field training objectives will be determined and communicated to the trainee;
- How the trainer will observe the trainee perform competencies during field training inspections and share feedback on their observations;
- How progress and accomplishments will be documented on the training plan; and
- VDACS criteria for determining a trainee's readiness to conduct independent inspections of retail food facilities.

E. Conducting Retail Field Training Inspections

Field training inspections are a core component for preparing a FSS to perform their job responsibilities independently. There are two types of field training inspections: demonstration (trainer-led) and those where the trainee takes the lead (trainee-led).

Field training will initially be comprised of demonstration (trainer-led) inspections. Providing an opportunity for the FSS to observe experienced staff conducting food safety inspections is an essential step in preparing a trainee for taking the lead during field training inspections. Even if the trainee is in the final stages of the training program, trainers should still conduct at least one (1) trainer-led inspection.

Trainee-led inspections provide the opportunity for the trainer to observe the trainee build their skills and successfully demonstrate competencies. Inspections led by a trainee are ***not*** part of an examination or audit process. They are intended to be part of a structured training process where learning is still occurring, where trainers are providing feedback, and where correct demonstration of competencies is continually being re-enforced.

A sufficient number of field training inspections led by the trainee are to be conducted to allow the demonstration of ***all*** competencies identified in the training plan. Upon completion of the field training process, the trainee should have successfully demonstrated all competencies in the training plan and be ready to conduct independent inspections of retail food and/or foodservice facilities.

When conducting field training inspections focus on the performance elements within each of the inspection training areas.

Equipment review and proper use

Go over all the equipment necessary to conduct an inspection. Verify that the trainee has the equipment and forms necessary to conduct an inspection. This includes: inspection forms, lab coat, hair net or equivalent,

probe type thermometer, temperature sensitive tape for verifying hot water warewashing final rinse temperature, sanitizer test strips, flashlight, alcohol swabs, sample collection kits, black light, cell phone, laptop computer, printer, computer paper, and digital camera. Also, inform the trainee that light meter, pH meter, data loggers and foodborne illness investigation kits are available as needed and to contact their Regional Manager to obtain use of them.

Train with as much different equipment as possible. For example - have the trainee take and mount any pictures or just do a set of 'sample pictures' so that the trainee develops a comfort level with the camera and mounting pictures. Ensure that the trainee is using each piece of equipment correctly.

Establishment file review

Review the establishment file with the trainee and review previous inspection reports for out of compliance observations. Note any complaints on file; any documents indicating the need for a HACCP plan or variance; and any recent compliance action taken against the firm.

Proper identification

Instruct the trainee to verbally provide their name and agency (VDACS) to the person in charge. Ensure that proper regulatory identification is presented and that the purpose of the visit is stated. Train the new FSS to request and confirm permission to conduct an inspection.

VDACS laws, rules, and regulations review

Inform the trainee of the critical limit specified in the Retail Food Establishment Regulations when an observation is made. For example, the cold holding temperature for potentially hazardous foods is 41°F, while the hot holding temperature is 135°F. Cite the specific rule/regulation for out of compliance observations. Take the time to ensure that the trainee is knowledgeable and can apply the laws/regulations appropriately. Review FOMs on a daily basis. In order to ensure that all FOMs are covered, the trainee will choose the FOM for discussion. At least three (3) FOMs should be discussed throughout the week. Explain any FOM used during a particular inspection. FOMs that address foodborne illness risk factors should be heavily emphasized.

Risk-based inspection methodology

Teach the trainee that inspections should be conducted using a risk based approach. Review the demonstration of knowledge requirement. Go over each of the three ways that the requirement can be met. Show the trainee where they can access a list of Certified Food Manager courses. Go over questions and answers that relate to the specific food operation.

Explain approved food sources. Address shellfish tags and the Interstate Certified Shellfish Shippers List. In addition, teach the trainee about requirements for parasite destruction for certain species of fish intended for raw consumption.

Instruct the trainee on food safety practices for preventing cross-contamination of ready to eat food and ensuring that food contact surfaces are cleaned and sanitized and protected from contamination. Inform the new FSS of the no bare hand contact regulation and instruct them on proper handwashing.

Educate the trainee on the employee health requirement. Review restrictions and exclusions for ill employees and mandatory reporting for specific illnesses. Show the trainee where they can access a blank employee health policy to hand out to their firms.

Explain the date marking requirement. Emphasize that date marking is necessary for refrigerated, ready-to-eat, potentially hazardous foods prepared in the firm and held for more than 24 hours. State that food held at 41°F shall be consumed on the premises, sold, or discarded within 7 days and the day of preparation shall be counted as day 1.

Discuss temperatures with the trainee, including cold holding temperatures, hot holding temperatures, cooking temperatures, cooling temperatures and procedures, reheating temperatures and procedures, and thawing temperatures and procedures.

Explain the consumer advisory for foods of animal origin that are served raw or undercooked and identify procedures/processes that require a HACCP plan per the Retail Food Establishment Regulations.

Corrective Action Review

Discuss notifying the person in charge of any out of compliance observations and review corrective actions with the person in charge/employees. Make sure that action is taken immediately for severe out of compliance observations. Instruct the trainee on situations that require seizure or destruction of food products.

Other VDACS regulations

Review the Infant Formula, Apple Marking, and Ground Beef regulations with the trainee. Expiration dates on foods are generally not enforced with the exception of two products: infant formula and Grade A Dairy Products. If out dated infant formula is found, it must be destroyed. If out date grade A dairy is found, like sour cream or milk, request that management remove it from sale. The destruction of grade A dairy cannot be enforced by the Food Safety Program.

Oral Communication

Demonstrate to the trainee effective communication skills and how to provide courteous customer service. Make sure they know not to interrupt when the person in charge is speaking. Explain the need to provide prompt/timely responses to client requests. Educate the trainee on asking open ended questions. For example, asking “What concentration is your sanitizer?” instead of “Your sanitizer strength is 200 ppm, isn’t it?” Tell the trainee that it is okay not to know the answer to a question, but inform them they should find out the answer and contact the establishment. Avoid using jargon and acronyms without explanation. Explain that the trainee may need to use interpreters, drawings, demonstrations, or diagrams to overcome language barriers. State that the trainee may need to ask the person in charge to demonstrate information/instructions to confirm their understanding. Go over the VDACS policy in relation to confidentiality laws. Stress to the trainee the importance of not becoming argumentative and removing themselves from a confrontation or threat. Explain the public health significance of out of compliance observations. Review the entire inspection report with the person in charge and answer all questions or concerns pertaining to items on the report. Don’t just hand the inspection report to the person in charge. Explain where the person in charge signs the inspection report and initials for sampling or destruction of food.

Written Communication

Make sure the trainee is using correct grammar and sentence composition and that spell check is being used. Assist the trainee in determining what conditions are "objectionable but not actionable." Provide information on how to classify the inspection. Make clear what justifies a NAI/VAI/OAI classification and why. Explain appropriate follow up dates. Clarify how to word observations using the general format of "how many, what, where." Some flexibility in the wording of observations should be expected and is acceptable, however only factual observations and information should appear on the printed inspection reports. Make sure the trainee is aware that paperwork must be uploaded to the LAN within 2 working days of the completion date.

Sampling

Show the trainee how to use proper hygiene before and during the sampling process. Ensure that the trainee knows that they must offer to pay the vendor for the sample and determine if the vendor desires a portion of the sample. Show the new FSS where they can find information relating to appropriate size of samples as per DCLS recommendations. Explain collecting a representative sample for large lots when required. Show the trainee the sample collection bags that are to be used and explain to them how the collection bag should be labeled. Demonstrate sample sealing in the presence of management and information required on the sample seal. Demonstrate collecting a sterile sample and the need to use a separate sterile utensil to collect each different sample item. Discuss the pesticide and aflatoxin residue sampling program (Schedule III). Explain how to pack and ship sample items and make sure the trainee knows that most samples should be shipped within 24-48 hours. Stress the importance of proper refrigeration for temperature sensitive (Temperature Control for Safety, or "TCS") samples. Explain the sample collection report form, including the use of the laboratory analysis catalog; the significance of the "priority code"; and the meaning of collecting samples in "1, 2, or 3 parts." In addition, the trainee should be shown how to fill out a chain of custody form. Discuss when a sample should be sent under chain of custody. Review the applicable sampling FOMs.

Complaints

Discuss timeframes involved in working a complaint. Explain when it is appropriate to collect samples and discuss official samples vs. service samples. Ensure that the circumstances of the complaint are reviewed and go over the need to contact the complainant for additional information, if necessary. Discuss the nature of the complaint with management to determine their awareness. Teach the trainee to provide details of the complaint to management while protecting the confidentiality of the complainant. Educate the trainee about conducting a thorough investigation and providing a detailed written summary of the complaint. Go over the complaint form and discuss complaint related FOMs. Review tampering protocol (i.e. FOM II-02).

Disasters

Disasters cannot be planned for the purpose of training, however, several things can be done to address this issue. If a disaster or emergency situation should arise in an adjacent territory, then you should notify the Training Coordinator about shifting the trainee to that area. Otherwise, take the time to review/discuss previous disasters to which you responded. Insights into dealing with insurance adjusters, law enforcement, landfill operators, etc. would be beneficial.

Compliance Process

Review FOM Procedure I-00 Compliance and Enforcement Procedures and Inspection Classification. Explain proper documentation, when to sample, and when to take photographs.

Evaluating the Trainee

Review the Retail Field Training Worksheet and make notes throughout the week so nothing is forgotten. Discuss all faults or areas needing improvement. If the trainee makes mistakes, provide immediate feedback; give the trainee a chance to correct the mistake during the week. Use diplomacy. Don't be demeaning. Do not criticize the trainee in front of management. Allow ample time for discussion and review of the evaluation. Encourage or praise the trainee if they are doing a good job. If you have serious concerns about the trainee's ability, call the Training Coordinator directly.

SELECTING APPROPRIATE TRAINERS

A trainee can garner important knowledge and perspective from observing different inspection approaches from experienced staff. During the course of these joint inspections, it is expected that a trainee will observe experienced staff demonstrate all performance element competencies that are part of the training plan.

CONDUCTING DEMONSTRATION (TRAINER-LED) INSPECTIONS

Trainers will lay the foundation for the trainee's assimilation of the knowledge and skills needed to conduct food safety inspections as they will be initially demonstrating how to correctly perform specific job tasks.

The trainee will be paired with several different trainers during demonstration inspections to allow exposure to different inspection approaches and techniques. Moreover, these trainer-led inspections should be conducted in a variety of establishments that cover the spectrum of retail food and foodservice operations that the FSS will eventually be inspecting on their own.

The level of preparedness and time needed to assimilate knowledge from observations made during demonstration inspections will vary with each trainee. When a determination has been made that the trainee is ready to take the lead during an inspection, it is important to keep in mind that training has not stopped. Trainees will still need trainers to demonstrate competencies and provide feedback. The training process is designed to facilitate a continuous improvement learning experience.

PREPARING FOR INSPECTIONS LED BY THE TRAINEE

Inspections led by the trainee consist of two inter-related but separate activities: one is specific to the role of the trainer, the other relates to the role and responsibilities of the trainee.

- The trainer is responsible for observing the trainee as he/she demonstrates competencies identified in the VDACS training plan.
- The trainee is responsible for conducting the inspection in the presence of the trainer, per VDACS administrative procedures and policies.

Even though there is a relationship between these activities, it is important to recognize the need to view them separately.

Trainer's Role

During trainee-led inspections, the trainer observes the trainee conducting the inspection and demonstrating the competencies. The trainer participates *only* when the inspection process dictates their assistance or intervention.

No single field training inspection will provide an opportunity for the trainee to demonstrate all the competencies listed in the training plan. The trainer should allow the inspection process to unfold as it normally would. Requesting that a trainee demonstrate a competency that is not integral to the inspection that is occurring may be disruptive and create unwanted confusion and stress for the trainee.

As the field training process progresses, the trainer may note that the selection of establishments has not provided the trainee an opportunity to demonstrate some competencies. The trainer can try to remedy this situation by selecting establishments that may provide appropriate environments where the trainee can demonstrate the job tasks. If this is not feasible, the trainer can set up field exercises during inspections led by the trainee; however, the exercise should be conducted at a time that will not disrupt the flow of the inspection and the trainer should discuss these exercises with the trainee prior to the inspection so expectations are clear.

Trainee's Role

Since the trainee will be taking the lead during these field training inspections, their focus should be on observations of food safety practices and procedures within the establishment. During these inspections the trainee is responsible for:

- Initiating contact with the person in charge;
- Explaining the purpose of the inspection;
- Directing the inspection process;
- Establishing a dialogue with management and employees;
- Making the observations of food safety practices;
- Obtaining corrective actions for out-of-compliance foodborne illness risk factors;
- Preparing the inspection report; and
- Facilitating and conducting the exit discussion of the report.

The trainee's inspection approach, communication techniques, and food safety priorities should be reflective of those they would implement if inspecting independently. The inspection should *not* be structured solely around the demonstration of competencies. The trainee should concentrate on conducting an effective food safety inspection. Providing an appropriate variety of establishments will help ensure the competencies listed on the training plan do not drive the inspection approach.

SELECTING ESTABLISHMENTS FOR INSPECTIONS LED BY TRAINEE

The ideal establishment for conducting a food safety inspection led by the trainee is one that will provide an opportunity for the trainee to successfully demonstrate the greatest number of competencies. The majority of these inspections should be completed in establishments that are representative of the highest risk categories.

DETERMINING THE NUMBER OF INSPECTIONS LED BY TRAINEE

The number of inspections necessary is one that provides adequate opportunity for all competencies to be demonstrated. Some of the competencies, such as those related to conducting a risk-based inspection, must be continually demonstrated throughout the course of the field training process.

OBSERVING TRAINEE DEMONSTRATE COMPETENCIES

There is no single "correct" method for making a determination as to when a trainee has successfully demonstrated a competency during field training inspections. Throughout the series of training inspections, the trainer will observe the trainee demonstrate many competencies. For some competencies, the trainer will be able to ascertain relatively quickly whether a trainee has demonstrated the job task correctly. For example, once a trainee successfully demonstrates the proper use of inspection equipment, he/she generally will maintain that skill throughout the training process.

Almost all of the competencies listed, however, should be demonstrated by the trainee several times. The trainer should observe the trainee successfully demonstrate a consistent pattern of behavior for each competency. As defined in this document, a **"consistent pattern of behavior"** means:

- The trainee can explain the purpose/objective of the job task and the steps necessary to carry it out effectively;
- The demonstration of a clear understanding of a given competency; and
- A collective set of trainer observations which predominately indicate that the trainee can successfully demonstrate the competency correctly and repeatedly.

Trainees will be on a continuous learning curve throughout the training process; inconsistencies in their inspection approach from one facility to another should be expected. Trainers will need to determine whether these inconsistencies are due to a lack of understanding, an inability to successfully demonstrate a competency, or simply inexperience.

In some cases, a trainee may be capable of successfully demonstrating a competency but fails to do so during an inspection. For example, he/she may not address an important food safety risk (such as employee health) with the person in charge. The trainee may understand and can demonstrate the proper approach to assessing an employee health policy within an establishment, but forgets to do so because they may have become distracted by other risk related observations and the need to work with management to obtain corrective actions. This is an example of a trainee who is still in the process of developing his/her own organized risk-based inspection approach.

It is important for trainers to recognize that during the training process, trainees are not only learning competencies but are also becoming acclimated to their working environment. Trainer's decisions regarding a trainee demonstrating a competency should be based on a collective set of observations which predominately indicate the job task is being performed correctly.

REVIEWING FIELD TRAINING

Consistent and on-going feedback regarding inspection competencies is the cornerstone of the FSS field training process presented in this manual. The trainer should share his/her observations with the trainee during each of

the inspections. Discussions should include competencies successfully demonstrated by the trainee, as well as those where additional training is needed. Trainers should provide continuous positive reinforcement for competencies correctly demonstrated by the trainee.

For areas where additional training is needed, the trainer should demonstrate the competency to the trainee during joint inspections and determine if other training methods may benefit the trainee's understanding and application of the competency. Field training objectives should continually be reviewed with the trainee and updated as needed during the field training process.

F. Release from Training

In order to be released from training to conduct independent retail inspections, the trainee must meet the following requirements:

- Completion of Prerequisite Courses
- Completion of a minimum of twenty-five (25) joint field training inspections (or a sufficient number as determined by the training coordinator) including documentation that confirms the trainee is trained on and has demonstrated the performance element competencies needed to conduct independent inspections of retail food establishments

If possible the trainee should work with a Field Supervisor during the last week of training before being released.

The Training Coordinator will verify the requirements above are met and will officially release the trainee from training.

G. Continuing Training

The prerequisite coursework, training plan, and field training inspection process presented in this manual are based on the minimum performance competencies a FSS should be able to successfully demonstrate ***prior*** to conducting independent food safety inspections. This process should be considered but a first step in the development of inspection staff in a regulatory retail food protection program. Additional training opportunities and standardization should be provided on a continual basis to advance the development of a FSS's ability to implement a risk-based inspection approach and communicate food safety principles to the regulated industry and the public.

Additional Food Safety Courses

Over 100 food safety related courses are accessible from the FDA ORAU web site. The Conference for Food Protection has worked with FDA to identify courses that a FSS should complete within the first 18 months of hire or assignment to the retail food program. It is expected that most FSS would complete this second phase of post coursework ***after*** they have started to conduct independent inspections. These courses must be completed prior to Standardization.

This additional coursework is part of the criteria contained in *Standard 2 - Trained Regulatory Staff, FDA Voluntary National Retail Food Regulatory Program Standards* and includes:

Course Name	Course Number	Course Provider	Course Type	Web Link
Food Microbiological Control 7C Control by Retorting	MIC10	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 8: Technology Based Food Processes	MIC11	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 9 Natural Toxins	MIC12	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basics of HACCP: Overview of HACCP	FDA16	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basics of HACCP: Prerequisite Programs and Preliminary Steps	FDA17	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basics of HACCP, The Principles	FDA18	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Allergens	FD252	ANR Online Learning (FDA Course Hosted by UC Davis Agriculture and Natural Resources)	Online	ANR Online Learning
Foodborne Illness Investigations 1: Collecting Surveillance Data	FI01	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Foodborne Illness Investigations 2: Beginning an Investigation	FI02	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Foodborne Illness Investigations 3: Expanding the Investigation	FI03	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Foodborne Illness Investigations 4: Conducting a Food Hazard Review	FI04	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Foodborne Illness Investigations 5: Epidemiological Statistics	FI05	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Foodborne Illness Investigations 6: Final Report	FI06	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)

ANR Online: http://class.ucanr.edu/login/index.php
ORAU website: https://www.compliancewire.com/Net/Secure/login.aspx

All of the courses will be accessed through the ORA U website with the exception of Food Allergens (FD252).

Standardization and Continuing Education

Each inspector must be Standardized by a Field Supervisor/Standardization Officer within the first 18 months of employment. Prior to Standardization each inspector must have completed the post coursework above. The Training Coordinator will provide documentation to the Standardization Officer verifying completion of the post coursework. The inspector must also conduct a minimum of twenty-five (25) independent inspections of high risk firms prior to Standardization. This information will be pulled out of VIPRS by the Training Coordinator and provided to the Standardization Officer prior to Standardization.

Every thirty-six (36) month interval, each inspector is required to receive 36 contact hours of classroom training. The Food Safety Specialist shall send documentation of continuing education to the Training Coordinator who will then track contact hours in the FSS's training log. See Procedure I-24 for additional information on continuing education. The 36-month continuing education interval starts when Standardization is complete – no later than 18 months after the employee's start date. The Retail Specialist shall verify that each Standardized inspector has met their continuing education hours before issuing the Re-Standardization certificate.

H. Veteran Inspectors

Prior to implementation of Standard 2 of the Voluntary National Retail Food Regulatory Program Standards in 2010, VDACS FSS completed an intensive 3-6 month training program which included both trainer-led and trainee-led inspections. However documentation to support that the training was completed is not available for all personnel hired before 2010 since training protocol at this time did not require records to be kept. All FSS hired prior to 2010 were required to complete the prerequisite and post coursework listed in section A. Prerequisite Curriculum and in section F. Continuing Training in September 2014. In addition, these veteran inspectors have at a minimum over two (2) years of experience and have completed well over 500 independent retail food inspections. Therefore all veteran inspectors have met the course and field work requirements for Retail Training. All veteran inspectors have also been Standardized and since being Standardized are required to meet their continuing education requirements as stated above in section F. Continuing Training.

VDACS asserts that the procedure described above qualifies the veteran inspectors as meeting the training requirements described in the Food Safety & Security Program training plan and is in full compliance with the requirements of the VNRFRPS.

III. Manufacturing Training Program Overview

Wholesale Training Program Overview

After the FSS has successfully completed the retail training program, they will usually work independently in their own territories conducting retail food inspections for a period of time. The new FSS will then undergo manufacturing training, normally during the FDA contract time period which usually occurs in the fall/winter. During this time the trainee will work with an experienced FSS who is considered a qualified trainer near their territory or the trainer's territory. A qualified trainer for Basic (GMP only) inspections is defined as an individual who has successfully completed the coursework and field training requirements as outlined below for Basic Training. A qualified trainer for Advanced (Seafood HACCP, Juice HACCP, Acidified Foods, Low Acid Food products, and/or Dietary Supplements) inspections is defined as an individual who has successfully completed the coursework and field training requirements for that specific discipline in which they will serve as a trainer as outlined below for Advanced training. Veteran inspectors as defined below in Section H will be considered qualified trainers.

Training schedules will be set up and supplied to all parties involved in advance so that all necessary arrangements (meeting time and place, etc.) can be made.

During this time, the trainers will be explaining the various operations, the conditions observed and how these conditions relate to the VFL and/or regulations (Code of Federal Regulations, etc). The trainers will also explain how to correctly fill out the FDA contract paperwork.

As the trainee becomes familiar with these activities, they will begin to handle portions of the inspection and paperwork on their own under the supervision of the trainer Food Safety Specialist. At this time the trainee begins to move into the next stage of their training. During this period, the trainee will be working alongside and comparing notes with the trainer concerning the observed objectionable conditions. The trainee should also be composing the majority of the paperwork at this stage with some assistance from the trainer. At this time the trainee will become comfortable with conducting wholesale inspections, filling out paperwork, conducting a

label review, using the FDA code builder, and how objectionable conditions observed in the firm relate to the VFL and CFRs.

During the ending stages of training, the trainee will be handling all aspects of the inspection, including discussions with management, with little or no assistance from the trainer. The trainer, however, will be observing the actions, techniques and knowledge developed by the trainee in order to determine when they will be ready to be released from training and able to conduct wholesale inspections in their own territory.

A. Field Training Overview

All trainers should emphasize quality rather than quantity during the workweek. This should not be a rushed week. There should be ample time allowed in each firm and part of the inspection for questions and discussion. Take the time to explain and see that the trainee understands what they see and what or why something is being done. In order to expose the trainee to all aspects of a firm's operation, comprehensive firm inspections that focus on foodborne illness risk factors should be performed. The manufactured food standards divide wholesale establishments into two (2) categories – Basic and Advanced/Specialized.

- Basic wholesale establishments are subject to 21 CFR 110, and will be observed for sanitation deficiencies for the most part
- Advanced/Specialized wholesale establishments fall into one of five categories: Seafood HACCP (21 CFR Part 123), Juice HACCP (21 CFR Part 120), Acidified foods (21 CFR Part 114), Low acid food products (21 CFR Part 113), and Dietary Supplements (21 CFR Part 111)

For Basic Food Inspection Training, each trainee must participate in a minimum of ten (10) joint trainee-led inspections with a qualified trainer and receive a minimum of two (2) "Acceptable" ratings before being released to conduct independent Basic Food Inspections. For each type of Advanced/Specialized Food Inspections the trainee must participate in two (2) joint field training inspections, complete the specific advanced food inspection curriculum course, and then participate in one evaluation or field inspection audit that is found to be acceptable by a qualified field inspection trainer or auditor before being released to conduct independent Advanced Food Inspections. An "Acceptable" rating is defined as a trainee-led inspection in which the trainee demonstrates the knowledge, skills, and abilities necessary to perform basic and advanced wholesale food inspections. Trainees will not begin conducting trainee-led training inspections in Advanced/Specialized firms until they have completed the educational requirements for that particular type of Advanced/Specialized establishment.

B. Coursework

The FDA Manufactured Food Regulatory Program Standards has identified a curriculum designed to provide a FSS with a solid understanding of essential food safety and public health principles needed to conduct effective wholesale food safety inspections. The FSS shall complete the Basic and Advanced Food Inspection Coursework within 24 months of his or her start date with VDACS. The Training Coordinator will verify that the Basic and Advanced Food Inspection Coursework is completed within 24 months of the trainee's start date.

Basic Food Inspection Coursework

Basic coursework includes training for each of the following elements and are the courses suggested in MFRPS Appendix 2.4: Curriculum Example Basic Food Inspector Training:

- Prevailing statutes, regulations, and ordinances
- Public health principles
- Emergency management
- Communications skills
- Microbiology
- Epidemiology
- Basics of HACCP
- Allergen management
- Basic food labeling
- Food defense awareness training
- Sampling technique and preparation

Course Name	Course Number	Course Provider	Course Type	Web Link
Public Health Principles	FDA36	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basic Food Law for State Regulators	FDA35	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basic of Inspection: Beginning Inspection	FDA38	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basic of Inspection: Issues & Observations	FDA39	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Communication Skills for Regulators	None	IFPTI	Online	IFPTI Training
Food Microbiological Control 1: Overview of Microbiology	MIC01	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 2A: Gram-Negative Rods	MIC02	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 2B: Gram-Positive Rods and Cocci	MIC03	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 3: Food borne Viruses	MIC04	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 4: Food borne Parasites	MIC05	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control: Mid-Series Exam	MIC16	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 5: Controlling Growth Factors	MIC06	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 6: Control by Refrigeration and Freezing	MIC07	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 7A: Control by Thermal Processing	MIC08	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 7B: Control by Pasteurization	MIC09	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 10: Aseptic Sampling	MIC13	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)

Course Name	Course Number	Course Provider	Course Type	Web Link
Food Microbiological Control 12 : Cleaning and Sanitizing	MIC15	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 7C Control by Retorting	MIC10	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 8: Technology Based Food Processes	MIC11	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 9 Natural Toxins	MIC12	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basics of HACCP: Overview of HACCP	FDA16	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basics of HACCP: Prerequisite Programs and Preliminary Steps	FDA17	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Basics of HACCP, The Principles	FDA18	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Allergens	FD252	ANR Online Learning (FDA Course Hosted by UC Davis Agriculture and Natural Resources)	Online	ANR Online Learning
Foodborne Illness Investigations 1: Collecting Surveillance Data	FI01	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Foodborne Illness Investigations 2: Beginning an Investigation	FI02	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Foodborne Illness Investigations 3: Expanding the Investigation	FI03	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Foodborne Illness Investigations 4: Conducting a Food Hazard Review	FI04	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Foodborne Illness Investigations 5: Epidemiological Statistics	FI05	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Foodborne Illness Investigations 6: Final Report	FI06	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Evidence and Proof	FDA22	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food & Drug Law: FDA Jurisdictions	FDA01	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food & Drug Law: Prohibited Actions	FDA02	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food & Drug Law: Judicial Actions	FDA03	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food & Drug Law: Criminal Acts Violations	FDA04	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food & Drug Law: Imports & Exports	FDA05	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Active Listening Skills	EHS02	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Microbiological Control 11: GMPS	MIC14	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Food Labeling	FDA45	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Controlling Food Allergens in the Plant	FOOD2	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Sample Collection	FDA23	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Bioterrorism Act of 2002 -- Registration of Food Facilities	FDA58	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Bioterrorism Act of 2002 - Prior Notice	FDA59	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)

Course Name	Course Number	Course Provider	Course Type	Web Link
Food Defense 101 (including ALERT)	FD101	FDA	Online	Food Defense 101
Introduction to Incident Command System, ICS100	IS-100.b	FEMA (Federal Emergency Management Agency)	Online	FEMA
ICS for Single Resources and Initial Action Incident, ICS-200	IS-200.b	FEMA (Federal Emergency Management Agency)	Online	FEMA
National Incident Management System (NIMS) An Introduction	IS-700.a	FEMA (Federal Emergency Management Agency)	Online	FEMA
National Response Framework, An Introduction	IS-800.b	FEMA (Federal Emergency Management Agency)	Online	FEMA

ComplianceWire (FDAORAU): https://www.compliancewire.com/CW3/Standard/Authentication/LogIn
IFPTI: https://ifpti.absorbtraining.com/
ANR Online Learning: http://class.ucanr.edu/login/index.php
Food Defense 101: http://www.accessdata.fda.gov/scripts/FDTraining/
FEMA: http://training.fema.gov/is/nims.aspx

Advanced Food Inspection Coursework

Course Name	Course Number	Course Provider	Course Type	Web Link
Food Labeling: Requirements for Labeling on Food & Dietary Supplements, Nutrition Labeling, & Allergen Labeling	None	FDA (CFSAN Training Video)	Online	FDA CFSAN Training Videos
Traceback Investigations 1: Introduction	TI01	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Traceback Investigations POS	TI02	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Traceback Investigations Distributor	TI03	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Traceback Investigations Eggs and other Commodities	TI04	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Traceback Investigation: Concluding the investigation and reporting the results	TI05	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Recalls of FDA Regulated Products	FDA24	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Interviewing Techniques	FDA27	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Destruction and Reconditioning	FDA33	ComplianceWire (FDAORAU)	Online	ComplianceWire (FDAORAU)
Procedures to Investigate Foodborne Illness	FBI	VDACS	PPT	
Good Manufacturing Practice, Application and Evidence Development	FD180	FDA - Classroom	Classrm	
FSPCA Preventive Controls for Human Food	None	Food Safety Preventive Controls Alliance	Classrm	
Preventive Controls for Human Food Regulators	FD254	FDA - Classroom	Classrm	

Course Name	Course Number	Course Provider	Course Type	Web Link
Conducting Acidified Food Inspections	FD202	FDA - Classroom	Classrm	
Basic Seafood HACCP	None	Seafood HACCP Alliance		
Conducting Seafood Inspections	FD249	FDA - Classroom	Classrm	
Food Processing and Technology	FD152	FDA - Classroom	Classrm	
Conducting Low Acid Canned Food Inspections	FD203	FDA - Classroom	Classrm	
Juice HACCP and Conducting Juice Inspections	FD219	FDA - Classroom	Classrm	

C. The VDACS Wholesale Field Training Worksheet

VDACS WHOLESALE FIELD TRAINING WORKSHEET

The *VDACS Wholesale Field Training Worksheet* (see Attachment B), provides a structured approach for tracking the FSS's progress in successfully demonstrating specific performance elements and competencies. This worksheet should be reviewed prior to training so the trainer knows what they will be looking for during the training process. The trainer should review with the trainee the competencies that will be included as part of the field training inspections.

The *VDACS Field Training Worksheet* provides areas for documenting:

- Trainee and Trainer information;
- Whether or not there was an opportunity to demonstrate a competency; and
- When a FSS consistently demonstrates a competency correctly.

INSPECTION TRAINING AREAS

The *VDACS Field Training Worksheet* is divided into seven (7) inspection training areas:

I. Pre-Inspection
II. Inspection Observations and Performance
III. Oral Communication
IV. Written Communication
V. Professionalism
VI. Sampling
VII. Seafood/Juice HACCP

The VDACS Wholesale Field Training Worksheet is filled out using the same principles described in the Retail Training Program Overview. Every item marked “No” under “Competency demonstrated during joint field training inspection” must be accompanied by an explanation/comment in the comment box.

Only one (1) *VDACS Wholesale Field Training Worksheet* will be filled out at the end of the week when training is complete. When the worksheet is complete, a copy is emailed to the Training Coordinator by COB Tuesday of the following week. The Training Coordinator will in turn forward the document to the Regional

Managers and Field Supervisors and a copy will also be placed on the LAN. The form does not need to be printed.

D. The Wholesale Establishment Log

The *Individual FSS Training Log* provides a method of documenting the number and type of establishments within which training has been conducted and the overall rating of the FSS during a trainee-led inspection of a specific firm. The log contains a section specifically for listing the joint inspections conducted during manufacturing/wholesale training. The "Risk Category" and “Specialized Food Inspection Type” column provides a quick reference as to the complexity of food preparation processes that have been included in the FSS's training and assists in determining what types of establishments to include in future field training inspections. In addition, the wholesale establishment log provides a quick method for distinguishing trainer-led (demonstration) inspections from those that are trainee-led. As previously stated, during Basic Food Inspection Training, each trainee must participate in a minimum of ten (10) joint trainee-led inspections and receive a minimum of two (2) “Acceptable” ratings before being released to conduct independent Basic Food Inspections.

For each type of Advanced/Specialized Food Inspections the trainee must participate in two (2) joint field training inspections, complete the specific advanced food inspection curriculum course, and then participate in one evaluation or field inspection audit that is found to be acceptable by a qualified field inspection trainer or auditor before being released to conduct independent Advanced Food Inspections. This information will be tracked in VIPRS and recorded on the FSSs training log by the Training Coordinator.

E. Preparing for Joint Wholesale Field Training Inspections

STEP 1 – IDENTIFY SOURCE DOCUMENTS FOR ORIENTATION

Information that a trainer should review as part of the FSS's orientation to the wholesale food protection program includes but is not limited to:

- The *VDACS Wholesale Field Training Worksheet* that identifies the specific performance element competencies that a FSS will need to successfully demonstrate during joint field training inspections;
- 21 CFR Part 110- current Good Manufacturing Practices, other adopted CFRs, and the Virginia Food Laws;
- The FOMs;
- The FDA contract inspection paperwork;
- Any instructions that assist trainees with documenting inspection findings and completing paperwork;
- The use of the FDA Code Builder;
- The difference between the PAC Codes;
- Other documents specific to VDACS that the trainer has determined are integral to the wholesale food protection training program.

The inclusion of the above list of source documents is not meant to imply that all material must be reviewed during a single dedicated FSS orientation session. The documents are included here to provide a starting point for a checklist of materials a trainer will likely need to review with the FSS during training.

STEP 2 – REVIEW TRAINING PLAN WITH TRAINEE

A review of the VDACS wholesale food protection training plan should include a discussion of:

- The performance elements, how they were determined, and their impact on conducting effective wholesale food safety inspections;
- The specific competencies that comprise each performance element so the trainee has a clear understanding of what job tasks they will be expected to successfully demonstrate during the course of the wholesale field training process;
- Training methods and approaches that will be offered to facilitate a trainee's demonstration of the competencies;
- How field training objectives will be determined and communicated to the trainee;
- How the trainer will observe the trainee perform competencies during wholesale field training inspections and share feedback on their observations;
- How progress and accomplishments will be documented on the training plan; and
- VDACS criteria for determining a trainee's readiness to conduct independent inspections of wholesale food facilities.

F. Conducting Wholesale Field Training Inspections

As previously stated, the main focus of the inspection will be to address those risk factors that are known to contribute to foodborne illness. Teach the FSS to follow the process flow; start at the beginning with the raw materials and follow the process through to the end product. Be knowledgeable and follow the applicable CFR. Explain to the trainee that the retail regulations are not relevant to manufacturers. Go over the FDA paperwork. Expose the trainee to all aspects of the FDA paperwork, including the use of the Product Code Builder, FDA Inspection Report, eSAF, the Food Facility Registration Module (FFRM), etc. Discuss NLEA and labeling requirements. Focus on health claims, the need to list sub ingredients, net weight requirements, and allergens. The same principles that apply to conducting Retail Field Training Inspections will apply. The only difference will be that the trainer will be focusing on teaching the current Good Manufacturing Practices (21 CFR 110) and other applicable CFRs.

G. Release from Training for Basic GMP Inspections

In order to be released from training to conduct independent Basic (GMP) inspections, the trainee must meet the following requirements:

- Completion of a minimum of ten (10) joint trainee-led field inspections and receive a minimum of two (2) “Acceptable Ratings”

If possible the trainee should work with a Field Supervisor during the last week of training before being released. The Training Coordinator will verify the requirements above are met and will add the required documentation to the Training Course Catalog (equivalent to MFRPS Appendix 2.2: Inspector Training Record Summary) and also to the Individual FSS Training Log (equivalent to MFRPS Appendix 2.3: Inspector Training Record). The Training Coordinator will then officially release the trainee from training.

H. Advanced Food Inspection Training

In order to conduct independent Specialized (Seafood, Juice, Low Acid, Acidified, or Dietary Supplements) inspections, the trainee must meet the following requirements:

- Participate in two joint field training inspections.
- Completion of the specific Advanced Food Inspection Curriculum Coursework.
- After successful completion of the course participate in one evaluation or field inspection audit that is found to be acceptable by a qualified field inspection trainer or qualified field inspection auditor prior to conducting independent inspections.
- Within one year after being released to do specialized food inspections complete a second evaluation or field inspection audit that is found to be acceptable by a qualified field inspection trainer or a qualified field inspection auditor in the area of specialty.

The Training Coordinator will verify the requirements above are met and will add the required documentation to the Training Course Catalog (equivalent to MFRPS Appendix 2.2: Inspector Training Record Summary) and also to the Individual FSS Training Log (equivalent to MFRPS Appendix 2.3: Inspector Training Record). The Training Coordinator will then email the trainee's supervisor who will officially release the trainee from training.

I. Continuing Education

Each inspector must participate in continuing education that includes coursework and inspections. Every thirty-six (36) month interval, each inspector is required to receive 36 contact hours of classroom training and participate in at least two (2) joint or audit inspections with a qualified trainer. These joint inspections are intended to assist the inspector with applying what was learned in the classroom to what should be covered during the inspection. Documentation of continuing education shall be sent to the Training Coordinator who will then track contact hours in the FSS's training log. Note: The 36-month continuing education interval starts when the employee completes Retail Standardization (within 18 months of hire). The Training Coordinator shall verify that each Standardized inspector is meeting their continuing education requirement.

J. Veteran Inspectors

Prior to enrollment in the Manufactured Foods Regulatory Program Standards (MFRPS) in 2010, VDACS FSS completed an intensive 3-6 month training program which included basic and advanced joint inspections. However documentation to support that the training was completed is not available for all personnel hired before January 2012 since training protocol at that time was still being finalized to meet all the requirements of the MFRPS. All FSS hired prior to January 2012 were required to complete the Basic coursework listed in Section B. Coursework in September 2014. In addition, these veteran inspectors have at a minimum over two (2) years of experience and have completed well over 100 Basic Food Inspections. Therefore all veteran inspectors have met the course and field work requirements for Basic Food Inspection Training.

All FSS hired prior to January 2012 were required to complete the following Advanced coursework listed in Section XI. Coursework in September 2014:

- Nutrition Labeling
- Traceback Investigations
- Recalls

- Emergency Management
- CARVER + SHOCK

In addition all veteran inspectors have completed the following Advanced FDA Classroom Training listed in section XI Coursework:

- Conducting Acidified Food Inspections, FD202
- Conducting Seafood HACCP Inspections, FD249

These veteran inspectors have participated in numerous joint and independent Advanced Food Inspections during their tenure all of which have been reviewed by Regional Managers. In addition, many of these inspections were conducted as part of the FDA contract and were therefore reviewed by both VDACS staff and personnel within the Baltimore District Office of FDA. Any noted deficiencies with these inspections were immediately addressed by the Regional Manager with the FSS. Due to the years of experience these veteran inspectors have and the high number of Basic and Advanced Food Inspections they have conducted, at this time these inspectors do not have to complete the following FDA Classroom Training (unless they are listed as prerequisites to other courses):

- Good Manufacturing Practice, Application and Evidence Development, FD180
- Food Processing & Technology, FD152

FSS hired prior to January 2012 that have Juice HACCP firms in their territories were/are required to complete the FDA Classroom Training Juice HACCP and Conducting Juice Inspections, FD219.

At this time no FSS are required to attend the Conducting Low Acid Canned Food Inspections course, FD203, as all Low Acid Canned Food Inspections are currently being completed by FDA Investigators in the Baltimore District Office. In addition, at this time, only the Manufactured Foods Specialist has attended the Dietary Supplements course, FD340. All inspectors must be accompanied by the Manufactured Foods Specialist when conducting dietary supplement inspections.

Therefore all veteran inspectors have met the course and field work requirements for Advanced Food Inspection Training.

Documentation of all training for inspectors hired prior to January 2012 is kept in the FSS's training file. Appendix 2.1 and Appendix 2.2 will not be filled out for veteran inspectors.

VDACS asserts that the procedure described above qualifies the veteran inspectors as meeting the training requirements described in the Food Safety Program training plan and is in full compliance with the requirements of the MFRPS. A Training Waiver is on file for each veteran inspector that documents the waived training requirements for each type of inspection where specific training is not documented in the training records.

IV. Field Operations Manual

The VDACS Field Operations Manual provides instructions and directions for the day-to-day operation of the Food Safety Program. The procedures, or FOMs, within the manual are essential to ensure consistency and quality in inspections and services. The FOMs are also a training tool for new FSS, as well as a reference tool for all FSS. The program uses a system of Document Control to ensure that all FSS have been trained on and utilize for their work only the most current version of each FOM. For complex procedures, training on new and

updated FOMs will occur at regional or annual meetings; for simple procedures that do not require in person training, simple acknowledgement of receipt and understanding is sufficient. Each FSS signifies they have received and understand each current FOM in use by signing (physical or electronic signature) an Acknowledgement of Receipt and Understanding form upon request by the Training Coordinator or designee. Documentation of the receipt and understanding of each current FOM in use, by each FSS, is maintained by the Training Coordinator.

Attachment A

Attachment B

Procedure I-24: Continuing Education

Introduction

The goal of continuing education is to enhance the Food Safety Specialist's (FSS) knowledge base, skills, and ability to perform regulatory inspections. The criteria in this field operations procedure are based on the requirements of the FDA's Voluntary National Retail Food Regulatory Program Standards and FDA's Manufactured Food Regulatory Program Standards (MFRPS)- Standard 2 – Trained Regulatory Staff.

Number of Contact Hours Required

A FSS must accumulate 36 contact hours of continuing education training every 36 months. VDACS FSS inspect both retail and manufactured food firms. Due to the overlapping of the programs and for ease of tracking, the 36-month continuing education interval for both programs starts when Retail Standardization is complete – no later than 18 months after the employee's start date. The 18 month date is more stringent than the 24 month date allowed by MFRPS.

Continuing Education Activities

A FSS qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine (9) activities that are related specifically to food safety or food inspectional work. Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 36-month continuing education period.

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops (e.g., CASA, AFDO);
5. Distance learning opportunities that pertain to food safety, such as: WEB based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and Satellite Broadcasts.

Only a maximum of ten (10) contact hours may be accrued every 36-month period from the following activities:

1. Delivering presentations at professional conferences;
2. Providing classroom and/or field training to newly hired FSS, or being a course instructor in food safety; or
3. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

NOTE: Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSS delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.

Only a maximum of four (4) contact hours may be accrued every 36-month period for:

- Reading technical publications related to food safety.

Documentation

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- Certificates of completion indicating the course date(s) and number of hours attended or Contact Hours granted;
- Transcripts from a college or university;
- A letter/email from the administrator of the continuing education program attended;
- A copy of the peer-reviewed article or presentation made at a professional conference;
- Documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports;
- Course sign-in sheet that documents course name, date, and number of hours attended. If the course is multiple days then multiple sign-in sheets would be needed for full credit; or
- A letter/email from FSS's Regional Manager who verified attendance/participation in an activity when other documentation is not available.

Documentation of continuing education shall be sent to the Training Coordinator who will then track contact hours in the FSS's training log. The Training Coordinator will be responsible for determining if the course(s) attended will be applicable for continuing education hours toward Retail, MFRPS, or both.

Contact Hours vs. Continuing Education Units (CEU)

VDACS will only track Contact Hours on the FSS employee training log. If the FSS attends a course and the certificate is issued in CEU's the Training Coordinator must convert the CEU's to Contact Hours prior to entry onto the employee training log. The following conversion will be applied: 0.1 CEU equals 1 Contact Hour.

MFRPS Joint or Audit Inspections

During every 36-month continuing education period the FSS must participate in at least two (2) joint or audit inspections with a qualified trainer. These joint inspections are intended to assist the inspector with applying what was learned in the classroom to what should be covered during the inspection.

Changes in Retail Regulations

Training on any changes in VDACS prevailing statutes and/or laws must be included as part of the continuing education hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

Verification

Once Standardized the FSS must be Re-Standardized every 36 months. The Retail Specialist shall verify that each Standardized inspector has met their required 36 contact hours before issuing the Re-Standardization certificate. The Training Coordinator will verify that the MFRPS audit inspections have been completed.

Procedure I-25: Work Day Standard

The duties and responsibilities of a Food Safety Specialist are numerous and varied such that a singular number of activities per day/week is not a true reflection of an individual's productivity or appropriate use of their time. Rather, effective territory management should be the 'standard' that you strive for in planning your work day/week.

While the primary duty of a Food Safety Specialist is to inspect the firms in his or her territory, sound planning and organizational skills are needed to do this in the most effective manner. Effective territory management utilizes a risk-based approach to ensure that Agency goals and business needs are accomplished. Scheduling priorities would include compliance (follow-up) inspections, consumer complaint investigations and new firm (pre-opening) inspections. In addition, Inspectors need to be cognizant of past-due firms and prioritize them for inspection.

Routine inspectional scheduling priorities are to be based on establishment type and inspectional history with high-risk firms taking precedence over medium/low risk firms and medium risk firms taking priority over low risk firms. These examples are but just a few of the many responsibilities of a Food Safety Specialist. Activities such as disaster work, providing coverage to another territory, training of new hires, FDA contract inspections, etc. while not routinely encountered every week would certainly be priority responsibilities. Inspectors should communicate with their respective Regional Manager if they have questions regarding the priority of an assignment or when the completion of a high priority assignment is in doubt.

Again, it is important to reiterate that 'numbers' will not be a sole source of performance evaluation. The expectation is that you will work 40 hours/week and utilize your time appropriately to effectively manage your territory. Inspectors are to document both their inspectional and non-inspectional activities. Memos should be submitted for outside work such as car maintenance, etc. The failure to work a full work day will reflect on your performance evaluation and may result in other disciplinary actions.

It is imperative that you document your daily activities in your 'date book' (as detailed in the Written Correspondence FOM, procedure I-06). If you are questioned on your performance for certain days, the date book provides a reference you can use to recall your activities for those particular days.

FIELD OPERATIONS MANUAL

PROCEDURE I-27
November 20, 2014

EXPENSE REIMBURSEMENT VOUCHERS

Field employees may incur certain travel-related expenses for items directly related to inspections or other official activities. Expenses need to be submitted on the appropriate form in order to receive reimbursement. Two (2) different vouchers are used depending on the expenses incurred.

ACCOUNTING VOUCHER Field Expenses ONLY - This voucher can only be used to get reimbursed for common items purchased in the field. Appropriate expenses to place on this form include: the purchase of samples for testing, ice, postage or shipping costs for samples or reports. For any other items, please consult your Manager.

The ACCOUNTING VOUCHER Field Expenses ONLY is a Microsoft Word document that can be found on the Local Area Network (LAN) in the "everyone" drive > FORMS folder > Finance folder. If you are connected to the network (direct connection or by VPN), you may access the Finance folder using this hyperlink: Finance

Expense vouchers should be submitted to your supervisor as soon as possible after the expense is incurred, and at least monthly.

Note: Accounting vouchers may not overlap fiscal years. In Virginia, the fiscal year ends on June 30th and begins on July 1st. June and July expenses are not to be submitted on the same voucher.

Documentation - All purchases must be supported by itemized invoices or receipts. Add your signature to the receipts.

Travel Expense Reimbursement Voucher - State policy provides for the reimbursement of travel expenses that are both reasonable and necessary. Vouchers must be submitted to the traveler's supervisor within 30 days after completion of any trip involving overnight travel. Personnel in training should submit their vouchers on a weekly basis. For reimbursement of travel expenses (lodging, meals, parking, road tolls, or personal vehicle mileage), use the most current version of the Travel Expense Reimbursement Voucher (TERV) found in the "Travel Forms Master Copy" Microsoft Excel workbook.

Documents to use/reference in seeking approval to travel, and in completing the TERV include:

- Policy 4.2 VDACS Travel Policy
- The State Travel Regulations found in the Commonwealth Accounting Policies and Procedures (CAPP) Manual, topic number 20335.
- The "Travel Forms Master Copy" – Always use the most current version.

- Travel Authorization and Travel Expense Reimbursement Voucher Guidance

These documents may be accessed on the Local Area Network (LAN) in the TRAVEL GUIDANCE folder located on the ODF drive H:\(F-o-o-d S-a-f-e-t-y and Security Program)\Travel\TRAVEL GUIDANCE. If you are connected to the network (direct connection or VPN), the folder may also be accessed using this hyperlink: TRAVEL GUIDANCE

Travel Authorization
All overnight travel must be pre-approved at the appropriate management level.

Travel under $500: Approval from your manager is required. The method of approval (email, travel approval form, etc) is the manager's choice. If more than three (3) VDACS employees are travelling overnight to the same location, a Travel Authorization Form (TAF) is required regardless of cost.

Travel over $500 that is routine field work: Approval from the ODF Program Manager is required. Examples of routine field work requiring overnight travel include: a Food Safety Specialist (FSS) conducting inspections or responding to emergencies; a new employee travelling to another territory to train with another FSS.

Travel over $500 (non-routine): All trips costing over $500 (including state vehicle costs) must be submitted on a Travel Authorization Form (TAF) to Betty Ragsdale, through your manager, at least **20 business days prior to travel**. In addition to the TAF, a Cost Estimate must be submitted to show the anticipated cost of each travel expense, and a justification for why the travel is essential. There is a VDACS Cost Estimate Worksheet that can be used located on the ODF drive in a Travel folder at this location: TRAVEL GUIDANCE

Personal Mileage Claims
Employees are permitted to use their personally owned vehicle (POV) when a State-owned or a State contract Enterprise Rent-A-Car vehicle is not available or when the use of a POV is cost beneficial to the Agency. Use of a POV is considered cost beneficial under the following circumstances:

- When occasional travel is planned for distances up to 100 miles per day. For overnight travel, consider the average mileage over the period the State vehicle would otherwise be needed.
- A State vehicle or Enterprise vehicle is unavailable as confirmed by the Agency Transportation Officer (ATO).
- When an emergency exists and is approved by the Commissioner or designee. This justification and approval must be documented and attached to the Travel Reimbursement Voucher. The employee may be reimbursed at the higher IRS mileage rate when the circumstances meet one of the criteria above.

An employee assigned a state vehicle who chooses to use their POV as a matter of convenience will be reimbursed at the fleet rate listed in the State Travel Regulations. If the use of a POV is for a reason other than convenience, document the reason(s) on the voucher (e.g. state car out for repairs). When using a POV, the specific travel destinations should be included on the voucher under the column header "Location at which expense incurred". For example, the description,

'Richmond to Southside Virginia Farmer's Market, Danville" will assist the employee's supervisor in determining whether or not the personal vehicle was used for valid work-related purposes. A description such as 'used car for routine work' is not adequate.

Home based employees that use a POV must deduct their first and last trip of the day which is considered personal commuting expense by the IRS. In all cases, reimbursement will be limited to the most direct, economical route.

Lodging

Lodging guidelines for in-state cities are provided in the State Travel Regulations, and in the Travel Forms Master Copy workbook (look for the worksheet labeled "Meals and Lodging Guides").

Lodging guidelines *exclude* local taxes and surcharges. However, lodging taxes and surcharges are reimbursable. Lodging expenses incurred beyond approved amounts will NOT be reimbursed. In such cases, taxes and surcharges will be prorated only for the appropriate amount.

You need to submit original, itemized hotel bills if you are requesting reimbursement. Direct agency billing of lodging expenses incurred during overnight travel is permitted. Notify the hotel of travel plan changes as soon as possible when a confirmed reservation is being held. Since hotels can charge for non-canceled reservations, these charges will not be reimbursed if the traveler is negligent in canceling reservations.

Meals & Incidental Travel Expenses (M&IE)

Generally, meals and certain incidental travel expenses are reimbursable for overnight official business travel outside the traveler's official station. Incidental expenses include bellhop/taxi tips, personal telephone calls, laundry, and travel between lodging and places where meals may be consumed.

Meals and incidental expense (M&IE) guidelines are provided in the State Travel Regulations, and in the Travel Forms Master Copy workbook (look for the worksheet labeled "Meals and Lodging Guides").

The following reimbursement policies apply:

- The M&IE per diem must correspond to the location specified for the overnight lodging.
- Direct agency billing of meal expenses incurred during overnight travel, including charging meals to direct billed hotel rooms, is NOT permitted.
- On a travel departure or return day, 75% of the **meals per diem** is allowable (the **meals per diem** is the total per diem minus the **incidental expenses per diem**). The M&IE Rate Table found in CAPP topic 20335 should be used to determine the total per diem for travel days.

Overtime Meals

In an approved exception to the State Travel Regulations, breakfast and dinner meal allowances will be paid during overtime work periods at a fixed dollar amount of $4.00 for breakfast or $8.00 for dinner. No receipt is required.

To qualify for reimbursement, the employee must, out of business necessity, leave home prior to 6:00 AM or return after 7:30 PM. This does not include normal commuting time for employees not on official overnight travel status. Time of departure or return must be stated on the travel reimbursement voucher. Employees who leave home prior to 6:00 AM and return after 7:30 PM will be reimbursed a fixed dollar amount of $12 for overtime meals for that day.

The employee's scheduled hours AND actual hours worked including lunch break must be documented on the Travel Expense Reimbursement Voucher or as an attachment to the Voucher.

For Example:
Monday, November 29, 2010
Scheduled Hours: 8:00 AM to 4:45 PM with 45 min. for lunch
Actual Hours: 8:00 AM to 8:45 PM with 45 min. lunch

Completing the TERV

- Consult your manager for the appropriate cost code
- Include the "Vendor ID", which is your state ID number (used in lieu of your SSN)
- Include your assigned work location (e.g. home, Richmond office, etc.)
- List each day's expenses on a line that includes only that day's expenses
- If a POV is used, mark the appropriate selection in the Personal Vehicle Use Statement section. (Mileage rates will be calculated automatically based on those selections)
- Mark the appropriate "Purpose of Trip". Consult your manager if you are not sure which purpose to select.
- Describe the trip in sufficient but concise detail for a reviewer to determine the travel was necessary to conduct official business of the Commonwealth or to accomplish job duties.
- Accounting distribution: Your regional office can complete this section for you. Each applicable object code is listed separately with the corresponding cost. A list of codes may be found in the Travel Forms Master Copy workbook on the worksheet labeled "Meals and Lodging Guides".
- Attach to the TERV all applicable supporting documentation, with all receipts signed by the traveler (e.g. hotel bill when seeking direct reimbursement for charges, approved and signed TAF, copy of registration receipt, parking/toll receipts in amounts greater than $20, airline boarding passes when seeking direct reimbursement for flight tickets).
- When not requesting reimbursement for mode of transportation or lodging, indicate on the TERV how travel to/from the destination was accomplished (e.g. "travel was in a state vehicle"), and how lodging for overnight travel was paid (e.g. "lodging was direct billed", or "paid by PCard" - name the PCard holder).
- Provide the completed TERV to your manager as soon after travel as possible, and within 30 days after the completion of the travel.

REVISED November 2014

Procedure II-01: Foodborne Illness Complaint Investigations

Any VDACS Food Safety staff who receive consumer complaints or any other reports in which foodborne illness is alleged, suspected, or confirmed will immediately forward all information, including complainant contact numbers, to the Rapid Response Team (RRT) Coordinator or their designee.

Steps for handling foodborne illness complaints:

1. The Coordinator or designee will contact the complainant and collect all pertinent information regarding the complaint, symptoms of the illness, and history of medical treatment.

    a. A foodborne illness complaint form should be filled out when discussing the event with the complainant. Information for each field on the complaint form should be collected from the complainant.

    b. Special attention should be given to the illness experienced by the complainant including onset times, symptoms, and duration of sickness. Additionally, any medical attention or treatment sought by the complainant should be carefully noted.

2. Whenever possible the complainant should be encouraged to seek medical attention for their illness including the collection of stool or vomit samples. Clinical samples such as these are essential for isolation of the organism(s) involved and will aid greatly in determining what type of testing should be performed if a food sample is collected.

3. Using information provided by the complainant and other sources, e.g., the involved firm, the food manufacturer, and other state or federal agencies, the Coordinator or designee will compare the reported symptoms, onset, and duration of the illness against known parameters for the major foodborne pathogens of concern to determine if a possible agent(s) can be identified.

4. Once all details of the complaint have been reviewed and information provided has been compared against known microbial diseases, the Coordinator or designee will determine a course of action based upon all available data and notify the appropriate Food Safety Specialist, Field Supervisor and Regional Manager for the involved firm. If email is used to reach the FSS, it should be indicated that, in the absence of their response, the complaint will be directed to the Regional Manager who will determine to which inspector the complaint should be forwarded to. One exception being that email should never initially be used to contact an inspector when the illness has been confirmed by a laboratory; a phone call must be made instead. An email can be used to document pertinent information after the inspector has been notified by phone.

5. When any member of the VDACS inspectional staff receives a complaint from the Coordinator or designee they shall respond to that message indicating that they received the complaint.

a. For confirmed illness complaints: If the inspector cannot be reached within 30 minutes of the initial call, the Coordinator needs to work with the Regional Manager to identify who is available to respond.

b. Foodborne illness complaint assignments from the Rapid Response Team staff will have an associated allowable time to complete the firm investigation and all other related activities. All foodborne illness complaints will be responded to within 24 hours. The initial response will involve obtaining the details of the complaint by the RRT Coordinator or designee, as described above. Confirmed foodborne illness complaints will be investigated within 24 hours whereas unconfirmed or alleged foodborne illness complaints will be investigated in a timeframe not to exceed 10 working days.

6. The field investigation should be performed using procedures from the International Association for Food Protection's (IAFP) *Procedures to Investigate a Foodborne Illness, Sixth Edition* and *Procedures to Investigate a Waterborne Illness, Second Edition*. Attachment A in this FOM provides some guidance from the previously mentioned manual. Information from the investigation should be documented on the complaint form, and if samples are collected or violations are noted, an inspection report must also be issued to the firm.

a. The Coordinator or designee will work with the inspector to determine the best course of action and to ensure that the Food Safety Specialist has the appropriate tools and training to conduct any required activities.

b. As part of the investigation, complaint records are to be reviewed. Attention should be given to similar complaints and any related corrective action taken by the firm should be noted. Inspectors will indicate whether a complaint record review was conducted as part of their investigation summary documentation on the complaint form.

c. If the field investigation reveals factors that could have led to the reported illness (temperature abuse, employee illness, similar complaints against firm or food, poor employee hygiene, cross contamination, etc.) the Food Safety Specialist should immediately contact the Coordinator or designee by phone so that additional actions can be discussed. Additional actions might include:

(1) The collection of food samples (if not already requested),
(2) Notification of local health department officials (employee illness), or
(3) Swabbing of environmental surfaces in the firm

7. Once the field level investigation has been completed, any paperwork or other information should be emailed to the Coordinator or designee and uploaded to the LAN. For confirmed foodborne illness complaints, the paperwork needs to be reviewed immediately due to the urgency. Required information needs to be entered on the Foodborne Illness Complaint Tracking log by the Coordinator. For unconfirmed illness related complaints, the submitted paperwork needs to be reviewed within a week

8. Once all required paperwork has been received by the Coordinator or designee, it will be determined if additional actions on the part of the program are warranted. If no additional action by VDACS is required, the Coordinator or designee will record the final determination of the complaint and close out the investigation. If additional actions are required such as follow-up on testing of collected foods, consultation with VDH

epidemiologists, or notification of additional state and/or federal partners, the Coordinator or designee will conduct those activities.

9. For any complaints where foodborne illness has been confirmed by clinical testing of the involved person(s), the Coordinator will contact Core Membership of the RRT to report the findings and provide information about the complaint to the membership so that they can provide additional input into the situation and aid in the investigation. In these instances, once reported to the RRT Core Group, the complaint will remain active until all members agree that the event has been investigated fully and all necessary actions on the part of Virginia and federal food safety agencies have been completed.

10. A record of all complaints will be maintained on the LAN for review by the RRT Coordinator. In addition, a spreadsheet of all complaints and their outcomes will also be kept for tracking purposes and to ensure that complaints have been effectively responded to and closed according to established procedures. Each month, a complaint wrap-up will be completed that documents patterns related to specific food products, types of food processes, or contributing factors to foodborne illness.

Special Considerations:

If, at any time, inspection personnel note information or behavior that would lead to the belief that the complaint could be due to intentional contamination or terrorism, they should immediately notify the Coordinator. At that time, the investigation will switch to protocols established for those types of intentional events. See FOM II-02 Suspected Tampering and Bioterrorism Investigations, for procedures.

The above referenced procedures will apply for products manufactured within the Commonwealth of Virginia or for instances where the product was potentially contaminated during transport, storage, or sale within the state. Whenever a food product is noted to have been manufactured outside of Virginia and the contamination is believed to have occurred before the product entered the state, e.g. sealed food product with original seal intact, canned food with intact packaging, etc., the Coordinator will provide all complaint information to the Emergency Response Coordinator (ERC) or Complaint Manager in the FDA Baltimore District Office. The Coordinator will work with that individual to ensure that the appropriate federal and state agencies are notified of the complaint and provided with any and all available data.

Whenever a complaint received by the Food Safety Program falls under the jurisdictional area of another program or agency, the Coordinator or designee will contact the appropriate personnel with the involved program or agency and provide them with any and all available information on the complaint. Examples of such situations could include: firms under VDH Environmental Health Services jurisdiction, meat/poultry products regulated by OMPS or USDA, milk and/or dairy products under Dairy Program or VDH authority, and shellfish products where VDH Division of Shellfish Sanitation participation is necessary.

Attachment A

Topics Covered in IAFP *Procedures to Investigate A Foodborne Illness, Sixth Edition.*

Each Food Safety Specialist will be provided a copy of IAFP's handbook. Included is detailed information to be used while investigating a complaint concerning a foodborne illness. The following is a list of some of the content.

1. Preparing in advance for the on-site visit such as determining what inspection and sampling equipment to take;
2. Coordinating the investigation with the person who has normal regulatory responsibility over the facility and reviewing prior inspection reports, etc.;
3. Maintaining instructions for conducting the on-site investigation including flow diagrams specific to the suspect foods, or all foods under production on the day in question if suspect foods have not been narrowed down;
4. Identifying critical control points in the various food production processes;
5. Identifying possible points of contamination and determining the likelihood of survival or destruction of pathogens during heat or other inactivation processes;
6. Obtaining information on temperatures; size of containers; depth of foods in containers; name of person performing the operations, etc.;
7. Interviewing food workers and gathering facts that may alter or enhance the flow diagrams;
8. Documenting any conditions that were out of the ordinary on the day in question;
9. Obtaining information about foods that may have been prepared hours or days before the suspect meal;
10. Maintaining instructions on sample collection procedures, including guidance on the types of samples to be taken and how the samples are to be packed and transported; and
11. Identifying possible contributing factors to the outbreak, i.e., including conditions and circumstances present in the facility on the day in question that may have contributed to the outbreak.

Procedure II-02: Suspected Tampering & Bioterrorism Investigations

Any VDACS Food Safety staff who receive consumer complaints or any other reports in which intentional contamination, product tampering or bioterrorism is alleged, suspected or confirmed will immediately contact the Rapid Response Team (RRT) Coordinator and provide all available information concerning the event.

OFFICE RESPONSE

The RRT Coordinator will contact the complainant/contact and collect all necessary information regarding the event. This information will be collected and transmitted to the Complaint Form and entered into the Complaint Log on the LAN maintained by the RRT Coordinator or designee. Once the initial call with the complainant/contact is completed, the RRT Coordinator or designee will review the available information and determine next steps for the investigation. Possible outcomes at this point would include:

1. Complaint or interview does not appear to be a valid report of intentional contamination, tampering, or bioterrorism. Complaint will then be handled as a routine foodborne illness or product specific event and corresponding procedures will apply (See Procedures II-01 Foodborne Illness Complaint Investigations and Procedure III-39 Consumer Complaint Investigations).
2. Information supplied by the complainant/contact is sufficient to determine that an act of intentional contamination, tampering, or bioterrorism has possibly occurred. The RRT Coordinator or designee will immediately contact appropriate law enforcement personnel. The RRT Coordinator will be responsible for maintaining updated contact information for law enforcement partners and for determining the appropriate agency(ies) to notify.

FIELD RESPONSE

Once law enforcement personnel have assumed responsibility for an investigation involving suspected or confirmed intentional contamination, tampering, or bioterrorism, VDACS will assume a supportive role to their response providing assistance and technical guidance when requested. Of paramount concern is the safety of all personnel involved in responding to these types of incidents.

1. The RRT Coordinator or designee will serve as the Event Lead for VDACS throughout the duration of the event. He/she will serve as the main point of contact for law enforcement and other participating agencies and this person will direct VDACS response efforts when required or requested.
2. Whenever VDACS participation in field level events is requested or required, the RRT Coordinator or designee will assume responsibility for identifying and notifying the appropriate Food Safety Specialist, Field Supervisor, Regional Manager, or other program personnel. Identification of program staff to respond will be made in conjunction with management within the Food Safety Program.
3. When responding to the event in a field level capacity, VDACS staff should immediately report to the on-scene commander upon arrival. Contact information, if available, for the commander will be provided to VDACS staff prior to deployment. Deployed VDACS staff should coordinate their activities with the on-scene incident commander and follow his/her direction at all times when at the firm or on scene.

Additionally, VDACS staff should discuss personal safety issues including known chemical or biological hazards with the incident commander and ensure that they have the appropriate supplies, training, and personal protective equipment to carry out their assignment. As in all emergency response situations, safety of first responders and the public is the ultimate priority. Whenever, field inspectors or other responding VDACS staff have concerns of this nature or believe that exposure has or may occur, they should contact their Regional Manager and the RRT Coordinator for direction on how to proceed with the investigation.

4. As described above, VDACS personnel under the direction of the RRT Coordinator or designee will continue to serve a supportive role in the investigation until law enforcement personnel close out the investigation or turn over the event to VDACS or other agencies.

AFTER ACTION REPORTING

The RRT Coordinator will maintain investigational findings, distribute final investigation/environmental assessment reports of illness or injury implicating food to relevant agencies responsible for reporting contributing factors and antecedents to the CDC and distribute recommendations from investigation/environmental assessment reports to relevant agencies and stakeholders responsible for prevention, education and outreach.

You may want to refer to the information below that provides information on biological agent categories as well as research results for products previously investigated for suspicious white powders. In addition, a list of products that could appear to have powder on the outside put together by the Food Marketing Institute (FMI) has been included for your reference.

Biological Agent Categories

Agents in Category A have the greatest potential for adverse public health impact with mass casualties, and most require broad-based public health preparedness efforts. Category A agents also have a moderate to high potential for large-scale dissemination or a heightened general public awareness that could cause mass public fear and civil disruption.

Most Category B agents also have some potential for large-scale dissemination with resultant illness, but generally cause less illness and death and therefore would be expected to have lower medical and public health impact. These agents also have lower general public awareness than Category A agents and require fewer special public health preparedness efforts. Biological agents that have undergone some development for widespread dissemination but do not otherwise meet the criteria for Category A, as well as several biological agents of concern for food and water safety, are included in this category.

Biological agents that are currently not believed to present a high bioterrorism risk to public health but which could emerge as future threats were placed in Category C.

Critical biological agent categories for public health preparedness

Biological agent(s)	Disease
Category A	
Variola major	Smallpox
Bacillus anthracis	Anthrax
Yersinia pestis	Plague
Clostridium botulinum (botulinum toxins)	Botulism
Francisella tularensis	Tularemia
Filoviruses and Arenaviruses (e.g*., Ebola virus, Lassa virus*)	Viral hemorrhagic fevers
Category B	
Coxiella burnetii	Q fever
Brucella spp.	Brucellosis
Burkholderia mallei	Glanders
Burkholderia pseudomallei	Melioidosis
Alphaviruses (VEE, EEE, WEE[a])	Encephalitis
Rickettsia prowazekii	Typhus fever
Toxins (e.g., Ricin, Staphylococcal enterotoxin B)	Toxic syndromes
Chlamydia psittaci	Psittacosis
Food safety threats (e.g., *Salmonella spp*., *Escherichia coli* O157:H7)	
Water safety threats (e.g., *Vibrio cholerae*, Cryptosporidium parvum)	
Category C	
Emerging threat agents (e.g., *Nipah virus*, hantavirus)	

Research Results on Previous Products with Suspicious White Powders

1. Statement on Potential Presence of White Powder on Bananas, October 18, 2001 by the International Banana Association.

On occasion, bananas may show a white powder-like substance on their exterior peel and crown. Most likely, the presence of such powdery matter is the result from a routine processing step in banana packaging, which does not present any health risk or indicate a change in product quality.

Immediately after harvesting a banana stem, bananas are divided into clusters and placed into a tank of clean flowing water where they are thoroughly washed. Just before packing, a commonly used and U.S. government-approved preservative is applied to maintain freshness and quality. Residues from the preservative solution or from the wash water itself, due to water hardness, may form on the banana peel as it dries. After applying the preservative, bananas are immediately packed in cartons lined with plastic sheets and stored on pallets under controlled conditions for transportation to your market.

The process of washing and preserving the freshness of bananas in this manner has a long and dependable history of safe use. Of course, the edible part of bananas is further protected by the natural peel, which serves as a physical barrier in preserving the quality of the fruit.

The presence of the powder on the peel is likely from the banana producer's efforts to preserve product freshness and quality. Consumers should not be concerned. We encourage consumers to remain confident in the quality of bananas and continue to eat them as part of a nutritious diet involving at least 5 servings of fruits and vegetables a day.

2. E-mail from Jerry Williams, retired Field Supervisor, on White Residue on Apples.

I spoke with Keith Yoder from VA Tech Research Lab in Winchester, VA on 10-22-01. According to Keith, it is not uncommon to find a white residue on apples. This may be a wax residue or a non-harmful pesticide spray. Apples are sprayed with a product called SURROUND WP and a product called BORDEAUX. Surround is a clay related product that is sometimes sprayed with lime for insect control. Bordeaux is a copper based material that is also sometimes sprayed with lime for disease control. Surround will leave a white residue and Bordeaux will leave a bluish residue. Both are very low toxic and non-harmful. The apples may be wiped off or washed.

3. Statement on Turkey Package Residues, October 18, 2001 from the National Turkey Federation.

Recent terrorist attacks on the United States create heightened concern about residues found on any type of package. Therefore, to avoid any unnecessary fear, we'd like to explain a powdery material that may appear on the exterior of fresh or frozen whole turkey packages.

The normal chilling procedure for whole turkeys involves immersing the packaged turkey in a solution of cold water and salt. Salt is added to lower the temperature of the chilling solution for food safety and quality reasons. Once the turkey has been removed from the solution and dried, a tacky or powdery salt residue may remain on the outside of the bag. This is a normal part of the process and is not a safety or quality issue.

The turkey industry takes great pride in providing the safest, most wholesome product possible. The industry maintains procedures designed to protect the safety of the products we produce from the farm to market; because of recent events, security procedures are receiving the utmost attention.

For more information, contact Sherrie Rosenblatt. (Phone: 202-898-0100 ext 233; E-mail: srosenblatt@turkeyfed.org)

4. White Residue on Bell Peppers—Information provided as a result of a complaint investigation on October 17, 2001 by Kerri Martin, Food Safety Specialist, Senior.

A dusting of white powdery residue was noticed around the stem and on the outer skin of bell peppers in a local grocery store. After contacting the grower/packer of the peppers, it was found that the powder was a bacterial compound used in the fall planting season to fight off insects. The compound is called Dipel. It is a wetable powder and is a biological insecticide with the technical name of *Bacillus thuringiensis*. EPA explained that Dipel is commonly used and is not harmful to humans with no tolerance level.

PRODUCTS THAT COULD APPEAR TO HAVE POWDER ON THE OUTSIDE [1]

Grocery:
- Baby food cereal
- Baby powders and talcum powders
- Baking powder
- Baking soda
- Boxed dinners
- Boxed potatoes
- Bread crumbs and coatings
- Cake and other bake mixes
- Cat litter, baking soda added or dust
- Cocoa products
- Coffee creamers
- Croutons
- Flour products
- Gelatin and pudding products
- Oatmeal canisters
- Pancake mixes
- Pasta
- Powdered baby formula
- Powdered carpet deodorizers
- Powdered cleansers: Comet, Ajax, Bon Ami, Cameo, Spic-n-Span
- Powdered drink mixes (i.e., Kool Aid, Iced Teas, Mixed Drinks)
- Powdered laundry detergents, dish detergents and bleaches
- Powdered milk
- Protein powder and meal replacement powder containers
- Rice
- Rice side dishes (from the flavor packet)
- Soup and meal cups
- Spices/Salts
- Stuffing
- Sugar products, especially confectioner sugar
- Wool pads: S.O.S.

Bulk:
- Almonds – roasted, salted
- Cocktail peanuts – roasted, salted
- Coconut – unsweetened no salt
- Coconut flakes
- Company name-brand snack mix
- Flour (several varieties)
- Goelitz Chocolate Toffee Almonds
- Gummies – some varieties
- Honey roasted cashews
- Honey roasted peanuts
- Honey roasted sunflower
- Jaret – several varieties
- Jellies – several varieties
- Loose pretzels
- Oat bran – fine
- Peanut mix
- Quick oats
- Rice (several varieties)
- Rolled oats
- Sesame seeds hulled
- Snack mixes – salted and with Coconut
- Spanish peanuts
- Sunflower seeds – roasted, salted
- Toasted corn nuts

Dairy:
- Grated Cheese
- Pepperoni (salt will occasionally be visible on the casing)
- Shredded Cheese (anti-caking agent)

Frozen:
- Company name-brand Cookie Dough
- Company name-brand Pizza Dough and Bread Dough
- Oronoque Pie Shells
- Pasta
- Pizza
- Tiramisu

Dairy/Frozen:
- Activated Dry Yeast
- Corn Tortillas
- Flour Tortillas
- Fresh Pasta
- Plastic gallons of milk with dried milk residue around the caps
- Refrigerated Bagels
- Refrigerated Pizza

Deli/Prepared:
- Pizza
- Salami

General Merchandise:
- Auto Air Fresheners
- Baby Powder
- Bath Powder
- Broken Light bulbs
- Brooms & Cleaning Brushes
- Certo & Sure Gel
- Chalk
- Dry Pool Chemicals
- Easter Eggs
- Epson Salt
- Face Powder
- Flocking and Flaking
- Foot Powder
- Foot Soap
- Greeting Cards
- Latex Balloons
- Latex Gloves
- Latex Products
- Magazines
- Moth Balls
- Newspapers
- Packing Material
- Padded Mailing Envelopes
- Paper Products
- Plant Food Packets
- Plastic Housewares Packing
- Powdered Sprays
- Puzzle Dust
- Sachets
- Seeds
- Silica Gel Packs
- Talcum Powder

Additional Notes

Playtex Gloves:

The powder in Playtex products is calcium carbonate and cornstarch. It is used as an aid in putting the gloves on (known as donning) and also as an anti-tack agent for the latex surface. Some powder will rub off onto hands or other surfaces. All powdered gloves have powder residue on them.

Turkey:

National Turkey Federation (Sherrie Rosenblatt, 202-898-0100, x233)

A powdery material may appear on the exterior of fresh or frozen whole turkey packages. The normal chilling procedure for whole turkeys involves immersing the packaged turkey in a solution of cold water and salt. Salt is added to lower the temperature of the chilling solution for food safety and quality reasons. Once the turkey has been removed from the solution and dried, a tacky or powdery salt residue may remain on the outside of the bag. This is a normal part of the process and is not a safety or quality issue.

Produce:
Recent events have caused some customers to be concerned about the natural bloom (a thin white or off-white haze) that appears on some fruits and vegetables. Bloom is produced by Mother Nature to protect fruits and vegetables, and it wipes off easily. Organic produce tends to have more natural bloom than conventional produce. Examples include: Apples, Artichokes, Avocados, Blueberries, Cucumbers, Fresh figs, Grapes, Mangoes, Nectarines, Oranges and other citrus items, Plums, and Tomatoes.

There may also be concerns about the wax coatings that are applied to some fruits and vegetables after washing to help maintain freshness. Some fruits and vegetables are treated with a food grade, or edible, vegetable or mineral wax to replace naturally occurring waxes that are removed during washing and processing. If the wax is not at the right temperature when applied, or if too much is applied, it can get a milky off-white appearance. It can be wiped off easily. Apples may be treated with a lac-resin instead of the vegetable or mineral wax. Lac-resin is the same product that gives sheen to chocolate. In either case, these are not "suspicious" powders or residues and should not cause undue alarm. The following items are treated to reduce moisture loss and maintain freshness: Apples, Batata, Cucumbers, Eggplant, Grapefruit, Lemons, Limes, Melons, Name, Oranges, Parsnips, Passion Fruit, Peppers, Pineapples, Rutabagas, Squash, Sweet Potatoes, Tangerines, Turnips, Yautia, Yucca.

Watermelon may be dusted with a white powder resembling baby powder to prevent the outside skin from being sunburned. It is recommended that customers wash produce before consumption.

Magazines (from the FBI):
A common practice in the publishing industry involves applying a light coating of cornstarch to the cover and pages of glossy magazines and other printed materials. This prevents the pages from sticking to each other during shipping. The fine white or light brown powder produced during this process, called printers' spray powder, is not toxic and poses no health risk. It is most closely associated with "high gloss" magazines, although recent shipments of inspirational booklets (low gloss, I presume) distributed by a Catholic missionary organization based in Mississippi prompted calls to law enforcement agencies.

Food Packaging…Use of Starches and Other Compounds:
From national trade associations, including: American Meat Institute, Grocery Manufacturers of America, International Dairy Foods Association, National Chicken Council, National Food Processors Association, National Turkey Federation, Snack Food Association. Manufacturers routinely "dust" packaging materials with food grade starches to prevent them from sticking together. In use for more than 25 years, this starch is approved by U.S. Dept of Agriculture and the Food and Drug Administration. In processing plants, the packaging materials can become tacky and stick to production lines. To prevent this, processors often dust lines with cornstarch, baking soda, etc. Like the dusting of packaging above, this practice is also approved by regulatory agencies. Occasionally, a trace amount of white powder may remain on a product after it has been packaged.

[1]Information provided by FMI, November 14, 2001.

Procedure II-03: Guide to Conducting GMP Inspection Audits

Standard 4 of the Manufactured Food Regulatory Program Standards (MFRPS) requires that field audits (on-site performance evaluations) of inspections be conducted to verify the quality of inspections conducted through Food Contracts with the FDA. Audits ensure that inspections are consistently performed according to the established policies and procedures. Audits are conducted by individuals who are trained to conduct inspections and also trained on auditing procedures, and who have the authority to conduct the audits. Virginia's Food Safety Program's Field Supervisors participate in the FDA Contract Inspection Audit Program and are in "Phase III" of that program. In Phase III, the State agency assumes full responsibility for conducting the minimum number of contract audits to meet the audit rate specified by the Audit Program and the Food Contract Statement of Work. The quality of each inspection is audited using the performance factors identified in the Contract Audit Form FDA 3610, and follows the process described in FDA's Field Management Directive No. 76 (FMD-76). Those documents may be accessed by clicking on the icons below.

FMD-76 Contract Audit Form FDA 3610

FMD-76 requires a minimum of two field inspection audits of each inspector be conducted every 36 months. Inspections selected for audit should include high-risk food firms such as seafood facilities, juice processors, and low-acid canned food operations. These field audits will occur during the FDA contract season. Also, in Phase III of the Audit Program, the State agency must audit its own auditors every 36 months considering the inspection priorities listed in the food contract SOW and the inspections performed under contract. According to FMD-76, FDA also conducts a minimum of one audit of each State auditor every 36 months.

The purpose for evaluating the quality of inspections purchased through contracts with state agencies is to determine if the inspection is acceptable. The success of the evaluation depends on how well the auditor and auditee understands his/her role and responsibilities. Appendix A of FMD-76 defines the roles and responsibilities of both the auditor and auditee.

FMD-76 Appendix A

Appendix B-1 of FMD-76 provides guidance for Field Supervisors on assigning ratings during an audit for each of the performance factors listed on the Contract Audit Form (FDA Form 3610). For each performance factor, examples of actions and observations that would likely result in a "needs improvement" rating are provided.

FMD-76 Appendix B

Within five working days of the completion of an inspection audit, the Field Supervisor must email the completed FDA 3610 to the auditee's manager and to the contract manager. The FDA 3610 will be forwarded to the FDA District Office with all other documents for the inspection. When the inspection findings are entered into eSAF, the "Inspection Type" will be marked as "Audit" rather than the default "State".

If three or less items on the FDA 3610 are marked “needs improvement”, the overall rating is “acceptable”. If four or more evaluated items are marked as "needs improvement," the overall rating is “needs improvement”. If an auditee’s rating is found to be “needs improvement”, management, in consultation with the FDA District Office, will develop and initiate a plan for remedial training in the deficient areas. No Food Safety Specialist receiving an overall rating of “needs improvement” will be allowed to resume conducting contract inspections until competency in the deficient areas is demonstrated.

Procedure II-05: Equipment Verification/Calibration

PURPOSE

This document describes in detail the processes used to calibrate testing equipment assigned to Food Safety Specialists, Field Supervisors, and other Food Safety Program personnel. In particular this document focuses on temperature measuring devices and pH meters used when conducting inspections of food firms under VDACS jurisdiction.

DEFINITIONS

- **Calibration**: the process of standardizing an instrument to a known standard to ensure that it has the capacity and capability to measure data within a specific parameter range (temperature, pH, etc.) in which the instrument is designed to operate.
- **Accuracy**: the measure of an instrument's ability to measure data correctly without error.
- **Verification**: the process to confirming that an instrument can measure accurately within a specific parameter range (temperature, pH, etc.) in which the instrument is designed to operate.

SAFETY

Temperature measuring devices often have sharp tips which can pose a physical hazard in the form of cuts and stab wounds. Care should be taken when handling these items. Any staff performing equipment calibration should read and adhere to all safety precautions included in the product inserts associated with their assigned equipment (thermometers, pH meters) and associated calibration supplies (pH buffers).

EQUIPMENT/MATERIALS NEEDED

Temperature Measuring Device verification

- Sturdy container (glass or hard plastic)
- Ice (small pieces, or preferably crushed)
- Water (preferably distilled or deionized, but tap water may be used as long as it has not been "softened". Water softeners add salts that can change the freezing point of water)
- Accuracy verification log (see Appendix A)

pH Meter Calibration

- 2- Sturdy, non-reactive containers (glass or hard plastic)
- pH 4 buffer solution
- pH 7 buffer solution
- Electrode storage solution
- Deionized or distilled water
- Calibration log (see Appendix A)

Equipment Verification

Equipment such as thermometers and pH meters must be checked for accuracy prior to performing inspections. It is the responsibility of the Food Safety Specialist (FSS) to maintain the equipment in good working order and to maintain all records associated with accuracy checks and calibration.

Each FSS shall maintain a separate calibration log (See Appendix A) for each piece of testing equipment (temperature measuring device[s], pH meter) assigned to them. These files shall note any identifiers on the equipment such as serial or model numbers. This file shall also note the date on which the factory calibration will expire if that information is provided with the equipment documentation/packaging. Calibration logs shall be maintained on the LAN at H:\(F-o-o-d S-a-f-e-t-y and Security Program)\(Food Inspect)\Calibration Logs for review by Regional Managers. All FSS are required to keep any packaging or fliers included with the equipment which have directions for use, required maintenance, and proof of calibration. Examples of equipment that should be noted in the files described above include:

- Digital Thermometers
- Thermocouples
- Thermopens
- pH meters

Equipment that is frequently replaced, quickly exhausted through routine use, or not utilized to measure enforceable data do not need to be listed in the employee's files. Examples of this type of equipment would include light meters, infrared thermometers, sanitizer test strips, sanitizing wipes, black lights, and flashlights.

Thermometer Accuracy Verification

Accuracy of a thermometer is its ability to measure temperature correctly without error. A thermometer must be within ±2°F (±1.0°C) of the actual temperature to be considered an accurate device.

Thermometers must be tested for accuracy at least once monthly using the ice water bath method. Food Safety Specialists shall document accuracy checks on the logs listed in Appendix A. These logs will be stored on the LAN for review by Regional Managers.

It is best to use distilled or deionized water for the ice water bath. However if these materials are not available it is acceptable to use tap water to complete the thermometer accuracy verification (tap water that is softened may not be used – the salts added by a water softening system will alter the freezing point of water).

Materials necessary to calibrate a thermometer:

- Sturdy glass or hard plastic container (at least 1 pint or 500 ml capacity)
- Water (distilled or deionized preferred; tap water acceptable if not softened)
- Ice (small pieces, or preferably crushed)

Thermometer Verification Procedure:

1. Place crushed ice in a beaker or container; add just enough water to make a uniform slush ice medium to facilitate even contact with the thermometer and allow the mixture to equilibrate for a minute or two.
2. Place the thermometer in the ice bath. It is important to keep the tip of the thermometer immersed a minimum of 2 inches without touching the bottom of the container.
3. The thermometer should read 32°F (0°C) when placed in the slush ice bath.
4. If the temperature is above 32°F (0°C), add more crushed ice to the beaker.
5. If the thermometer is not equilibrating to 32°F (0°C) in the slush ice bath, start over.
6. If the thermometer will still not equilibrate note the temperature displayed and the amount of deviation from 32°F (0°C).
7. Document the check with the name and type of thermometer in the appropriate accuracy verification log.

Note: If the temperature noted during the accuracy check is <±2oF or <±1oC, you may still use the thermometer. Place a sticker on the thermometer noting the date of the latest accuracy check, the difference from 32.0°F (or 0.0°C) and your initials.

Example: You complete the accuracy check procedure described above on October 22, 2013. In several different attempts your thermometer consistently reads 33.5°F when placed into the ice water bath. You would note this finding within your equipment accuracy verification log and label that specific thermometer using a sticker, tape or other material noting the following information.

DATE: 10/22/2013
DIFFERENCE: +1.50F
INSPECTOR: Your initials

Although dial thermometers may be easily and efficiently calibrated/adjusted in the field, Food Safety Specialists shall not use the devices to measure temperatures during inspections. The dial thermometers can, however, be used to show firm personnel the correct way to calibrate a dial thermometer. Some thermometers, such as the blue PDT300 digital thermometer, may be easily and efficiently calibrated/adjusted in the field following the instructions that came with the unit. However, other units are not able to be calibrated economically using the resources VDACS has available. Examples of these types of thermometers would include thermocouples and thermopens/thermisters which cannot be calibrated/adjusted by program staff. For this equipment, maintenance of all packaging materials and records of calibration from the manufacturer will complete the FSS calibration records. These thermometers will need to be replaced when in need of calibration (i.e. if the temperature is >±2oF) or when the factory calibration expires. Please contact your Regional Office who will order a replacement. Remember to log the new equipment into your log with the proper identification (packaging, calibration certificate and serial numbers). Monthly accuracy verification checks must still be completed for thermometers which cannot be calibrated/adjusted by the program.

If any equipment is broken or measures a temperature difference in excess of 2oF/1oC in the ice water bath, remove it from use and contact your Regional Office to order a new unit. Inspectors shall have accurate back up temperature measuring devices for use until the new unit arrives and the accuracy of these devices shall be verified and documented using the method above.

pH Meter Calibration

A pH meter is an electronic device that measures pH (hydrogen ion concentration in a solution) via a glass electrode. All pH meters lose some of their accuracy with every use.

Because of this, their accuracy and function must be verified before use at each establishment through a calibration procedure. Calibration is done by measuring buffer solutions with a known pH and setting the measurements of the meter to those levels. The pH meter uses these controlled measurements as a guide with which to judge the accuracy of measuring other substances.

Below are detailed instructions for calibrating your pH meter. These same instructions can be found in the package insert supplied with the unit in its original packaging. pH meters must be calibrated on each day of active use. Food Safety Specialists shall document calibration checks on the logs listed in Appendix A. These logs will be stored on the LAN for review. Scheduled calibration is not required when the pH meter is not in use.

Meter setup:

Before beginning the actual calibration of the meter you will need to ensure that the unit is using the correct buffer set. To check this issue you will need to follow the instructions below.

- Press and hold the ON/OFF/MODE button for about 6 seconds, until CAL on the bottom display is replaced by TEMP and the current temperature unit (e.g. TEMP°C). You can toggle between temperature units using the SET/HOLD button.
- After the temperature unit has been selected, press ON/OFF/MODE to enter the buffer selection mode
- The meter will show the current buffer set: pH 7.01 BUFF or ph 6.86 BUFF. Use the SET/HOLD button to toggle the unit until the ph 7.01 BUFF is displayed.
- Press the ON/OFF/MODE button to return to normal use.

Materials need to calibrate the pH meter:

- Kim wipes
- 3- Beakers or other glass/non-reactive containers
- Container of pH 7 Buffer Solution
- Container of pH 4 Buffer Solution
- Electrode storage solution
- Squirt bottle filled with distilled or deionized water or beaker with distilled or deionized water to rinse the electrode (do not use tap water)

pH Meter Calibration Procedure:

1. Ensure that the meter electrode has not dried out. If the electrode has been left dry, soak it in storage solution for 30 minutes to reactivate it.
2. Press and hold the ON/OFF/MODE button until OFF on the bottom display is replaced by CAL
3. Release the button. The LCD should display “ph 7.01 USE. If the LCD displays ph 6.86 USE repeat the setup procedure described above and then restart calibration
4. Place the probe in ph 7 buffer. The LCD displays the recognized buffer value and OK for 1 second
5. After 1 second “ph 4.01 USE” is displayed
6. Place the probe into the pH 4 buffer
7. When the second buffer is recognized the LDC displays OK for 1 second and the meter returns to normal measuring mode

Once the meter has been calibrated, note the date that you performed the calibration and your initials on the appropriate calibration log. If any problems or deficiencies are noted during the calibration process note these in the calibration log and contact your regional manager and a replacement device may be issued.

APPENDIX A – ACCURACY VERIFICATION LOGS

TEMPERATURE MEASURING DEVICE ACCURACY VERIFICATION LOG	
Employee Name	
Equipment Identifiers (Serial/Model #, Calibration Date)	

Date	Temperature displayed on device in ice water bath	Amount of Deviation	Employee initials

pH METER CALIBRATION LOG

Employee Name	
Equipment Identifiers (Serial/Model #, Calibration Date)	

Date of Calibration	**Employee Initials**

Procedure II-06: Product Recall

Recalls are actions taken by a firm to remove a product from the market. It is important for food establishments to have a recall plan in place in order to identify and recover potentially adulterated, misbranded, and/or hazardous foods in order to prevent potential food safety problems or economic fraud. There are a number of situations that could result in a recall. Some examples might include undeclared allergens, bacterial or chemical contamination, or foreign objects.

It is the legal responsibility of the food manufacturing company to ensure that their products are safe, sanitary, and accurately labeled. This includes the prevention of product tampering and terrorism by purposeful contamination. It is important to note that the laws and regulations do not give VDACS the ability to "order" a recall (though VDACS does have seizure power); however, it is in the best interest of the company to voluntarily recall products when VDACS "requests" that they do so. While the firm is encouraged to voluntarily issue a recall of potentially affected products, many recall efforts are collaborative and are often overseen by more than one regulatory agency, such as VDACS, FDA, USDA, etc. Therefore, it is important to determine which agency will take the lead in the recall investigation and follow up efforts.

The lead regulatory agency is responsible for:

- Overseeing the firm's recall strategy;
- Reviewing for accuracy and thoroughness any notification to consignees, news releases to the media, and any information disseminated to the public/consumers
- Conducting recall effectiveness checks when necessary for establishments and organizations recalling food products;
- Supervising disposition of the product; and
- Deciding when the recall may be terminated.

Many times food recalls will involve products distributed in interstate commerce, in which case FDA would most likely take the lead. **NOTE**: *FDA is the lead agency for recall coordination involving eggs, even though the jurisdiction for food safety of eggs and egg products is divided between USDA and FDA.*

If the product is limited to intrastate commerce (Virginia only) and the product is under VDACS jurisdiction then VDACS would be the lead agency with the Rapid Response Team (RRT) Coordinator overseeing the efforts. VDACS would also be responsible for maintaining all records associated with the recall. If a questionable food product is under the jurisdiction of more than one agency then the agency taking the investigative lead role will determine the need for a recall.

The lead regulatory agency would be responsible for contacting the company and gathering the following information: **Note**: ***When VDACS is deemed the lead agency in a recall the FDA Regional Recall Coordinator should be consulted for additional guidance in handling the recall investigation and follow up procedures.***

1. **Product Identity**
   - Product name, including all brand names and generic names.
   - Product code numbers (i.e. lot/unit numbers, expiration dates, use-by dates, UPC codes).
   - Product description (i.e. powder, liquid, ready-to-eat, expected shelf-life, packaging type and size).

2. **Manufacturer Identity**
   - Firm name, address, city, state, zip.
   - Most responsible individual for the firm (name, title, phone, fax, e-mail).
   - Recall contact (name, title, phone, fax, e-mail).
   - Contact for the public (name, title, phone, fax, e-mail).

3. **Reason for the Recall**
   - Explanation of the cause of the problem and date or time it occurred.
   - Explanation of how and when the problem was discovered.
   - Explain whether the problem affects all products in the lot or quantity being recalled or only a portion of the products being recalled. (If it is a portion, provide as accurate a quantity as possible.)
   - If the firm received complaints associated with the problem, they must provide date(s) of complaint(s), with descriptions that include details of injury or illness, lot numbers, code dates, etc.
   - If the recall is due to presence of a foreign object, describe the size, composition, hardness and/or sharpness of the object.
   - If the recall is due to presence of a chemical contaminant, explain the level of contamination, and provide labeling, list of ingredients and the Material Safety Data Sheet (MSDS) for the contaminant.
   - If the recall is the result of a labeling issue, the company must provide and identify the correct and incorrect label(s), description, and formulation.

4. **Firm's Assessment of the Health Risk Associated with the Product Deficiency, Including any Supporting Data or Information.**

5. **Volume of Product Being Recalled**
   - Total quantity produced.
   - Date(s) produced.
   - Quantity distributed.
   - Quantity on hold by recalling firm and its distribution centers.
   - Description of product quarantine procedures and conditions.
   - Estimated amount of product remaining in the marketplace at: distributor level, retail level, and consumer level.

6. Distribution Pattern

- List of consignees—the accounts the firm sells the product directly to. The list should include the name, address, city, state, contact name, phone number, fax number, and e-mail address of each consignee.
- Indicate quantity of product shipped to each consignee, including dates.

Once the data has been collected, the VDACS RRT Coordinator should review and evaluate the documentation and decide on a recall classification. At a minimum this evaluation should take into account at least the following factors:

- The nature of the violation or defect—adulterated product, misbranded product, improperly labeled product, etc.
- Whether any illnesses or injuries have already occurred from the use of the product.
- The likelihood that illnesses or injuries may result.
- Whether any existing conditions could contribute to a situation that could expose humans to a health hazard, and the types of illnesses or injuries that may result.
- An assessment of the hazard to particular segments of the population—children, elderly, expectant mothers, persons with compromised immune systems, etc. and the degree of seriousness of this hazard to these specific populations.
- An assessment of both immediate and long-term consequences of the hazard.

The timeliness of the completion of the evaluation depends on the nature of the alleged violation or defect. The more serious the potential health effects, the greater the need for an urgent response. Based on the results of the evaluation, a classification (Class I, II, or III) will be assigned to the recall to indicate the relative degree of danger.

Class I: A Class I recall means there is "a reasonable probability" that the use of the violative product will cause serious adverse health consequences or death. Examples of Class I recall situations include:

- Confirmed cases of *Clostridium botulinum* toxin in food.
- *Listeria monocytogenes* in ready-to-eat foods.
- All *Salmonella* in ready-to-eat foods.
- Undeclared allergens—a food that contains an ingredient that is a common cause of serious allergic reactions but is not labeled to indicate these contents. "Class I" recalls may include products containing peanuts, tree nuts, eggs, dairy products or milk derivatives including casein, fish, shellfish, and soy.
- Undeclared sulfite (also an allergen) content of 10 mg or more per serving.

Class II: A Class II recall means the use of a violative product may cause temporary or medically reversible adverse health consequences or the probability of serious adverse health consequences is remote. Examples of Class II recall situations include:

- Non-FD&C certified colors or undeclared FD&C Yellow #5 or #6.

- Botulinum potential.
- Norovirus (contamination in seafood).
- Undeclared sulfites (3.7 – 9.9 mg per serving).
- Undeclared allergen—wheat.
- Unapproved additives or ingredients (ex: coumarin, nitrites in certain species of fish, artificial sweetener, alcohol, etc.).
- Potentially hazardous products that have been temperature abused for sufficient time that they might potentially pose a risk to consumers.
- A diet product that contains more fat or calories than its label indicates and may be problematic for diabetics.
- A food that requires refrigeration but is not labeled with this precaution.

Class III: These are recalls for products that violate the Virginia Food Laws but are unlikely to cause adverse health consequences. Examples of Class III recall situations include:

- So-called "economic fraud" which includes incorrect weight or volume labeling, or non-organic products being labeled as organic.
- A diet soft drink that is mistakenly labeled as a regular soft drink.
- Minor labeling problems.
- Undeclared certified FD&C colors (other than FD&C Yellow #5 and #6).
- Undeclared sulfites (less than 3.7 mg per serving).
- A food that contains yeast or mold contamination (except fresh breads).
- A food product that may have been produced under unsanitary conditions or that is decomposing.

Once the VDACS RRT Coordinator has determined the classification of the recall it is the firm's responsibility to develop a recall strategy, which the RRT coordinator will review. The recall strategy should address the following topics:

1. **Depth of the Recall**—that is, exactly who returns the products? How far (up or down) the distribution chain did the product go?
   - **Wholesale Level**: includes wholesalers and distributors, but not retailers.
   - **Retail Level**: includes every distribution level except the consumer, both wholesale and retail.
   - **Consumer or User Level**: a recall to the final consumer or user of the product.

2. **Public Warnings**—A public warning may or may not accompany a recall. Public warnings are general warnings that may be issued in the news media (national, regional, local); through professional or trade press; or through specific professions or population segments such as doctors, hospitals, schools, nursing homes, etc. Firms should supply a public warning and a plan for distribution with their recall strategy to VDACS for review.

3. **Effectiveness Checks**—This is a way to measure how well the recall is working, whether the consignees have received the proper notification, and how they acted on it. Effectiveness checks require that the

recalling firm contact their consignees a second time to determine whether they have been properly notified and to further determine whether those consignees have followed the instructions of the recalling firm. VDACS will model FDA's rating program for levels of effectiveness which range from "A" to "E". The following levels indicate the number of firms to be contacted:

- Level A is 100%.
- Level B is more than 10% but less than 100% of consignees.
- Level C is 10% of consignees.
- Level D is 2% of consignees.
- Level E indicates no effectiveness checks.

The level at which effectiveness checks should be completed will be determined by the VDACS RRT Coordinator based on the depth and health hazard associated with the recall. Effectiveness checks may be done through the mail (information letter with attached questionnaire that would be completed and returned to the recalling firm), over the telephone, or in person. Firms will be responsible for conducting their own effectiveness checks, while VDACS may assist if necessary and may conduct audits of these checks (See Procedure II-07 RRT Recall Audit Checks for additional information).

Implementing the Recall

Notification—VDACS' role is to ensure that the firm gets the word out to their consignees in a timely manner to ensure quick removal of the product from the marketplace; with specific instructions for what to do with the product (how to return it, whom to contact, etc.); and that they include everyone both "upstream and downstream" on the product distribution chain, including secondary accounts, if applicable.

The VDACS RRT Coordinator should review the expected time frames developed for the exchange of communication/information between the recalling firm and the consignees involved in the recall to ensure a timely exchange of information.

The firm may choose to notify consignees via telephone initially, but a written letter of notification should follow. If notification is sent via U.S. mail, fax, or e-mail, the firm should include a mechanism to verify that the consignee actually received the notice.

The written notification should include:

- The words "Urgent Food Recall". Typically this is located in the headline or on the envelope in which the notice is mailed.
- The recalling firm's name, address, contact person, and telephone number(s).
- The date of the recall notification.
- An exact description of the product(s) being recalled, including name(s), packaging, and container size(s).
- Any product codes on the container(s) or packaging.
- Name of manufacturer/distributor (if different than the recalling firm).
- Reason for the recall.
- Instructions for disposition of the recalled product.

- Instructions for any further sub-recall action (i.e. notification to secondary accounts and beyond).
- A requested response to verify that the notification was received and to document the quantity of product at each account.

Issuing a News Release—Depending on the depth of the recall, not every recall situation requires that the news media be notified. However, when it is necessary, there are a few options. The VDACS RRT Coordinator may work with the firm to word the news release and must approve the final copy before it is sent out. VDACS can issue its own news release if necessary. The first of these options is usually in the company's best interest.

The content of the news release should include:

- The recalling firm's name, address, contact person, telephone number(s).
- The date of the news release and any guidelines for when it is to be released (ex: "For Immediate Release").
- A headline that very briefly describes the recall (ex: "Potential *Salmonella* Contamination", etc.)
- Specific product(s) being recalled (ex: quantity, label names, product codes and where they might be located on the container, container size and type, production dates, expiration dates).
- Specific reason for the recall.
- A mention of any particular group of persons who might be at risk,
- A description of symptoms.
- Status of the number and types of related illnesses confirmed to date.
- Area of distribution, naming each state and how it reached consumers (ex: retail, mail order, direct delivery).
- A brief description of how the problem was identified (ex: firm's QC processes, regulatory agency's routine product sampling program, regulatory agency's epidemiological investigation).
- Instructions for what consumers should do with the recalled product.
- Instructions and contact information for consumers to obtain additional information.

Disseminating the Information—The VDACS RRT Coordinator should work closely with its internal Communications Office, regardless of whether the firm or VDACS will be issuing the news release, in getting the information out to newspapers, wire services, TV and radio stations, etc. In addition, thought should be given to other groups or organizations that might need to be informed about the recall. Anyone who may have received the food or who might receive complaints or questions should be notified. Consider food banks, other state agencies, trade associations, consumer groups, military bases, school districts, hospitals, nursing homes, internet based sites (ex: www.recalls.gov), etc. **The news release should be released in all states where the product was shipped.**

Overseeing Product Disposition— The VDACS RRT Coordinator should work jointly with the recalling company to determine what to do with the recalled product. Recalled products may be reconditioned, but only if it brings the product into compliance with the law. Reconditioning may include cleaning, reprocessing, repackaging, relabeling, over-stamping, sorting, or segregating.

If the product must be destroyed, it must be carried out in such a way that the affected product will not be returned to human food channels. It is not sufficient to assume that down-line users will follow the correct guidelines and do it themselves. Therefore, it is important that the manufacturer physically recalls the product, gathers it in as few places as possible, and documents its destruction. VDACS Food Safety Specialists should observe destruction or reconditioning procedures and document them.

Audit Checks— During the recall, the firm should be conducting effectiveness checks as part of its recall strategy (as described above). In addition, VDACS Food Safety Specialists may be conducting audit checks. The extent of the audit checks will depend on the depth of the recall and the type of recall action requested such as, return, field correction, or destruction. Audit checks usually will begin within 10 days of notification that the firm needs to conduct a recall. However, with Class I recalls, audit checks should begin within 24-48 hours after VDACS learns of the need for the recall. It is preferable that audit checks be performed in person, particularly for Class I recalls, however, resource restraints may make it necessary to conduct some audit checks via telephone. If telephone audit checks prove to be ineffective, it may be necessary to follow up with a visit to ensure the effectiveness of the recall action. See Procedure II-07 Recall audit checks for more information.

If at any time during the audit of the recall it is apparent that the recalling firm's recall effort is not effective, the VDACS RRT Coordinator will need to discuss the situation with the firm and determine what actions the firm intends to take to improve its recall efforts. This may include issuance of additional recall communications, etc. A letter should be sent to the firm indicating that it has been ineffective in its recall efforts. If the firm is unwilling to extend or modify its recall, VDACS may need to take further action, such as public warnings, seizures, etc.

Recall Termination— The VDACS RRT Coordinator will determine when the recalling firm has completed all of its recall activity, including monitoring and final product disposition. Once VDACS is satisfied that the firm has brought the product into compliance or has disposed of it in an acceptable manner, VDACS will terminate the recall.

With respect to Class I recalls, the firm should provide the VDACS RRT Coordinator with preventive measures taken by the firm to reduce the likelihood that such an incident will occur again.

Generally speaking, recalls should be terminated within three months after the firm completes the recall. A letter should be sent to the firm indicating that the recall has been terminated.

Model Company Recall Notification Letter

Date

Customer Firm Name & Address
ATTN: Contact Person Name & Title

Re: Recall of Type of Product

Dear Sir or Madam:

This letter is to confirm our telephone conversation that (Company Name) is recalling the following product because (Specify Recall Reason).

Describe the product, including name, brand, code, package size & type, establishment number, etc.

We request that you review your inventory records and segregate and hold the above product. If you have shipped any of this product we request that you contact your customers and ask them to retrieve the product and return it to you. Once you have retrieved all of the product, please contact us. We will arrange to have the product shipped to our facility. Please do not destroy the product. We will credit your account for the product returned.

We are undertaking this action in cooperation with the Virginia Department of Agriculture and Consumer Services' (VDACS) Office of Dairy and Foods. VDACS officials may contact you to confirm that you have received this notice and are cooperating in this action.

Your prompt action will greatly assist (Company Name) in this action. If you have any questions, please do not hesitate to contact (Company Recall Coordinator) at (Phone Number).

Thank you for your cooperation.

Sincerely,

Company Office Name & Title

Model Notification of Classification Letter (VDACS to Recalling Firm)

Date

Mr. John Doe, President
J.D. Laboratories, Inc.
Somewhere, VA

Re: Recall No. D-000-9

Dear Mr. Doe:

We agree with your firm's decision to recall (product), Code Numbers _____ due to (reason for recall).

We have reviewed your action and conclude that it meets the formal definition of a "recall". This is significant, as your action is an alternative to a VDACS legal action to remove your product from the market.

This recall has been classified by VDACS as a Class __ recall. This means (insert definition).

Our evaluation indicates that this recall should be conducted to the (consumer or user, retail, wholesale, etc.) level and that level ___ effectiveness checks should be conducted by your firm. Level ___ effectiveness checks are (definition).

In addition to your recall efforts, it is equally important to assure that all returned merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped.

Our past experience in similar situations has shown that the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse. We, therefore, urge you to immediately begin making plans to destroy the product or recondition it to bring it into compliance with the law.

Either method should be done under the supervision of a Food Safety Specialist from this office.

We request that you advise us within ten days of the steps you have taken or will take to ensure that the recalled merchandise is properly inventoried and maintained to prevent unintended use or shipment, and provide your proposed method of disposition of the returned goods.

In addition, we request that you submit to our (RRT coordinator) a recall status report at (monthly, bi-weekly, etc.) intervals. These recall status reports should contain the following information:

- Number of consignees notified of the recall, and the date and method of notification.
- Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
- Number of consignees that did not respond.
- Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
- Number and results of effectiveness checks that were made.
- Estimated timeframes for completion of the recall.

These periodic status reports should be addressed to: (insert name and address).

Our judgment regarding the effectiveness of your recall will largely be based upon your implementation of the enclosed recall guidelines (enclose modified VDACS recall policy). Please be advised that failure to conduct an effective recall could result in seizure of the violative product or other legal actions under the Virginia Food Laws.

Your response to this letter should be addressed to (insert appropriate person).

Sincerely,

Name & Title

Model Press Release Foreign Object

Virginia Company Recalls (Product) That May Contain (Hazardous Material, ex: Glass)

(City, Date)—(Company Name), a (City, Virginia), establishment is voluntarily recalling approximately (# of pounds) of (product) because the product may contain (hazardous material, ex: glass). Consumption could cause (lacerations).

Specific information on how to identify the product (i.e. type of container (plastic, metal, glass), size or appearance of product, product brand name, establishment number and location on package, flavors, codes, and expiration dates, etc.)

Product was distributed (listing of the states and areas where the product was distributed and how it reached the consumers (ex: through retail stores, mail order, or direct delivery)).

Status of the number of and types of related illnesses that have been confirmed to date (ex: "No illnesses have been reported to date.")

Brief explanation about what is known about the problems, such as how it was revealed, and what is known about its source. An example of such a description: "The recall was the result of the plant finding several pieces of glass on routine examination of the product. The company immediately contacted VDACS and has ceased distribution of the product as VDACS and the company continue their investigation as to what caused the problem."

Because of the potential hazard, (company name) urges consumers who have purchased these products not to eat them but return them to the place of purchase.

Information on what consumers should do with the product and where they can get additional information (ex: "Consumers who have purchased Brand X are urged not to eat the product but return it to the place of purchase for a full refund.")

Consumers with questions about the recall may contact (name and position or company division) at (phone number), or the consumer hotline at (toll free number). Media with questions may contact (name and position) at (phone number).

Model Press Release—Allergen

Virginia Company Recalls (Product) Because of Undeclared Allergen

FOR IMMEDIATE RELEASE

Date

Company Contact and Phone Number

FOOD CO. ISSUES ALLERGY ALERT ON UNDECLARED ALLERGEN IN PRODUCT

(Company Name) of (City, Virginia) is recalling (quantity and type of product) because it may contain undeclared (specific type of allergen, ex: egg, milk, etc.). People who have an allergy or severe sensitivity to (specific type of allergen) run the risk of serious or life-threatening allergic reaction if they consume these products.

Specific information on how the product can be identified (i.e. type of container (plastic, metal, glass), size or appearance of the product, product brand name, establishment number and location on package, flavors, codes, expiration dates, etc.)

Product was distributed [listing of the states and areas where the product was distributed and how it reached consumers (ex: through retail stores, mail order, or direct delivery)].

Status of the number of and types of related illnesses that have been confirmed to date (ex: “This company has received two reports from consumers allergic to (specific allergen) of mild adverse reactions.”).

Brief explanation about what is known about the problem, such as how it was revealed, and what is known about its source. An example of such a description: “The recall was initiated after it was discovered that product containing (the allergen) was distributed in packaging that did not reveal the presence of (the allergen).”

Information on what consumers should do with the product and where they can get additional information (ex: “Consumers who have purchased Brand Z are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX”).

Sample Press Release—Allergen

XYZ Inc.
123 Smith Lane
Anywhere, VA

FOR IMMEDIATE RELEASE **DATE**
Sam Smith /555-555-5555

XYZ ISSUES ALLERGY ALERT ON UNDECLARED PEANUTS IN "SNACKIES"

XYZ Inc. of Anywhere, MS, is recalling its 5 ounce packages of "Snackies" food treats because they may contain undeclared peanuts. People who have allergies to peanuts run the risk of serious or life-threatening allergic reaction if they consume these products.

The recalled "Snackies" were distributed nationwide in retail stores and through mail orders.

The product comes in a 5 ounce, clear plastic package marked with lot # 666666 on the top and with an expiration date of 12/12/99 stamped on the side.

No illnesses have been reported to date in connection with this problem.

The recall was initiated after it was discovered that the peanut-containing product was distributed in packaging that did not reveal the presence of peanuts. Subsequent investigation indicates the problem was caused by a temporary breakdown in the company's production and packaging processes.
Production of the product has been suspended until the Virginia Department of Agriculture and the company are certain that the problem has been corrected.

Consumers who have purchased 5 ounce packages of "Snackies" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

Model Press Release—Microbial Pathogen Contamination

Virginia Company Recalls (Product) For Possible *Listeria* Contamination

(City, date)--(Company Name) a (City, Virginia) company is voluntarily recalling approximately (quantity) of ready-to-eat (product) that may be contaminated with *Listeria monocytogenes*.

Specific information on how to identify the product can be identified (i.e. type of container (plastic, metal, glass), size or appearance of the product, product brand name, establishment number and location on package, flavors, codes, expiration dates, etc.)

Product was distributed (listing of the states and areas where the product was distributed and how it reached consumers (ex: through retail stores, mail order, or direct delivery)).

Description of illness: "Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Healthy people rarely contract listeriosis. Listeriosis can cause high fever, severe headache, neck stiffness, and nausea. Listeriosis can also cause miscarriages and stillbirths, as well as serious and sometimes fatal infections in those with weak immune systems—infants, the frail or elderly and person with chronic disease, HIV infection or in chemotherapy." Status of the number of and types of related illness that have been confirmed to date (ex: "No illnesses have been reported to date. Anyone concerned about an illness should contact a physician.").

Brief explanation about what is known about the problem, such as how it was revealed, and what is known about its source. An example of such a description: "The problem was discovered through routine VDACS microbiological testing."

Information on what consumers should do with the product and where they can get additional information (ex: "Consumers who have purchased Brand X are urged to return it to the place of purchase for a full refund. Media with questions about the recall may contact (name and position) at (phone number). Consumers with questions about the recall may contact (name and position) at (phone number.)).

Sample Press Release—*Listeria monocytogenes*

XYZ Inc.
123 Smith Lane
Anywhere, VA

DATE

FOR IMMEDIATE RELEASE
Sam Smith /555-555-5555

XYZ RECALLS "SNACKIES" BECAUSE OF POSSIBLE HEALTH RISK

XYZ Inc. of Anywhere, MS, is recalling its 5 ounce packages of "Snackies" food treats because they have the potential to be contaminated with *Listeria monocytogenes*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, listeria infection can cause miscarriages and stillbirths among pregnant women.

The recalled "Snackies" were distributed nationwide in retail stores and through mail orders.

The product comes in a 5 ounce, clear plastic package marked with lot # 666666 on the top and with an expiration date of 12/12/99 stamped on the side.

No illnesses have been reported to date in connection with this problem.

The potential for contamination was noted after routine testing by the company revealed the presence of *Listeria monocytogenes* in 5 ounce packages of "Snackies."

The production of the product has been suspended while FDA and the company continue to investigate the source of the problem.

Consumers who have purchased 5 ounce packages of "Snackies" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

Sample Press Release—*Clostridium botulinum*

XYZ Inc.
123 Smith Lane
Anywhere, VA

DATE

FOR IMMEDIATE RELEASE
Sam Smith /555-555-5555

XYZ RECALLS "SNACKIES" BECAUSE OF POSSIBLE HEALTH RISK

XYZ Inc. of Anywhere, MS, is recalling its 5 ounce packages of "Snackies" food treats because they have the potential to be contaminated with *Clostridium botulinum*, a bacterium which can cause life-threatening illness or death. Consumers are warned not to use the product even if it does not look or smell spoiled.

Botulism, a potentially fatal form of food poisoning, can cause the following symptoms: general weakness, dizziness, double-vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

The recalled "Snackies" were distributed nationwide in retail stores and through mail orders.

The product comes in a 5 ounce, clear plastic package marked with lot # 666666 on the top and with an expiration date of 12/12/99 stamped on the side.

No illnesses have been reported to date in connection with this problem.
The potential for contamination was noted after routine testing found that the product had been under-processed.

Production of the product has been suspended as VDACS and the company continue their investigation as to the source of the problem.

Consumers who have purchased 5 ounce packages of "Snackies" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

Sample Press Release--*Salmonella*

XYZ Inc.
123 Smith Lane
Anywhere, VA

DATE

FOR IMMEDIATE RELEASE
Sam Smith /555-555-5555

XYZ RECALLS "SNACKIES" BECAUSE OF POSSIBLE HEALTH RISK

XYZ Inc. of Anywhere, MS, is recalling its 5 ounce packages of "Snackies" food treats because they have the potential to be contaminated with *Salmonella*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis and arthritis.

The recalled "Snackies" were distributed nationwide in retail stores and through mail orders.
The product comes in a 5 ounce, clear plastic package marked with lot # 666666 on the top and with an expiration date of 12/12/99 stamped on the side.

No illnesses have been reported to date in connection with this problem.

The potential for contamination was noted after routine testing by the company revealed the presence of *Salmonella* in some 5 ounce packages of "Snackies."

Production of the product has been suspended while FDA and the company continue their investigation as to the source of the problem.

Consumers who have purchased 5 ounce packages of "Snackies" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

Sample Press Release—*E. Coli* O157:H7

XYZ Inc.
123 Smith Lane
Anywhere, VA

DATE

FOR IMMEDIATE RELEASE
Sam Smith /555-555-5555

XYZ RECALLS "SNACKIES" BECAUSE OF POSSIBLE HEALTH RISK

XYZ Inc. of Anywhere, MS, is recalling its 5 ounce packages of "Snackies" food treats because they have the potential to be contaminated with *Escherichia coli* O157:H7. *E. coli* O157:H7 causes a diarrheal illness often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called Hemolytic Uremic Syndrome (HUS). HUS is most likely to occur in young children and the elderly; the condition can lead to serious kidney damage and even death.

The recalled "Snackies" were distributed nationwide in retail stores and through mail orders.

The product comes in a 5 ounce, clear plastic package marked with lot # 666666 on the top and with an expiration date of 12/12/99 stamped on the side.

No illnesses have been reported to date in connection with this problem.
The potential for contamination was noted after routine testing by the company detected the presence of *E. coli* O157:H7.

Production of the product has been suspended while FDA and the company continue their investigation as to the cause of the problem.

Consumers who have purchased 5 ounce packages of "Snackies" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

Model Audit Check Questionnaire

Consignee Name & Address

John Doe Product Recall

After contacting the consignee and locating the person responsible for handling recall notifications and/or the product involved, a questionnaire similar to the following may be used to help complete Form 3177.

I am (name of interviewer). I am calling from the VA Department of Agriculture, Office of Dairy & Foods to check the effectiveness of (recalling firm) recall of (product description, including codes). On (date), (recalling firm) notified (how: letter, telephone, visit, mailgram, etc.) all firms which may have purchased (product) that all stock should be (returned, destroyed, modified, relabeled, etc.). I have the following questions to ask you about this recall:

Date: ____

1. Did your firm receive notification that (product name) products manufactured by John Doe Company are being recalled?

Yes____ No____

2. Did your firm receive shipment of the product being recalled? (If no, terminate questioning and go to the closing.)

Yes ___ No___

3. Do you have any of the recalled product on hand? (Please check inventories before answering.)

Yes___ No___

4. If the answer to question 3 is yes, do you intend to return the product to the John Doe Company as requested?

Yes___ No ___

5. If the answer to question 4 is no, please explain your intentions:

_____

6. Have you received any reports of illness or injury related to this product?

Yes___ No___

If yes, please provide details:_____

Thank you for your cooperation.

And your name is _____, and your title _____.

Interviewer _____, Date _____

If respondent has any further questions, ask him/her to contact the John Doe Company, Someplace, Somewhere, VA.

Model Ineffective Recall Letter

Mr. John Doe, President
J.D. Laboratories, Inc.
Somewhere, VA

Dear Mr. Doe:

This confirms our telephone conversation/visit with you that our audit of your firm's Class __ recall of (product) indicates that the recall is ineffective at the (Distributor, Wholesale, Retail, etc.) level. This determination is based on the fact that (detail all audit findings—for example):

- Review of your submitted recall status reports found that (number and type of consignees) have not responded to your recall communication.
- Review of documentation at your firm found that sub-recall was not initiated by (number) wholesale distributors.
- Audit checks conducted by VDACS found that…

It is therefore reasonable to assume that the defective product could still be in the hands of these consignees.

Based on these findings, please advise us in (*) days of the steps you plan to take to rectify this situation.

(*) Two days for Class I
Five days for Class II
Ten days for Class III

Sincerely,

Name & Title

Model Recall Termination Letter

Mr. John Doe, President
J.D. Laboratories, Inc.
Somewhere, VA

Dear Mr. Doe:

The Virginia Department of Agriculture and Consumer Services' Office of Dairy and Foods has completed the audit of your firm's actions concerning the recall of (product, code number(s), recall number(s)). We conclude that the recall has been completed and there has been proper disposition of the recalled articles. Therefore, VDACS considers the recall terminated.

This letter is not intended to imply that VDACS will not recommend civil or criminal legal action related to this matter. It does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Virginia Food Laws in the future.

Sincerely,

Name & Title

HEALTH HAZARD EVALUATION GUIDELINES for UNDECLARED SULFITES

The consumption of 10 mg or more of sulfites per serving has been reported to elicit reactions in some asthmatics who have been given such challenge doses. It is probable that a severe anaphylactic shock could occur in certain sulfite sensitive individuals upon ingesting 10 mg or more of sulfites.

The absolute minimum challenge dose of sulfites that has been reported to elicit a reaction and pose a hazard to health in exquisitely sensitive individuals is 3.7 mg.

MG SULFITE CONSUMPTION PER SERVING	HEALTH HAZARD EVALUATION	RECALL CLASS
10 mg or more	Acute - Life threatening hazard	I
3.7 - 9.9 mg	Moderate - Acute	II
Less than 3.7 mg	None	III

CALCULATIONS OF SULFITE DOSE:

Sulfite results are usually reported as parts-per-million (ppm).
1 ppm = 1 microgram/gram = 0.001 mg/gm

To convert ppm results to mg/gm, divide ppm results by 1000.

Example A: Pears in 16 ounce container contain 125 ppm undeclared sulfites
Serving Size: Assume 4 ounces
Dose: 125ppm/1000 = 0.125mg/gm x 4oz x 28.4gm/oz = 14.2 mg

Example B: Orange drink in gallon container contains 12.5 ppm of undeclared sulfites
Serving Size: Assume 6 ounces
Grams of drink per serving = 6oz x 28.4 gm/oz = 170.4 gm
Mg sulfite serving = 12.5 ppm/1000 x 170.4 = 2.13 mg

If the orange drink was in a 12 or 16 ounce container, we would assume that the entire contents would be consumed as one serving. The 12-ounce container would give a sulfite dose of 4.26 mg, while the 16-ounce container would give 5.68 mg.

Conversion Reference

1 gram = 0.035 ounce
1 dram = 3.888 grams
1 fluidounce = 8 fluidrams
1 tablespoon = 4 fluidrams (1/2 fluidounce)

The following tables show REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING as determined by FDA. These tables are derived from 21 CFR 101 Food Labeling.

TABLE 1.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: INFANT AND TODDLER FOODS

Product category	Reference amount
Cereals, dry instant	15 g
Cereals, prepared, ready-to-serve	110 g
Other cereal and grain products, dry ready-to-eat, e.g., ready-to-eat cereals, cookies, teething biscuits and toasts.	7 g for infants and 20 g for toddlers for ready-to-eat cereals; 7 g for all others.
Dinners, desserts, fruits, vegetables or soups, dry mix.	15 g
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, junior type.	110 g
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, strained type.	60 g
Dinners, stews or soups for toddlers, ready-to-serve.	170 g
Fruits for toddlers, ready-to-serve	125 g
Vegetables for toddlers, ready-to-serve	70 g
Eggs/egg yolks, ready-to-serve	55 g
Juices, all varieties	120 g

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY

Product category	Reference amount
Bakery products:	
Biscuits, croissants, bagels, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies	55 g
Breads (excluding sweet quick type), rolls	50 g
Bread sticks--see crackers	
Toaster pastries--see coffee cakes	
Brownies	40 g
Cakes, heavy weight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combined) [6]	125 g
Cakes, medium weight (chemically leavened cake with or without icing or filling except those classified as light weight cake; fruit, nut, and vegetable cake with less than 35 percent of the finished weight as fruit, nuts, or	80 g

vegetables or any of these combined; light weight cake with icing; Boston cream pie; cupcake; eclair; cream puff) [7]	
Cakes, light weight (angel food, chiffon, or sponge cake without icing or filling) [8]	55 g
Coffee cakes, crumb cakes, doughnuts, Danish, sweet rolls, sweet quick type breads, muffins, toaster pastries	55 g
Cookies	30 g
Crackers that are usually not used as snack, melba toast, hard bread sticks, ice cream cones [9]	15 g
Crackers that are usually used as snacks	30 g
Croutons	7 g
French toast, pancakes, variety mixes	110 g prepared for french toast and pancakes; 40 g dry mix for variety mixes
Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars	40 g
Ice cream cones--see crackers	
Pies, cobblers, fruit crisps, turnovers, other pastries	125 g
Pie crust	1/6 of 8 inch crust; 1/8 of 9 inch crust
Pizza crust	55 g
Taco shells, hard	30 g
Waffles	85 g
Beverages:	
Carbonated and noncarbonated beverages, wine coolers, water	240 mL
Coffee or tea, flavored and sweetened	240 mL prepared
Cereal and Other Grain Products:	
Breakfast cereals (hot cereal type), hominy grits	1 cup prepared; 40 g plain dry cereal; 55 g flavored, sweetened dry cereal
Breakfast cereals, ready-to-eat, weighing less than 20 g per cup, e.g., plain puffed cereal grains	15 g
Breakfast cereals, ready-to-eat weighing 20 g or more but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g	30 g
Breakfast cereals, ready-to-eat, weighing 43 g or more per cup; biscuit types	55 g
Bran or wheat germ	15 g
Flours or cornmeal	30 g
Grains, e.g., rice, barley, plain	140 g prepared; 45 g dry
Pastas, plain	140 g prepared; 55 g dry

Pastas, dry, ready-to-eat, e.g., fried canned chow mein noodles	25 g
Starches, e.g., cornstarch, potato starch, tapioca, etc.	10 g
Stuffing	100 g
Dairy Products and Substitutes:	
Cheese, cottage	110 g
Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese	55 g
Cheese, grated hard, e.g., Parmesan, Romano	5 g
Cheese, all others except those listed as separate categories--includes cream cheese and cheese spread	30 g
Cheese sauce--see sauce category	
Cream or cream substitutes, fluid	15 mL
Cream or cream substitutes, powder	2 g
Cream, half & half	30 mL
Eggnog	120 mL
Milk, condensed, undiluted	30 mL
Milk, evaporated, undiluted	30 mL
Milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa	240 mL
Shakes or shake substitutes, e.g., dairy shake mixes, fruit frost mixes	240 mL
Sour cream	30 g
Yogurt	225 g
Desserts:	
Ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones)	1/2 cup-includes the volume for coatings and wafers for the novelty type varieties
Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups)	85 g
Sundae	1 cup
Custards, gelatin or pudding	1/2 cup
Dessert Toppings and Fillings:	
Cake frostings or icings	35 g
Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and nondairy whipped toppings	2 tbsp
Pie fillings	85 g
Egg and Egg Substitutes:	
Egg mixtures, e.g., egg foo young, scrambled eggs,	110 g

omelets	
Eggs (all sizes) [9]	50 g
Egg substitutes	An amount to make 1 large (50 g) egg
Fats and Oils:	
Butter, margarine, oil, shortening	1 tbsp
Butter replacement, powder	2 g
Dressings for salads	30 g
Mayonnaise, sandwich spreads, mayonnaise-type dressings	15 g
Spray types	0.25 g
Fish, Shellfish, Game Meats [10], and Meat or Poultry Substitutes:	
Bacon substitutes, canned anchovies, [11] anchovy pastes, caviar	15 g
Dried, e.g., jerky	30 g
Entrees with sauce, e.g., fish with cream sauce, shrimp with lobster sauce	140 g cooked
Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake	85 g cooked; 110 g uncooked [12]
Fish, shellfish or game meat [10], canned [11]	55 g
Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters	55 g
Smoked or pickled [11] fish, shellfish, or game meat [10]; fish or shellfish spread	55 g
Substitutes for bacon bits--see miscellaneous category	
Fruits and Fruit Juices:	
Candied or pickled [11]	30 g
Dehydrated fruits--see snacks category	
Dried	40 g
Fruits for garnish or flavor, e.g., maraschino cherries [11]	4 g
Fruit relishes, e.g., cranberry sauce, cranberry relish	70 g
Fruits used primarily as ingredients, avocado	30 g
Fruits used primarily as ingredients, others (cranberries, lemon, lime)	55 g
Watermelon	280 g
All other fruits (except those listed as separate categories), fresh, canned, or frozen	140 g
Juices, nectars, fruit drinks	240 mL
Juices used as ingredients, e.g., lemon juice, lime juice	5 mL

Legumes:	
Bean cake (tofu) [11], tempeh	85 g
Beans, plain or in sauce	130 g for beans in sauce or canned in liquid and refried beans prepared; 90 g for others prepared; 35 g dry
Miscellaneous Category:	
Baking powder, baking soda, pectin	0.6 g
Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations	1 tsp or 4 g if not measurable by teaspoon
Batter mixes, bread crumbs	30 g
Cooking wine	30 mL
Dietary supplements	The maximum amount recommended, as appropriate, on the label for consumption per eating occasion, or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonsful, etc.
Drink mixers (without alcohol)	Amount to make 240 mL drink (without ice)
Chewing gum [9]	3 g
Meat, poultry and fish coating mixes, dry; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes	Amount to make one reference amount of final dish
Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits	7 g
Salt, salt substitutes, seasoning salts (e.g., garlic salt)	1/4 tsp
Spices, herbs (other than dietary supplements)	1/4 tsp or 0.5 g if not measurable by teaspoon
Mixed Dishes:	
Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc.	1 cup
Not measurable with cup, e.g., burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches	140 g, add 55 g for products with gravy or sauce topping, e.g., enchilada with cheese sauce, crepe with white sauce [14]
Nuts and Seeds:	
Nuts, seeds, and mixtures, all types: sliced, chopped, slivered, and whole	30 g
Nut and seed butters, pastes, or creams	2 tbsp
Coconut, nut and seed flours	15 g
Potatoes and Sweet Potatoes/Yams:	
French fries, hash browns, skins, or pancakes	70 g prepared; 85 g for frozen unprepared french fries
Mashed, candied, stuffed, or with sauce	140 g
Plain, fresh, canned, or frozen	110 g for fresh or frozen; 125 g for vacuum packed; 160 g for canned in liquid
Salads:	

Gelatin salad	120 g
Pasta or potato salad	140 g
All other salads, e.g., egg, fish, shellfish, bean, fruit, or vegetable salads	100 g
Sauces, Dips, Gravies and Condiments:	
Barbecue sauce, hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa)	2 tbsp
Major main entree sauces, e.g., spaghetti sauce	125 g
Minor main entree sauces (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce	1/4 cup
Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, marinades	1 tbsp
Minor condiments, e.g., horseradish, hot sauces, mustards, worcestershire sauce	1 tsp
Snacks:	
All varieties, chips, pretzels, popcorns, extruded snacks, fruit- based snacks (e.g., fruit chips,) grain-based snack mixes	30 g
Soups:	
All varieties	245 g
Sugars and Sweets:	
Baking candies (e.g., chips)	15 g
Hard candies, breath mints	2 g
Hard candies, roll-type, mini-size in dispenser packages	5 g
Hard candies, others	15 g
All other candies	40 g
Confectioner's sugar	30 g
Honey, jams, jellies, fruit butter, molasses	1 tbsp
Marshmallows	30 g
Sugar	4 g
Sugar substitutes	An amount equivalent to one reference amount for sugar in sweetness
Syrups	30 mL for syrups used primarily as an ingredient (e.g., light or dark corn syrup); 60 mL for all others
Vegetables:	
Vegetables primarily used for garnish or flavor, e.g., pimento, parsley	4 g
Chili pepper, green onion	30 g

All other vegetables without sauce: fresh, canned, or frozen	85 g for fresh or frozen; 95 g for vacuum packed; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash
All other vegetables with sauce: fresh, canned, or frozen	110 g
Vegetable juice	240 mL
Olives [11]	15 g
Pickles, all types [11]	30 g
Pickle relishes	15 g
Vegetable pastes, e.g., tomato paste	30 g
Vegetable sauces or purees, e.g, tomato sauce, tomato puree	60 g

Sources and Additional Information

Much of the information in this policy was taken from the following sources:

- The Food Recall Manual, an AFDO publication.
- FDA's Recall Procedures, Chapter 7 of the Regulatory Procedures Manual.
- 21 CFR 7.40-7.59.

Additional information on product recalls, including sample letters, sample press releases, and model instructions for firms to follow can also be found in these documents as well as FOM Procedure II-07 Recall Audit Checks. FDA's Regional Recall Coordinator should serve as a good source of information as well.

Procedure II-07: Recall Audit Check

This document describes the procedure for conducting recall audit checks and traceforward investigations as a part of the Recall Policy adopted by the VDACS Office of Dairy & Foods. This is a general procedure which details the actions taken by the RRT and the Food Safety Program once a recall has been initiated. The factors leading up to the issuance of a recall and the classification of individual recalls can be found in Procedure II-06 Recall Procedure.

Cooperation with other agencies

The VDACS Food Safety Program will cooperate with federal partners (USDA and FDA) in strategy development and implementation of recall audit checks. Once downstream recipients of implicated product have been identified, meetings between VDACS and/or federal/state partners will determine the number of firms visited by field staff and deployment of state and federal resources. If the audit checks show that the recalling firm has been successful at removing the implicated product from commerce, the VDACS Food Safety Program, in conjunction with the appropriate federal partner(s) will determine when audit checks may cease. If visits to identified firms show that the recall has not been effective, leading to additional downstream distribution of adulterated product, the VDACS Food Safety Program will consult with the appropriate federal partner(s) to determine the extent to which the audit checks should be expanded and the proportion of identified firms that should be visited by field staff.

The VDACS RRT Coordinator or designee will contact the FDA Regional Recall Coordinator within the Baltimore District FDA office whenever VDACS personnel will be conducting audit checks for recalled products. Whenever possible, a detailed list of the firms visited by VDACS staff will be provided to the FDA Regional Recall Coordinator for situational awareness and federal work planning. The FDA Regional Recall Coordinator will alert the RRT Coordinator or designee whenever retail distribution information becomes available. Information may include instructions for state personnel and a list of firms visited by FDA.

VDACS Food Safety Specialists will upload the completed FDA 3177 Recall Audit Form to the LAN and make their Regional Manager and the RRT Coordinator or designee aware it is available. The RRT Coordinator or designee will determine if the distributing firm's recall was effective. If products were distributed downstream, the RRT Coordinator or designee will contact appropriate Food Safety Specialists to conduct more audit checks. Once all VDACS audit checks are completed, the RRT Coordinator or designee will forward the completed FDA 3177 Recall Audit Check Forms to the FDA Regional Recall Coordinator.

For products regulated by USDA under recall, the state program will not take any action unless specifically contacted by USDA representation on the Core Group of the RRT. If for any reason the state plans to conduct audit checks on these types of products, USDA membership on the Core Group of the RRT will be notified.

Recall Audit Checks

Once the firms to be visited by staff from the VDACS Food Safety Program have been identified, Food Safety Specialists will be notified of their recall assignments by the RRT Coordinator or designee. The Coordinator will provide the Food Safety Specialist and his/her regional manager with the list of firms to visit, their address, contact information, and any appropriate supporting documentation pertaining to the recall. Field staff should respond to the requested audit checks within 24 hours of initial notification. If this turnaround time cannot be met, the inspector should notify their Regional Manager and the RRT Coordinator so that alternate staff can be identified to carry out the requested assignment.

When conducting a recall audit check, Food Safety Specialists should document all activities on the FDA 3177 Recall Audit Form. This form will be provided by the RRT Coordinator or designee and when possible will be pre-populated with known information about the recall and the involved firms.

When conducting a recall audit check at an identified facility, VDACS Food Safety Specialists should adhere to the following protocols:

A. Fill out appropriate fields within the FDA 3177 form (example attached) prior to visit.
    1. Field 1a: Recall Number- this information will be provided to field staff by the RRT coordinator or designee. The recall number may also be included in the original recall notice. Note: Field may be pre-populated by RRT staff
    2. Field 1b: Recalling Firm- Name of the firm that initiated the recall, provided to field staff by RRT Coordinator or designee or found in the recall notice. Note: Field may be pre-populated by RRT staff
    3. Field 1c: Recalled codes- The lot coding or other identifying features of the specific recalled products. This will be provided by the RRT coordinator or designee or found in the recall notice. Note: Field may be pre-populated by RRT staff
    4. Field 1d: Recalled product(s) - A description of the specific products involved in the recall. This will be provided by the RRT coordinator or designee or found in the recall notice. Note: Field may be pre-populated by RRT staff

**Whenever possible the RRT Coordinator or designee will complete these fields before sending the recall assignment to the Food Safety Specialist.

B. Notify firm management of the reason for the visit and conduct an opening interview. If the firm management indicates that they did/do not carry the recalled product and the audit check is not necessary, note that in Field 10 remarks. Conduct a visual examination of the sales and storage areas within the firm and if none of the recalled product is found, end the visit. If the firm was affected by the recall proceed with the visit and interview.
    1. Field 3a: Direct- The term direct applies to facilities or consignees specifically identified by the original recalling firm. This can include retail stores, distribution centers, warehouses, or processors. Note: Field may be pre-populated by RRT staff
    2. Field 3b: Sub-account (secondary)- Sub-accounts are firms identified as downstream recipients of recalled product by previous visits to direct accounts. For example the direct account was a

distribution center and the sub-account is a specific retail store of that firm. Whenever a sub-account field is being utilized, field 3a should be completed with all information for the direct account. Note: Field may be pre-populated by RRT staff

3. Field 4: Check the mode used to contact the firm (for Food Safety Specialists this will usually be a visit).
4. Field 4a: Name of Person Contacted and Title- Personal information for the firm representative aiding the inspector during the audit check.
5. Field 4b: Type Consignee- Check the box that best describes the business model of the firm visited.
6. Field 4c: Product Handling- Did the audit check firm handle the recalled product in any way

C. Determine if the audit check firm was aware of the recall.
   1. Field 5a: Recall notice received- Did the audit check firm receive any official notification regarding the recall from the initiating firm or any other upstream distributors. Official notification can also come from the parent company or corporate office of the firm being visited. If the answer to this question is no proceed directly to field 6c, if the firm was informed of the recall describe that process in the remarks section (Field 10).
   2. Field 5b: Notifying firm- Check the box that best describes the firm which notified the audit check facility of the recall
   3. Field 5c: Date Notified- The date the audit check firm received notification of the recall
   4. Field 5d: Type of Notification- How was the audit check firm notified of the recall

D. If the audit check firm was notified of the recall verify their actions.
   1. Field 6a: Check appropriate response to show if audit check firm followed recall instructions (dispose, hold, return for credit, etc.). If the answer is “no” note in Field 10 (Remarks) the firm’s actions upon contact with the Food Safety Specialist. This field is only completed if the audit check firm received official notification of the recall.

E. Determine or confirm the amount of recalled product received.
   1. Whenever possible, field staff will be provided with information on the amount of product distributed to a firm before the visit. This information should be reconciled with receiving documents at the firm. Example:
      a. Recalling firm identifies that 25 cases of affected product were sent to the audit check facility.
      b. Receiving records at the audit check facility show that 25 cases of recalled product were received over a two week period.
      c. Records from the two firms agree on amount of recalled product involved.
   2. If specific information on the amount of recalled product distributed to an audit check firm is not available field staff will have to rely exclusively on employee/management interviews and review of receiving documentation.

F. Make copies of all appropriate receiving documentation related to the recalled product (bills of lading, inventory sheets, stock records, etc.).
   1. Ensure that all copies are legible.

2. When appropriate, ask firm management or employees to explain documentation policies.
3. Ask firm management or employees to verify the meaning and content of any hand written comments.

G. Once the amount of recalled product received at the audit check firm has been determined or confirmed, proceed with the investigation.
   1. Field 6b: Amount of recalled product on hand at time of notification- Record the amount of affected product in the audit check firm at the time of recall notification. This field is only filled in if the firm was officially notified of the recall.
      a. The amount of recalled product on hand in the firm at the time of recall notification should be reconciled against the previously noted amount of recalled product received. The difference between the two numbers should be noted.
   2. Field 6c: Status of recalled items- Check the box that best reflects the actions, involving the recalled product, taken by the audit check firm. If the product is being held or is still offered for sale, confirm that the firm follows proper protocols established for the recalled commodity.
   3. Field 6d: Date and Method of Disposition - If the audit check firm discarded or disposed the recalled products record the date those actions occurred and the methods used (crushed in dumpster, denatured with bleach, etc.).

H. If the amount of recalled product on-hand or the amount destroyed/returned does not match the amount received attempt to determine the location and fate of the unaccounted for items.
   1. If the product was sold exclusively through retail sales directly to consumers check no in Field 7: Sub-Recall Needed and proceed directly to Field 8: Amount of product on hand currently- Record the amount of product in the facility at the time of the visit. This number may or may not match the amount of recalled product on hand at the time of recall notification (Field 6b).
      a. If only retail sales are noted, determine if the firm has a means of identifying the customers who purchased/received recalled items (receipts, credit card records, preferred shopper/discount cards, etc.). If this information is available contact the RRT Coordinator. The Coordinator will work with firm management to determine the best way to contact affected consumers.
   2. If the audit check firm sold the affected product to an additional facility/facilities (wholesale) and further downstream distribution is suspected check yes in Field 7: Sub-Recall Needed and record information on the potential downstream distribution in Field 10: Remarks. Include any known information on potential recipients including name, address, telephone number, and amount of recalled product distributed to that location. If needed, capture this information on a separate form (word document) and attach it to the 3177. The determination of whether a secondary recall is warranted or necessary will be made in cooperation with all applicable federal partners and the original recalling firm.
      a. If possible obtain copies of shipping records or other documentation showing the downstream distribution of recalled product.
         1) Ensure all copies are legible
         2) When appropriate, ask firm management or employees to explain documentation policies

3) Ask firm management or employees to verify the meaning and content of any hand written comments

I. Ask the firm if they have received any reports of illness/injury or complaints associated with the recalled product. Record all appropriate information in Field 9: Injuries/Complaints.
J. Collect any additional information or comments from firm management and employees and record in Field 10: Remarks
K. When the audit check is completed, the form should be uploaded to the LAN and your Regional Manager and the RRT Coordinator should be notified that it is available. Make sure to include copies of any receiving or shipping documents collected at the firm.

Note: Fields 3b and 3c are utilized when conducting audit checks at additional downstream recipients of recalled product. When conducting these types of visits all information is recorded as described above except the answers provided reflect information collected at the secondary or tertiary facility. In these instances Field 3a will contain the name, address, and contact information of the upstream provider of recalled product to the secondary or tertiary firm(s).

Termination of Recall

When it is determined by the joint federal/state team that all reasonable efforts have been made to remove or correct the affected product in accordance with the recall strategy, and when it is reasonable to assume that the product under recall has been removed and proper disposition and/or correction has been made, the investigation will be terminated.

All documents related to the recall will be stored on the LAN; the RRT Coordinator is responsible for maintaining all records related to recalls.

After-action Report

After the termination of the recall, the RRT Coordinator may prepare an After-action Report (AAR) to evaluate the effectiveness of the policies, procedures, and operations employed during the conduct of the recall.

Form FDA 3177

INVESTIGATIONS OPERATIONS MANUAL 2014 **EXHIBIT 7-2**

1. RECALL INFORMATION

a. RES/RECALL NUMBER(S)	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)

2. PROGRAM DATA

a. HOME DISTRICT	b. FEI NUMBER OF RECALLING FIRM

c. PAC CODE	d. HOURS

3. AUDIT ACCOUNTS

a. DIRECT	b. SUB-ACCOUNT (SECONDARY)
PHONE NO.:	PHONE NO.:

c. SUB-ACCOUNT (TERTIARY)	PHONE NO.

4. CONSIGNEE DATA

Contacted by: ☐ Phone ☐ Visit ☐ Other

a. NAME OF PERSON CONTACTED & TITLE

b. TYPE CONSIGNEE

☐ Distributor ☐ Consumer ☐ Pharmacy
☐ Retailer ☐ Physician ☐ Restaurant
☐ Processor ☐ Hospital ☐ School
☐ Other: _____

c. DOES (DID) THE CONSIGNEE HANDLE RECALLED PRODUCT?

☐ Yes ☐ No

5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED? *(If "No", skip to item 6c.)*

☐ Yes ☐ No ☐ Cannot be determined

(If answer is other than "No", explain in remarks.)

b. RECALL NOTIFICATION RECEIVED FROM

☐ Recalling Firm ☐ Other *(Specify below)*
☐ Direct Account
☐ Sub-Account

c. DATE NOTIFIED *(mm/dd/yyyy)*

d. TYPE OF NOTICE RECEIVED *(e.g., letter, phone)*

6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? *(If "No", discuss in "Remarks" action taken upon FDA contact.)* ☐ Yes ☐ No

b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION

c. CURRENT STATUS OF RECALLED ITEMS

☐ Returned ☐ None on Hand
☐ Corrected ☐ Was Still Held for Sale/Use*
☐ Destroyed ☐ Held for Return/Correction*

* = Ensure Proper Quarantine/Action

d. DATE AND METHOD OF DISPOSITION

7. SUB-RECALL NEEDED? *Did consignee distribute to any other accounts? (If "Yes", collect information and/or provide details in "Remarks" or Memo.)* ☐ Yes ☐ No

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND

9. INJURIES/COMPLAINTS

a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS?

☐ Injury ☐ Complaint
☐ Illness ☐ None

If answer is other than "None", report details in a separate memo to monitoring district and copy to OEO (HFA-615).

10. REMARKS *(Include action taken if product was still available for sale or use.)*

CHECK		ENDORSEMENT	
INVESTIGATOR		SCSO OR R&E COORDINATOR	☐ Effective ☐ Does Not Carry Product
Signature		Signature	☐ Ineffective (indicate level) ☐ Out of Business
Printed Name		Printed Name	☐ Recalling Firm ☐ Consignee
Date of Check *(mm/dd/yyyy)*	District	Date of Endorsement *(mm/dd/yyyy)*	☐ Other *(Specify)*: _____

FORM FDA 3177 (2/10) **RECALL AUDIT CHECK REPORT**

Procedure II-08: Traceback/Traceforward Investigation

A traceback/traceforward investigation is an intensive evaluation of food(s) to:

- Identify the source(s) and distribution of food(s) suspected of being adulterated, misbranded, or linked with human illness;
- Gather information to help ensure prompt removal of contaminated product from the market place; and
- Determine how the product became contaminated by evaluating involved retailers, wholesalers, distributors, processors, and growers.

VDACS traces food implicated in any chemical, physical, biological hazard.

TYPES OF TRACEBACK/TRACEFORWARD INVESTIGATIONS

There are two types of traceback/traceforward investigations;

1. **Regulatory**: Products proven to be adulterated, misbranded, or associated with human illness. Regulatory tracebacks are formal processes in which all information collected is confirmed through records review and the collection of supporting documentation. Regulatory tracebacks are directed by the Rapid Response Team (RRT) or designee, but the actual collection of data and physical evidence is the responsibility of Food Safety Specialists.
2. **Epidemiologic/Investigational**: Compare the distribution of particular illnesses with the distribution of a specific food product. Epidemiologic/investigational tracebacks are informal processes conducted by the Virginia RRT or designee. Resources utilized for the traceback may include epidemiologic data from the Virginia Department of Health. These tracebacks rarely involve field staff. A traceback that begins for epidemiologic reasons may develop into a regulatory investigation as evidence is obtained.

DEFINITION OF TERMS

1. Point-of-service (POS): A location where implicated or suspect foods were sold or served to affected individuals.
2. Routine Inspection: An unannounced inspection of a food establishment by regulatory officials to determine the level of compliance with established regulatory standards.
3. Environmental Assessment: A detailed review conducted by a Food Safety Specialist and/or response team investigators of food handling practices in a facility. Investigators use epidemiologic or laboratory evidence to focus on the preparation or handling of implicated or suspected foods. The investigation seeks to identify contributing factors related to the contamination.
4. Recall Effectiveness Checks: Where, in the event of a recall, the firm verifies that the recall notification was successful (See Procedures II-06 and II-07).

5. Recall Audit Checks: Follow up visits (in person or via phone) conducted by the Food Safety Program to verify that the firm's recall was successful in notifying all consignees about the recall and that all consignees have taken appropriate actions (See Procedures II-06 and II-07).

AUTHORIZATION

A regulatory traceback investigation of a product is authorized when:

1. Epidemiologic or laboratory evidence implicates a food product, and
2. The environmental assessment of the POS rules out on-site contamination of the food product and indicates that the causative agent was likely brought into the facility by purchase of a contaminated food item. Investigators ruled out :
   a. Cross contamination
   b. Illness of food workers
   c. Other sources of the agent within that facility

A regulatory traceback investigation is typically resource intensive and is initiated after review of the following:

1. Epidemiologic, laboratory and environmental evidence
2. Reliable exposure information (date and place)
3. Disease severity
4. Risk of ongoing exposure
5. Availability of shipping records, and
6. Availability of resources for conducting traceback investigations

Traceback investigations of sporadic cases are not routinely conducted due to the level of uncertainty regarding the source of the infection.

COORDINATION

The Food Safety Program within the Virginia Department of Agriculture and Consumer Services (VDACS) coordinates traceback investigations involving products with distribution only in Virginia.

The VDACS Food Safety Program Supervisor and/or the Rapid Response Team Coordinator or their designee is responsible for communicating with the appropriate federal agencies when traceback investigations lead to facilities outside of the Commonwealth. Federal regulatory agencies typically review epidemiologic and laboratory evidence before initiating a multi-state traceback investigation or regulatory response. Regional managers are responsible for ensuring timely submission of documentation prepared by VDACS Food Specialist staff to the main office.

SIGNIFICANCE OF LABELING AND PACKAGING REQUIREMENTS

For USDA regulated products, a code is printed on the product label. If this code is available, the product can usually be traced to the manufacturer and a recall can be initiated.

For FDA regulated products that are packaged, the name of a distributor or manufacturer should appear on the label; the product can usually be traced to the manufacturer and a recall can be initiated.

During investigations of incidents associated with unpackaged foods (example: fresh fruits and vegetables), packaging and labeling are rarely available. A traceback investigation is often the only way to determine the potential sources of the product. The methods described in the most current version of the FDA "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations" should be used.

Comminuted meat products are often reground and repackaged by retailers. Procedures used for traceback investigations of these products will be developed on a case-by-case basis as directed by the VDACS Food Safety Program Supervisor and/or The Rapid Response Coordinator, in conjunction with the RRT Core Group members from the VDACS Office of Meat and Poultry Services based on:

1. Information available from consumers (purchase dates, dates of illness onset, labeling),
2. Purchasing and processing records maintained by the involved establishment(s), and
3. Other epidemiologic information

PROCEDURES FOR CONDUCTING REGULATORY TRACEBACK INVESTIGATIONS

I. Point of Sale and Distribution Facilities

A. Prior to initiating a traceback investigation (procedures for RRT Coordinator or designee)
   1. Verify that a traceback investigation is needed .
   2. Identify the Food Safety Specialist and Regional Manager responsible for the firm(s) to be included in the traceback investigation.
   3. Assign the traceback investigation to the correct Food Safety Specialist and Regional Manager. Staff may be notified by phone of the traceback assignment but in all cases a confirmatory email will be sent to all personnel involved in the investigation to insure full understanding of the event.
   4. Determine the investigation priority/priorities and communicate to field staff.
   5. Identify the time period of interest for which to collect purchase/shipping records and communicate to field staff.
   6. Provide staff with a traceback checklist (Appendix A) to be completed as part of the investigation.

B. Response to notification of traceback assignment
   1. If notified of the traceback assignment via email, the Food Safety Specialist and Regional Manager should respond to the RRT Coordinator of designee as soon as possible to acknowledge receipt of the assignment and to identify a timeframe for response initiation.
   2. In all cases receipt of the assignment must be confirmed within 24 hours. If confirmation is not received within 24 hours the RRT Coordinator or designee will reassign the traceback to other staff.
   3. Unless otherwise directed, traceback investigations must begin no later than 48 hours after receiving the assignment. If this timeframe cannot be met the Food Safety Specialist should notify

the RRT Coordinator or designee and the appropriate Regional Manager. The Regional Manager should in-turn reassign the traceback to other staff.

C. Visit the facility (procedures for Food Safety Specialists)
   1. Do not conduct traceback investigations over the phone. Site visits are required unless otherwise authorized.
   2. Food Safety Specialists visiting implicated firms must:
      a) Explain the purpose of the visit to firm management.
      b) Determine if the firm manufactures, processes, or re-packages the product in any way. If manufacturing or processing of the product occurs at the firm conduct a manufacturer traceback visit (procedure described below in Section II Manufacturing/Processing Facility.). If no manufacturing or processing occurs at the facility proceed with investigation as described in this section (Section I).
      c) Collect records of all suppliers and shipments of implicated product(s) received by the firm for the time period of interest. Whenever possible obtain copies or photographs of invoices, product labeling, and other documents.
      d) Determine and document what the dates on each record mean and how they relate to receipt dates (example: production, order, billing, shipment, delivery).
      e) If additional downstream distribution is noted collect information on all shipments of implicated product for the time period of interest including amount of product shipped and all appropriate recipient information (name, address, telephone number). This data will be useful in outbreak investigations and may be critical if a recall is initiated.
      f) If only retail sale of implicated products is noted, attempt to obtain data on those transactions (credit card records, frequent shopper/discount cards, etc).
      g) Make sure all forms, copies of invoices and photographs, and other documentation are legible and complete before leaving the firm. Confirm the meaning and content of any handwritten comments.
      h) Samples may be required – Assure that all samples are taken correctly including use of Chain of Custody, that all forms are complete, and samples are properly sealed and identified.
      i) Record all findings on the Traceback checklist (provided by RRT Coordinator or designee)
      j) Report findings to Regional Manager and Food Safety Rapid Response Team Coordinator.

D. The Rapid Response Coordinator will report findings to the appropriate Federal and State partners via phone call, email, and/or fax. The Rapid Response Team Coordinator is also responsible for maintaining all records associated with the investigation.

II. Manufacturing/Processing Facility (All timeframes for response noted in Section I are applicable to Section II of this procedure)

A. Prior to initiating a traceback investigation (procedures for RRT Coordinator or designee)

1. When visits to all recipients of an implicated product, both upstream and downstream, fail to identify the likely cause/source of contamination, the traceback investigation must then progress to the original manufacturer of the identified food(s).
2. Evaluate any data collected during distributor/retailer visit(s) and other information to determine the next appropriate steps in the traceback investigation.
3. Obtain the geographical location and contact information for any manufacturer indentified during the distributor visit(s). If the manufacturer is located outside of Virginia:
   a) Communicate with representatives from the appropriate federal agency (USDA or FDA) to determine the next steps in the investigation.
   b) When asked, assist the federal agency in contacting manufacturing firms and in the collection of evidence to support the traceback investigation.
4. When the manufacturing firm is located within the Commonwealth of Virginia:
   a) Notify the appropriate field staff and regional management of the need to conduct a visit.
   b) Provide the responding Food Safety Specialist with all pertinent data and documentation collected during the POS and distributor visit(s).

B. Visit the manufacturing facility (procedures for Food Safety Specialists)
   1. Explain the purpose of the visit to firm management.
   2. Collect records covering all of the raw and prepared ingredients used to manufacture the implicated product. Confirm the shipper, receipt information, and lot coding for all raw and prepared ingredients received by the manufacturer which could have been utilized in the preparation of the implicated product during the timeframe of interest.
   3. Determine and document what the dates on each record mean and how they relate to receipt dates (example: production, order, billing, shipment, delivery).
   4. Collect distribution information on all shipments of implicated product for the time period of interest including amount of product shipped and all appropriate recipient information (name, address, telephone number). This data will be useful in outbreak investigation and may be critical if a recall is initiated.
   5. If retail sale of implicated products is noted, attempt to obtain data on those transactions (credit card records, frequent shopper/discount cards, etc).
   6. Organize data collected at the manufacturer so that it can be easily reviewed and analyzed.
   7. Make sure all forms, copies of invoices, photographs, and other documentation are legible and complete before leaving the firm. Confirm the meaning and content of any handwritten comments.
   8. Samples of finished product or ingredients may be required – Assure that all samples are taken correctly using Chain of Custody and all forms are complete and samples are properly labeled.
   9. Record all findings on the Traceback checklist (provided by RRT Coordinator or designee)
   10. Report findings to Regional Manager and RRT Coordinator.

C. The Rapid Response Coordinator will report findings to appropriate Federal and State partners via phone calls, email and/or fax. The Rapid Response Team Coordinator is also responsible for maintaining all records associated with the investigation.

III. Raw Ingredient Supplier (All timeframes for response noted in Section I are applicable to Section III of this procedure).

A. Raw Ingredient Supplier Level Tasks (procedures for RRT Coordinator or Designee)
   1. When visits to the manufacturing facility/facilities involved in the preparation/processing of an implicated product fail to identify the likely cause/source of contamination, the traceback investigation must proceed to additional upstream sources of the implicated product (raw ingredients).
   2. Evaluate data collected during the point of sale, distribution, and/or manufacturer tracebacks and other information to determine the next appropriate steps in the traceback investigation.
   3. Obtain the geographical location and contact information for the raw ingredient provider identified during the manufacturer visit.
   4. Since VDACS has no regulatory authority over agricultural commodities and other raw/unprocessed ingredients, investigations leading to this level of the food production chain will be handed over to the appropriate federal organization (USDA or FDA). VDACS personnel will only participate in these investigations under the direct invitation of participating federal partners. The Rapid Response Team Coordinator will be responsible for maintaining all records (if there are any) associated with the investigation.

Appendix A

VDACS Office of Dairy and Foods Traceback Checklist Section A			
Facility Name			
Date of Inspection/Investigation			
Contact information (address, phone number)			
Point of Contact During Inspection/Investigation (Name, Title, Contact Info)			
Product(s) under review			
Product Identifiers (Description, lot code, expiration date, production date)			
Timeframe of Interest			
Reason for Traceback (bacteriological, foreign object, etc.)			
Does the facility manufacture and/or further process the product? **(If no, fill out only Section A. If yes proceed to and only fill out Section B)**		**Yes**	**No**
Collect invoices for receipt of implicated product, during the timeframe of interest. (Includes all receiving information for product during that time regardless of supplier) A**ttach copies**			
Did the firm engage in retail sales of implicated product (directly to consumers)?		**Yes**	**No**
Collect retail sales information if available for the time period of interest (credit card receipts, shopper card info) A**ttach copies**			
Did the firm further distribute the implicated product?		**Yes**	**No**
Collect distribution/shipping information for the time period of interest A**ttach copies**			
Were all copies clear and legible? **(If no obtain new copies or clarify any illegible data)**		**Yes**	**No**
Ask firm to explain any coding systems or other unique identifiers on the collected invoices. A**ttach descriptions**			
Were any handwritten comments on invoices clear and legible? **(If no obtain new copies or clarify any illegible data)**		**Yes**	**No**
Ask firm to explain the meaning and content of any handwritten comments included on invoices. **Attach descriptions**			

VDACS Office of Dairy and Foods Traceback Checklist Section B		
Were invoices for ingredients used to manufacture the product, during the timeframe of interest, available (Includes all receiving information for ingredients during that time regardless of supplier)? **If yes attach copies**	**Yes**	**No**
Did the firm engage in retail sales of implicated product (directly to consumers)?	**Yes**	**No**
Collect retail sales information if available for the time period of interest (credit card receipts, shopper card info) A**ttach copies**		
Did the firm further distribute the implicated product?	**Yes**	**No**
Collect distribution/shipping information for the time period of interest A**ttach copies**		
Were all copies clear and legible? **(If no obtain new copies or clarify any illegible data)**	**Yes**	**No**
Ask firm to explain any coding systems or other unique identifiers on the collected invoices. A**ttach descriptions**		
Were any handwritten comment on invoices clear and legible? **(If no obtain new copies or clarify any illegible data)**	**Yes**	**No**
Ask firm to explain the meaning and content of any handwritten comments included on invoices. **Attach descriptions**		

Procedure II-09: RRT Communications Plan

Document #: FOM II-09	Effective Date: 12/30/2011
Title: Virginia Rapid Response Team Communications SOP	

Table of Contents

1. Purpose
2. Scope
3. Circulation
4. Responsibility
5. Related Documents
6. Contacts
7. Definitions
8. Safety
9. Equipment/Materials Needed
10. Process Description
    - 10.1 Communication Methods
    - 10.2 ICS Utilization
11. Attachments/Worksheets
12. Approval/Document History

1. PURPOSE

This document describes the process for communications within the Virginia Rapid Response Team from routine daily activities through complete activation in response to a food and/or feed emergency. The document also describes the process (triggers) for team activation.

2. SCOPE

This policy applies to Members of the Virginia Rapid Response Team Core Group, the Virginia Department of Agriculture and Consumer Services (VDACS) Office of Food Safety & Security, and all associate members of the Rapid Response Team.

3. CIRCULATION

This policy will be distributed to the members of the Virginia Rapid Response Team Organization including all associate members.

4. RESPONSIBILITY

RRT Core Group Members–RRT Core Group Members are responsible for the maintenance and implementation of this plan during both routine and response scenarios. The Core Group shall activate the Rapid Response Team in situations where food(s), feed(s) or an establishment(s) that sells, distributes, or manufactures those products has been indicated as a threat to public health that extends beyond the ability of the core group to mitigate and address or when other circumstances indicate that activation is necessary. Activation of the Rapid Response Team will be based upon a joint determination of the Core Group and will only occur when a majority of those individuals indicate that team activation is necessary. The RRT Core Group consists of:

- VDACS RRT Coordinator
- VDACS Food Safety & Security Program Supervisor
- VDACS Office of Dairy and Foods Program Manager

-VDACS Animal Feed representative
-VDACS OMPS representative
-VDH Foodborne Disease Epidemiologist
-VDH Office of Environmental Health representative
-VDH Shellfish Sanitation representation
-DCLS lead representative
-Director of the Baltimore District FDA Office
-Deputy Director of the Baltimore District FDA Office
-Direct of the Investigations Branch within the FDA Baltimore District office
-Baltimore District Office Emergency Response Coordinator
- FDA Regional Retail Foods Specialist

Each of these individuals has a designated backup that may take their place in determining when and how the RRT should be activated in response to a food/feed incident.

5. RELATED DOCUMENTS
TBD

6. CONTACTS
See RRT CORE Team contact directory

EMERGENCY RESPONSE INTERNAL CALL LIST

Please see attached document titled "Master Copy Office Phone List" that is updated multiple times per year by the ODF administrative support staff.

EXTERNAL STATE AGENCY CONTACTS

Division of Consolidated Laboratory Services – (DCLS)
600 North 5th Street
Richmond, Virginia 23219

24 Hour Emergency Pager 804-418-9923
If after 15 minutes there is no response to the page dial 1-800-283-8252. An operator will take information, contact DCLS employee and have that employee call you back.

Roles and Responsibilities:

- Provides generalized support to Food Safety Program sample analysis activities
- Provides comprehensive analysis of food, water and dietary supplement product samples when requested
- Provides rapid turnaround/analysis of food product samples when necessary
- Provides interpretive input regarding reported sample analysis when requested
- Ensures appropriate feedback and communication to Food Safety Program managers and staff

- Ensures appropriate communication and dissemination of necessary information to all stakeholder agencies and programs relative to a food related incident
- Responds to food related emergency concerns when and where necessary

Virginia Department of Emergency Management – (VDEM)
10501 Trade Court
Richmond, VA 23236

24 Hour Line 804-674-2423 (VDEM Staff)
Emergency Operations Center 804-674-2400

Roles & Responsibilities:

- Coordinates the state's emergency preparedness, mitigation, response and recovery efforts
- Declares State of Emergency
- Controls/Regulates Resources
- Directs Mandatory Evacuation
- Commits State Resources
- Expends "Sum Sufficient" Monies
- Suspends Normal Procurement Procedures
- Requests Federal Assistance
- All Actions Necessary for Protection of the Public
- Pre-Delegation of Authority

Virginia Department of Environmental Quality – (DEQ)
(Local Emergency Planning Committee – LEPC)

City of Richmond LEPC
Capt. Alan Brooke
LEPC Contact/HazMat Coordinator
Richmond Fire & Emergency Services
550 E. Marshall Street
Richmond, VA 23219
804-646-6660

Roles & Responsibilities:

- Coordinates the state's emergency preparedness, mitigation, response and recovery efforts
- Declares State of Emergency
- Controls/Regulations Resources
- Directs Mandatory Evacuation
- Commits State Resources
- Expends "Sum Sufficient" Monies
- Suspends Normal Procurement Procedures
- Requests Federal Assistance
- All Actions Necessary for Protection of the Public

- Pre-Delegation of Authority

Virginia Department of Health – (VDH)
Office of Environmental Health Services
109 Governor Street, 5th Floor
Richmond, VA 23219

Roles & Responsibilities:

- Monitors and inspects food service operations and food events
- Investigates food-borne illness and infectious disease outbreaks

Office of Commonwealth Preparedness
(State Homeland Security Contact)

Office of Commonweath Preparedness
Robert P. Crouch, Jr.
Assistant to the Governor for Commonwealth Preparedness
Contact: Constance McGeorge
Patrick Henry Building
1111 East Broad Street
Richmond, VA 23219
804-692-2595

Roles and Responsibilities:

- Advises the governor on appropriate courses of action to take during terrorist activity or during natural disasters

Virginia State Police – (VSP)
Administrative Headquarters
Bureau of Field Operations
P.O. Box 27472
Richmond, VA 23261
804-674-2088 (Office)

24 Hour Line 804-674-2026 (Duty Sergeant On-Call)
24 Hour Police Terrorism Hotline 1-866-488-8554

Roles & Responsibilities:

- Initial first responders to emergencies
- Collects evidence relative to a criminal investigation of food related emergencies

Virginia Department of Fire Programs – (VDFP)
James Monroe Building

101 N. 14th Street, 18th Floor
Richmond, Virginia 23219
Office 804-371-0220
Cell 804-221-2446
8009184568@my2way.com

Roles & Responsibilities:

- Provides financial assistance to communities and other organizations
- Provides operational support to communities in need during emergencies of all types
- Collects and analyzes data
- Provides technical assistance

FEDERAL GOVERNMENT CONTACT LIST

Center for Disease Control and Prevention – (CDC)
1600 Clifton Road
Atlanta, GA 30333
800-CDC-INFO
www.CDC.Gov

Emergency Response Hotline (24 hours) 770-488-7100 (for state & medical personnel)
Emergency Response Hotline (24 hours) 1-800-232-4636 (general public)

- Provides emergency information from subject matter experts in bioterrorism, chemical, emergencies, and natural disasters.

Roles and Responsibilities:

- Promotes health and quality of life by preventing and controlling disease, injury, and disability
- Provides clinical, epidemiological, and public health expertise
- Issues health alerts to government departments in order to increase surveillance on new or unfamiliar illnesses
- Assists food safety officials in addressing food-borne disease emergencies
- Develops public health policies

Department of Homeland Security – (DHS)
Washington, D.C. 20528
202-282-8000

State Homeland Security Contact:
Robert P. Crouch, Jr.
Assistant to the Governor for Commonwealth Preparedness
Patrick Henry Building
1111 East Broad Street
Richmond, VA 23219

804-692-2595

Roles and Responsibilities:

- Prevents and deters terrorist attacks
- Protects against and respond to threats and hazards to the nation
- Ensures the safety and security of borders (BTS)
- Coordinates federal disaster response
- Provides training for all hazards to effectively reduce loss of life and property

Federal Bureau of Investigation – (FBI)

FBI Richmond Office
1970 E. Parham Road
Richmond, VA 23228
24 Hour Line: 804-261-1044
www.FBI.Gov

FBI Norfolk Office
150 Corporate Boulevard
Norfolk, Virginia 23502-4999
24 Hour Line: 757-455-0100
www.FBI.Gov

Roles and Responsibilities:

- Enforces existing laws through the investigation of violations of federal criminal laws
- Protects the United States from foreign intelligences and terrorist activities
- Provides leadership and law enforcement assistance to federal, state, local, and international agencies

Federal Emergency Management Agency – (FEMA)

FEMA Central Office
615 Chestnut Street
One Independence Mall, Sixth Floor
Philadelphia, PA 19106-4404
215-931-5608
www.FEMA.Gov

Emergency Hotline (24 hour) 1-215-931-5757

Roles and Responsibilities:

- Manages federal response and recovery efforts following and national incident
- Trains first responders
- Initiates proactive mitigation activities

U.S. Environmental Protection Agency – (EPA)
Office of Solid Waste and Emergency Response

1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
www.EPA.Gov

National Emergency Response Hotline (24 hour) 1-800-424-8802

Roles and Responsibilities:

- Lead Federal Agency in the response and cleanup of hazardous materials
- Provides emergency response and vulnerability assessments of drinking water and wastewater systems
- Prevents the use of hazardous pesticides

U.S. Food & Drug Administration – (FDA)

FDA Baltimore District Office
6000 Metro Drive, Suite 101
Baltimore, MD 21215
410-779-5454
Serving States: MD, DC, VA, & WV
www.FDA.Gov

FDA Richmond Branch Office
2810 North Parham Road
Richmond, VA 23294

24 Hour Emergency Hotline 301-443-1240

Roles and Responsibilities:

- Protects the public health by ensuring safety and security of human and veterinary drugs, biological products, medical devices, cosmetics and the food supply
- Works cooperatively with states & localities during routine and incident related food and drug surveillance
- Undertake investigations to identify implicated products
- Conducts investigations to identify food and drug products of concern
- Conducts recall when necessary
- Issues press information relating to suspected food and drug products of concern
- Coordinates the Food Emergency Response Network with CDC and USDA
- Initiates embargos on food and drug products when necessary

U.S. Department of Agriculture – (USDA)

USDA District 75 Office
Dr. Mohamed Ibraheim, District Manager
5601 Sunnyside Avenue
Suite 1-2288B
Beltsville, MD 20705

Phone: 301-504-2136
Fax: 301-504-2140
Serving States: Delaware, D.C., Maryland, Virginia, & W. Virginia
www.USDA.Gov

Emergency 24 Hour Hotline 1-800-289-4116

Office of Food Defense & Emergency Response (OFDER)

Dr. Carol Maczka, Assistant Administrator for Food
Defense and Emergency Response
Room: 3130 South Building
202-720-5643 (Office)
http://www.fsis.usda.gov/About_FSIS/OFDER/index.asp

USDA Operations Center 202-720-5711 or 1-877-677-2369
Emergency Information Line (updated daily) 1-800-932-1902
TTY 1-800-877-8339

Roles & Responsibilities:

- Enhances food safety by taking steps to reduce the prevalence of food-borne hazards of meat, poultry and egg products from the farm to the table
- Works cooperatively with states during routine and incident related food surveillance
- Conducts investigations to identify meat and poultry products of concern
- Requests Industry recalls when appropriate
- Issues press information relating to suspected food products of concern

RESOURCES EMERGENCY CALL LIST

**The following information is a listing of some of the firms that could possibly be utilized while recovering from an incident that involves the destruction of food products. The Food Safety & Security Program is not endorsing or recommending these firms.*

A. Fire, Wind, and Water Restoration

- BelforUSA –
  www.belforusa.com
  Phone 757-544-4169

- BelforUSA 909 Executive Ct. Chesapeake, VA 23320
  Phone 757-547-9400
  Fax 757-547-3866

- BelforUSA
  2231 Dabney Rd., Ste. 200
  Richmond, VA 23230

Phone 804-342-7444

B. Landfills/Hauling

- Shoosmith Brothers, Chester, Va. (804.748.5823)
- BFI, Richmond, Va. (804.226.6198)
- Cycle Systems for South West Virginia
  434-237-6666 or 800-500-0056
  991 Lawyers Road
  Lynchburg,VA 24506
  *Offices also in Roanoke, Stuarts Draft, and Martinsville

C. Towing

- Robert Young's Towing and Accessories
  2780 Lee Hwy
  Troutville,VA 24175
  Mr. Robert Young-Owner
  540-797-2562 (cell) 540-982-3809 (office)
  540 - 983-3855 (fax)
  Light to Extra Heavy towing in SW/Roanoke area

D. Hazardous Materials Cleanup

- W.E.L. HazMat Cleanup Group
  Mr. Doug Witt – Owner
  540-871-6417 cell
  Roanoke/Lynchburg area**.**

7. DEFINITIONS

TBD

8. SAFETY

TBD

9. EQUIPMENT/MATERIALS NEEDED

- State issued phone and computer
- State issued cellular phone and email capable device
- List of RRT Core Group members including routine and after hours contact information

10. PROCESS DESCRIPTION

10.1 Communication Methods

The Virginia Rapid Response Team will communicate primarily using telephone conversations and email messages. Face-to-face meetings and other options may be utilized as necessary when circumstances dictate that email and phone contacts are inadequate or unnecessary.

10.1.1 Normal Operations or Minor Event

During normal operations the members of the Virginia RRT Core Group will speak on a weekly scheduled call where each represented agency (VDACS, VDH-Epi, VDH-Environmental Health, DCLS, FDA District Office) will give updates on current investigations, regulatory actions, training opportunities, or other items of interest to the Core Group. After each report the other members of the Core Group will be provided time for questions or to request additional information. When information discussed on this call would be of use to other parties, not represented on the Core Group, the Coordinator will, with the permission of the rest of the Core Group, pass that information onto the involved parties via voice or email communications. This passage of information to a selected group of individuals would not constitute an activation of the Virginia Rapid Response Team. It is understood that each member of the RRT core group is responsible for passing information discussed by the group onto the appropriate individuals within their specific program or agency.

10.1.2 Informal Incident

Informal incidents involve actions that are outside the traditional scope of the weekly call of the RRT Core Group but do not initially require activation of the entire Rapid Response Team. Informal incidents may be discussed on the weekly Core Group call or may be discussed via unscheduled voice or email communications within the Core Group. If a conference call is required for discussion of the event the Core Group member wishing to initiate the call should contact the RRT Coordinator who will inform the other Core Group members and provide a time, and conference line for the event. Communications during informal incidents will follow the format used in Normal Operations where each Core Group representative will give a report on his/her agency's operations and then answer any questions from the rest of the group. When information discussed as a part of an informal incident would be of use to other parties, not represented on the Core Group, the Coordinator will, with the permission of the rest of the Core Group, pass that information onto the involved parties via voice or email communications. This passage of information to a selected group of individuals would not constitute an activation of the Virginia Rapid Response Team. It is understood that each member of the RRT core group is responsible for passing information discussed by the group onto the appropriate individuals within their specific program or agency.

10.1.3 Formal Incident

Formal Incidents are situations where food(s), feed(s) or an establishment(s) that sells, distributes, or manufactures those products has been indicated as a threat to public health that extends beyond the ability of the Core Group to mitigate and address utilizing the communication strategies described above or when other circumstances indicate that activation of the complete Rapid Response Team is necessary. During formal incident responses the Core Group will meet as often as necessary to discuss the event and determine future steps in the investigation. These meetings may occur via phone or in person and will occur simultaneously with the activation of the expanded RRT. Activation of the RRT will be based upon a joint determination of the core group and will only occur when a majority of those individuals indicate that team activation is necessary. A formal incident response may be initiated spontaneously when one or more group members determine that an event requires RRT activation and requests that the Coordinator initiate that response. Formal activation may also follow normal or informal communications in which information shared leads to a decision to initiate a full team

response. Once RRT activation has been agreed upon by the core group members the Coordinator will prepare a summary of the event that prompted the activation including all information know to that point in the investigation. This summary will be sent to all members of the Rapid Response Team via email communication and will include a specific RRT number as the subject line (example: RRT-2012-0001). All future communications about the incident regardless of their source shall use this subject line to ease information sharing and avoid confusion should multiple response activities be ongoing. The full Rapid Response Team will include the core group individuals listed above and the following:

-VDACS Dairy Program representation
-VDACS Emergency Management
-VDH Emergency Management
-Selected VDACS Staff [Food Safety Specialist(s), Field Supervisor(s)]
-Selected VDH Environmental Health Staff
-Local/Regional Epidemiologist(s)
-Local Environmental Health Staff
-Others deemed necessary by the core group

Once a formal response is initiated and the full RRT has been activated, all communications should flow through the Coordinator. It will be the responsibility of the RRT Coordinator and his staff to receive and catalog all information about the incident from the responding agencies/personnel. Additionally, the Coordinator will be responsible for providing updated, summary emails to the entire team whenever new or important information about the event, response, or recovery are received. Communications with the entire RRT will involve primarily email and electronic attachments and will not proceed to phone or conference calls unless that action is requested and agreed upon within the membership of the core group. In an actual response, communications may expand beyond just the RRT as incidents unfold and more agencies become involved in response. When that occurs the Coordinator will assume the duty of informing those new groups of the communications procedures that need to be followed and a general introduction to the RRT. The Coordinator will also be responsible for communicating any information provided by these auxiliary personnel/groups to the remainder of the RRT. Communication as described above for formal incidents will continue until the membership of the RRT Core Group determines that the event has been mitigated to a degree that full involvement of the team is no longer warranted. At that time the Coordinator will distribute an email to all personnel (RRT and auxiliary) who have been involved in the incident notifying them of the decision to step down response and return to routine or informal communications. All individuals will be asked at that time for any information or reasoning for which the full response should not be stopped. If none is provided then operations will return to normal. If a compelling reason why the response should be continued is provided the Coordinator will provide this information to the core group and seek their input into continuing expanded RRT operations. If a majority of the core group votes to continue with full RRT deployment then a notification will be sent out to the team. Activities will continue as described above until a new point is reached where deactivation of the team is warranted.

10.1.4 After Action Reporting/Hotwash

Anytime the RRT enters formal incident communications and the entire response team is activated, an event summary will be prepared and distributed to all personnel by the Coordinator. This summary will not be distributed until the event has been completely mitigated, all response efforts have ceased, and recovery is underway. The document will include a detailed recounting of the event including all data provided by RRT membership or auxiliary personnel. It will also include any known or suspected barriers to rapid and effective communication and response that were noted during the event. All personnel receiving this document will be asked to review the information and submit any comments, suggestions, or lessons learned about areas of the response where procedures could be improved or where existing

communications/response were successful. The RRT After Action SOP/Plan contains additional information about this process.

10.2 ICS Utilization

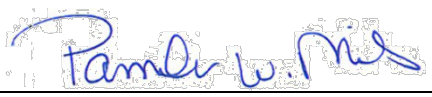
Whenever there is a full activation of the Virginia Rapid Response Team ICS procedures will be utilized to coordinate actions and manage the work done by the response team. At a minimum ICS will be utilized by staff within the VDACS Food Safety & Security Program. Trained staff members will be assigned to various positions within the ICS structure based upon their ICS experience/training, the scope of the incident, and the product(s) involved. In all instances where VDACS is the sole agency utilizing ICS principles the RRT Coordinator will be assigned as the Incident Commander. In most responses the VDACS Manufactured Foods Program Specialist will be assigned as the planning section chief and the Food Safety & Security Program, Field Incident Coordinator will be assigned as the Operations Section Chief. This basic structure may be amended as described above depending on the nature of the incident. For example, in a feed related response the RRT Animal Feed Specialist would be assigned to the role of Operations Section Chief and the Field Coordinator would be assigned to other duties. In cases where the distribution of a product extends beyond Virginia borders or when the scope of an event moves beyond the ability of VDACS response, the Food Safety & Security Program will operate in unison with personnel from the Baltimore District FDA Office (BLT-DO). In these responses a unified command consisting of the VDACS RRT Coordinator and other staff from BLT-DO will be tasked with the management and overall command of the response efforts. Other staff from VDACS or BLT-DO will be assigned to duties (Operations, Planning, Safety, etc.) as needed based upon the conditions surrounding the event and the agency designated as lead in the investigation. In a large scale response necessitating the involvement of the entire RRT a Unified Command consisting of the VDACS RRT Coordinator, the VDH Foodborne Disease Epidemiologist, and the Baltimore District Emergency Response Coordinator will be established and this group will be responsible for forming and staffing the remainder of the ICS.

11. ATTACHMENTS/WORKSHEETS

TBD

12. APPROVAL/DOCUMENT HISTORY

This document and all of the emergency contact names/numbers shall be updated annually by the RRT Coordinator or his/her designee.

Document History		
Version #	**Status (I, R)**	**Change History**
1	**I**	**Initial Policy Drafting- MRE**
2	**R**	**Revised Policy 4/30/15- EAB**
Approved By: 		**Date 4/30/15**

TITLE: **After Action Report/Improvement Plan (AAR/IP)**

CATEGORY: Incident Response

PROCEDURE NUMBER: FOM Procedure II-10

SCOPE:

Development of an **After Action Report/Improvement Plan (AAR/IP)** can apply to any agency response activity, whether to an emergency event, food or feed related incident, special investigation, or other activity, such as an exercise. The AAR/IP process will be implemented whenever there is a full activation of the Virginia Rapid Response Team (RRT). The AAR/IP serves as a method to assess response performance and suggest improvements for future responses with all involved entities.

OBJECTIVE:

This process will assess and evaluate actions taken during an event/incident/special investigation, etc., with input from all involved parties, to allow for continuous improvements to be implemented in future responses/events.

DEFINITIONS:

1. After Action Report: a report that analyzes results, identifies strengths to be maintained and built upon, identifies potential areas for further improvement and supports development of corrective actions following the response to an incident.
2. After Action Review: a no-fault process or meeting whereby everyone involved in the response/event collectively evaluates the response. Evaluation consists of identification of strengths and weaknesses of the jurisdiction's or multi-agencies' plan, protocols, and procedures and the tactics utilized to achieve the strategic goals. The evaluation is activity/action focused.
3. Improvement Plan: a formal document that lists responsible entities to be accountable for agreed upon improvements to a response process within a designated time frame.
4. Facilitator: a person uninvolved in the day-to-day management of the response, but familiar with the event

PROCEDURE:

Description:

The intention of the AAR/IP is to identify, evaluate and implement recommendations for improvement on response activities following rapid response incidents. Suggestions identified as issues with specific products, facilities or systems *and* those identified as coordination/collaboration issues are considered. Application of the vetted suggestions will improve the rapid response system and the regulatory programs as a whole.

Roles and Responsibilities:

- Administrators/Management –will participate in all After Action Reviews in relation to their involvement in the response.
- Planning Section Chief – If an event is managed using ICS, the Planning Sections Chief (PSC) will draft the *Summary of the Incident* to be included in the AAR. If the PSC position was not created for the particular response, the responsibility would default to the Incident Commander (IC). In exercises where the Incident Command Structure was not utilized an incident summary will be prepared by the personnel who designed, moderated, or served to coordinate the event or response.
- Response Facilitator – The response facilitator (hereafter referred to as "facilitator") will conduct an after action review survey and/or meeting to gather feedback from the response participants. The facilitator will develop the After Action Report, ensure its completion and distribution and report to the RRT Core Group on the status of the IP deliverables. Ideally the facilitator should be an individual with technical knowledge of food/feed safety and/or Rapid Response procedures who was not directly involved in the investigation or event. In the absence of such an individual, the IC or coordinator will assign a person to serve as facilitator.
- Participants – Anyone involved in the day to day management of the response or who participated in the exercise will participate in the *after action review meeting*. Any participant can and should contribute to the *after action review survey*. This includes inspectors, epidemiologists, subject matter experts, liaisons, public information officers, laboratorians, etc.
- Rapid Response Team Core Group – will develop the Improvement Plan utilizing the After Action Report data.

AAR Preparation:

The preparation for the AAR will be addressed at the beginning of the response whenever possible. All participants will be reminded that they will be asked to provide feedback at the

end of the response regarding significant strengths and areas for improvement for possible inclusion in an AAR. The AAR will be *completed within 45 days* of the response.

Before the After Action Review:

- Establish points of contact for each contributing agency lead and others as needed to solicit input and/or participation.
- The written Summary of the Incident/exercise begins with the first notification and finishes with the final outcome or current status of the incident/exercise. This summary, to be completed by the PSC) or IC (if no PSC is utilized), will be clear and concise and include the following:
    - Findings and/or outcome of the incident
    - Agencies participating in the response
    - Type of incident command structure used to facilitate interagency work
    - Key tasks involved and objectives
    - Possible root cause and mitigation steps
    - Timeline of events
- The timeline of events will clearly show the sequence of event/actions during the response
- Legal issues that may arise due to sensitive information concerning participating agencies being disseminated will be determined before the AAR is shared. These shall be identified by the Rapid Response Team (RRT) Core Group who will consult with participating agency leads and legal counsel when appropriate.

After Action Review:

- At the beginning of the event, the facilitator will inform participants of the method(s) that will be utilized to conduct the after action review (survey, meeting, interviews, etc.). The facilitator will encourage participants to speak freely during review meetings or write anonymously via survey or other written form of feedback.
- Participants shall record difficulties that arise and possible solutions/remedies as well as strengths and effective procedures throughout the response.
- The critique will be activity/action focused vs. people focused.
- The facilitator will collect the recorded information for use in the AAR.

Full Summary (After Action Report: AAR/IP):

- The complete and concise AAR/IP will include the incident summary, process review, timeline, communication flowchart, identified strengths and weaknesses, and improvement plan. The facilitator will distribute the report to all involved parties (i.e.

RRT Core Group, participating agency management personnel, epidemiologists, field force, etc.) If modifications of existing protocols/procedures/training are included in the improvement plan, the RRT Core Group will request a committee, comprised of policy and planning personnel from the participating agencies, be created to provide final approval and management sign off for agency commitment. In addition, a specified timeline for implementation will be requested. If release of the AAR/IP to the public is requested or required, review by legal counsel prior to the release of the is required.

- The length of an AAR/IP is based on the event and the number and types of agencies involved. For a simple incident, the AAR/IP should be no more than one to two pages and addressed recommendations and strengths should total no more than 3 each.
- The Improvement Plan (IP) will be developed by the RRT Core Group following the management/agency leader after action review meeting. Information gathered from that meeting and the participant surveys will be evaluated and considered. The IP will address policies, procedures and resources to future responses. Areas needing improvement and possible solutions to the identified problems will be included as well as strengths to ensure they are repeated during future responses. Personnel responsible for implementing the suggested recommendations for corrective action will be identified with a timeline for completion.
- The facilitator will follow-up with the designated agencies/individuals responsible for implementing the suggested improvements within the specified time frames. He/she will then report to the RRT Core Group, by the deadline specified in the IP, on the AAR/IP status and outcome regarding the recommendations.

SAFETY REQUIREMENTS:

No additional safety requirements are necessary in conducting an After Action Review or in the development of an After Action Report/Improvement Plan.

November 18, 2014 (new)

Procedure II-11: RRT Media Policy

Recalls, Consumer Advisories and other Media Alerts

PURPOSE

This document describes the process and procedure for the agency release of investigation information and reports to the public, handling of media releases and other public communication activities. It also addresses communication between the Virginia Rapid Response Team (RRT), agency Office of Communications, and the Virginia Department of Health (VDH).

RESPONSIBILITY

Office of Communications – The agency Office of Communications Director is responsible for the release of investigation information and reports to the public and/or partnering agencies during a foodborne illness outbreak, recall, or other food related issue. The Office of Communications Director will take the lead; in that person's absence, the Public Relations Specialist would coordinate the effort. Currently, the Director is Elaine Lidholm, elaine.lidholm@vdacs.virginia.gov (804.786.7686).

RRT Coordinator – The RRT Coordinator is responsible for coordinating with the Communications Office regarding the release of investigation information and reports to the public and/or partnering agencies during a foodborne illness outbreak, recall, or other food related issue.

PROCESS DESCRIPTION

Recalls and Press Releases

The agency may see the need to alert the public to an imminent health hazard or issue a voluntary recall on behalf of a firm. When an imminent health hazard that may necessitate a recall or media alert is discovered, the RRT Coordinator will then review all relevant information with the appropriate Food Safety Regional Manager, Program Supervisor and Program Manager and will then provide specifics to the Office of Communications Director. It is the responsibility of the Office of Communications Director to draft the initial press release and then send it back to the RRT Coordinator, the Food Safety Program Supervisor and Program Manager for review. Once reviewed it will again be forwarded back to the Office of Communications Director. After review the Office of Communications Director will forward to the Division and all other relevant parties for final review and approval. Once final approval is received it will then be sent by the Office of Communications to media outlets for release to the public.

Coordination with other Jurisdictions

VDACS may need to partner with other agencies to alert the public to an imminent health hazard or issue regarding a firm where jurisdiction may be shared. The following points of coordination should be followed:

- Identify the main media representative, i.e. VDACS or the Virginia Department of Health (VDH)
    - VDH: The Manager of Risk Communication will take the lead. Currently Maribeth Brewster, Maribeth.brewster@vdh.virginia.gov (804.864.7008), is serving in acting

capacity. VDH will designate at least one Public Information Officer (PIO). Currently that position is TBD, (804.864.7963). It could be a regional PIO, depending upon the situation.

- If a joint release, determine key spokesperson(s)
    - If it is determined that VDACS will not serve as the agency key spokesperson then VDACS should finish their portion of the release and have it approved before it is sent to VDH for comment.
- Determine letterhead to use (VDACS, VDH, Cabinet Secretary, Governor) for press releases or media advisories
- Share information about the specific case, to include but not limited to:
    - Date, time, location of incident
    - Who first investigated
    - Findings
    - Public health concerns, including symptoms of illness
    - Actions taken: voluntary recall, seizure of product, etc.
    - Actions to follow: epidemiology, trace-backs, trace-forwards, removal of products from channels of trade, etc. (May or may not release to the public)
- Determine key people to review and approve releases:
    - In-house:
        - VDACS - Commissioner, Deputy Commissioner, Division Director, ODF Program Manager, Food Safety Program Supervisor and the RRT Coordinator.
        - VDH - TBD
    - Jointly, if needed:
        - Cabinet Secretaries for Health and Agriculture
        - Other involved governmental agencies
        - Governor
- Determine method(s) of information distribution: news release(s), press conference, Social Media, etc.
- Determine target audiences to receive information: other federal/state/local officials, the public, schools, hospitals, etc.

FOIA Requests

Information regarding current/active investigations shall not be released to the public under the FOIA request until the investigation is complete. It is the responsibility of the Office of Communications Director to work with the Food Safety Program Supervisor and the ODF Program Manager for all FOIA requests.

RELATED DOCUMENTS

1.1. VDACS Incident Response Plan Policy and Procedure 7.7 revision 10/1/2010

1.2. Procedure II-09 RRT Communications Plan

1.3. RRT Best Practices Manual

FIELD OPERATIONS MANUAL

Procedure III-01

SEAFOOD HACCP INSPECTIONS

Background

The Virginia Department of Agriculture and the Food and Drug Administration have entered into an annual contract whereby the State will conduct inspections of selected food establishments for FDA to determine compliance with the food provisions of the Federal Food Drug and Cosmetic Act and/or state laws. Under the terms of the contract a set number of Seafood HACCP inspections must be conducted.

Seafood HACCP inspections shall be conducted to determine compliance with the Seafood HACCP regulation as well as to address violations of other regulations that relate to food sanitation (GMP's) and labeling. The Seafood HACCP Regulation can be found at 21CFR Part 123.

It is important to note that Virginia has not adopted the Seafood HACCP regulation. The only time Seafood HACCP inspections are to be conducted is when indicated under the contract. Routine inspections of seafood facilities do not involve Seafood HACCP reviews. Seafood HACCP inspections shall only be performed by inspectors that are Seafood HACCP trained and certified.
NOTE: If you are assigned a Seafood HACCP inspection and feel you need additional training contact your Regional Manager.

FDA Contract Work---Identifying Seafood HACCP Inspections

Once the FDA/VDACS contract planning session is completed, inspectors will receive the assignment log for their respective territory. On your assignment log, Seafood HACCP inspections are identified by the PAC code 03S002 and highlighted in yellow.

CONDUCTING THE INSPECTION

The inspections must be based on the Seafood HACCP regulation and FDA recommendations as opposed to Virginia requirements. *NOTE: Since Virginia has not adopted the Seafood HACCP regulation regulatory (enforcement) responsibilities for the Seafood HACCP Program rest with FDA.*

The Seafood HACCP inspection is to be performed in a manner consistent with the Seafood HACCP Regulator Training Manual. Inspectors should refer to and use the Fish and Fisheries Products Hazards and Controls Guidance (Third Edition) manual during the HACCP evaluation.

The inspector's role includes evaluating the adequacy of the firm's HACCP plan, the adequacy of the implementation of the plan, the presence or absence of adequate controls when there is no written plan, and sanitation monitoring.

For firms producing both high and low risk potential products, the HACCP inspection should focus on the high risk products being produced. High risk potential products include the following: Refrigerated seafood products packed in Reduced Oxygen Packaging (ROP), ready-to-eat fish or fishery products (ie: cooked/smoked product), seafood mixes, scombrotoxin-forming species, aquacultured seafood, stuffed seafood products, and salt-cured and/or air-dried, un-eviscerated fish.

In the event an investigator arrives at a firm prepared to do a HACCP inspection and the firm is not in operation, the inspection should be rescheduled if possible. If it is not feasible to reschedule (e.g., the firm is at a distant location), an inspection that includes a **complete HACCP Records Review** should then be conducted. The inspector should attempt to answer HACCP questions as completely as possible. HACCP records (HACCP plans, Critical Control Point (CCP) monitoring and corrective action records) and sanitation monitoring records covering previous production days should be reviewed. Any sanitation defects observed should still be noted on the inspection report.

PAPERWORK

Writing the Inspection Report

On the Inspection Report beneath (i.e. segregated from) the recorded GMP deficiencies the discrepancies in complying with the Seafood HACCP regulation should be documented. The HACCP deficiencies will be listed under the heading "THE FOLLOWING DEFICIENCIES WERE NOTED IN THE FIRM'S HACCP PLAN"

For firms that state a HACCP plan is not required, verification by the inspector is required. If the inspector disagrees and feels that a HACCP plan is needed, it should be documented under the "Deficiencies Noted" heading.

Completing FDA contract paperwork

You are also required to fill out the Domestic Seafood HACCP report. (Form FDA 3501). This Seafood HACCP report is included in with your cover sheet.

On the FDA cover sheet under the Products Covered section, the HACCP and non-HACCP (i.e. sanitation/GMP inspection) components of the inspection need to be documented separately. The GMP portion of the inspection will be reported under the PAC code 03S001. The HACCP evaluation will be reported under PAC code 03S002.

The information that has traditionally been filled out in relation to the PAC code (i.e.: Product Description, Product Code, Inspection Classification, Hours and Reschedule Date) must be filled out for both codes. It is important to note that for the time expended during the inspection, PAC code 03S001 will include time for the GMP inspection, and administrative work. PAC code

03S002 will record only the time spent on the HACCP evaluation. See example below.

PRODUCTS COVERED & INSPECTION TIME

PAC	PRODUCT DESCRPTION	PROD CODE	INSP CLSSF.	HOURS	RESCH DATE
03S001	**striped bass**	**16 A F C 75**	**NAI**	**4.00**	**11/2008**
03S002	**striped bass**	**16 A F C 75**	**NAI**	**2.00**	**11/2008**

In addition, you are also required to fill out the Domestic Seafood HACCP report. (Form FDA 3501). This Seafood HACCP report is included in with your cover sheet.

CLASSIFICATION

Initial Inspection

The GMP component (03S001) of the inspection would be classified as you normally do, NAI, VAI or OAI depending on the significance of the violations found during the inspection.

The Seafood HACCP component (03S002) of the inspection should be classified either NAI or VAI depending on whether there are adequate controls in place to address food safety hazards.

The following information should be used as a guide in classifying Seafood HACCP deficiencies:

1. VAI classification would include:

    a. The absence of a HACCP plan when one is needed, failure to identify a hazard or list a critical control point

    b. Deficiencies associated with monitoring procedures, including inadequate monitoring programs, failure to maintain monitoring records, or failure to implement monitoring procedures

    c. Deficiencies associated with critical limits, such as, failure to list a critical limit, inadequate critical limits and critical limits not validated

    Note: Inadequate and un-validated critical limit charges must be supported by inspectional observations, such as internal temperatures, or analytical results that demonstrate that the critical limits are inadequate to control the identified hazard

d. Failure to have an appropriate corrective action plan (when included in the HACCP plan), take a corrective action when a critical limit is exceeded, or document the corrective action

e. Failure to perform sanitation monitoring in facilities that process Ready-To-Eat products.

2. Assign a NAI classification to inspections that reveal:

a. Hazards other than those listed above

b. Failure to perform sanitation monitoring in facilities that do not process Ready-To-Eat products

The overall inspection report would be given the most serious classification of the GMP and Seafood HACCP portions of the inspection. If the inspection is violative, a follow-up inspection should be scheduled for thirty (30) days.

Follow-up Inspection

If the initial inspection was found to be violative, the follow-up inspection will be CONTRACT and all the associated paperwork, including the Domestic Seafood HACCP Report, must be completed.

The follow-up inspection will "target" the GMP violations and the HACCP deviations noted on the previous inspection, i.e. the inspector will only inspect the conditions written up on the previous Inspection Report and then review the HACCP plan to verify that the necessary corrections have been made.

If the follow-up inspection finds the HACCP plan still without adequate controls in place the inspection will be classified VAI-F. The firm will be forwarded to FDA for further regulatory action. This will end VDACS involvement relative to the HACCP deficiencies.

Other situations (ie: GMP inspection violative) should be handled according to established criteria.

Revised July 2010

FIELD OPERATIONS MANUAL

PROCEDURE III-02
Formerly 13

IN-HOME FOOD MANUFACTURING OPERATIONS

An opinion by the Assistant Attorney General assigned to this Department indicates that the Virginia Food Laws and related regulations do not prohibit the home manufacture of food products for sale to the public. Each home operation is to be evaluated on it's individual merits as to it's suitability for the commercial production of food products.

When you evaluate a home operation you will use the Virginia Food Laws and which ever of the Federal regulations we have adopted that is applicable. For the most part you will use Part 110, Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food. There will be instances where other regulations will apply. Many of the other regulations set general standards of identity for products. When you are inspecting a home manufacturer producing a product covered by one of the regulations be sure you are entirely familiar with that regulation and utilize it when making your evaluation and\or inspection.

The below regulations may apply to home operations of certain foods. Each Food Safety Specialist is responsible for being familiar with these regulations.

> Part 110, Current Good Manufacturing Practice In Manufacturing, Packing or Holding Human Food
>
> Part 114, Acidified Foods
>
> **Note: The processing of low acid canned foods and water bottling are considered as not feasible in a home.**

We have put together an information package containing the Virginia Food Laws, Part 110-Good Manufacturing Practices, a "Starting Your Food Business" guide (included as an attachment to this FOM), food safety literature and other information deemed necessary for prospective home operators.

NOTE: The home operator is required to provide the Office or the Inspector with certain process documentation (as enumerated in the Starting Your Food Business guide) for evaluation prior to receiving an inspection of their facility.

ADMINISTRATIVE GUIDELINES

Home Operations that produce a low volume of food product (this would apply to most home operations) which are also exclusively processing non-potentially hazardous foods may be scheduled for a **24-36 month follow-up**. Of course this is optional and depends on the existing circumstances within each Food Safety Specialist's territory. Any inspection precipitating a 24-36 month follow-up should be classified NAI. Furthermore, you may only assign a 24-36 month follow-up to your home processor after you have performed an inspection of the operation and have provided the required information indicated in the following paragraph.

After completing an inspection of a home operation you will need to place the phrase, ***"home operation"*** *directly beneath the CFN in the upper left hand corner of the inspection report. Please note that this requirement applies to* ***all*** *home operations and not just those which meet the low volume/non-potentially hazardous foods requirement noted above. Not only does supplying this information allow you to initiate the 2 year follow-up protocol-it also allows us the* ***capability to separate typical food processors from "home operation" food processors on our mainframe system.*** *In addition to providing the Food Safety Specialist with greater rescheduling flexibility, this alteration to our system will allow us to more accurately assess the food processors in the Commonwealth and will provide for a greater degree of refinement during territory restructuring*.

Finally, as you are inspecting your home processing operations please take note of the assigned CFN. If the CFN prefix does not accurately reflect the nature of the home operation (i.e. retail CFN vs the appropriate processor CFN), alert us via a short note directly beneath the CFN in the upper left hand corner

of the inspection report. The note should state, "Change CFN" and should further indicate why the CFN should be changed.

The above will allow all of you an additional allotment of time that can be directed towards monitoring those establishments that are more "critical" with respect to potential impact on public health.

DETERMINING FIRM STATUS-OUT OF BUSINESS

Generally speaking, most home operations do not operate during traditional business hours. Many of these firms may only operate in the evening, on weekends or be seasonal in nature. Consequently, finding the firm open for inspection and/or determining its status can be difficult.

The following protocol should be followed prior to placing a firm out of business (i.e. OOB). The Food Safety Specialist should make several attempts to inspect the firm, including calling the firm to set up an appointment. Inspectors should call at different times, including the evening, when attempting to contact firms. If contacting the firm is unsuccessful and there is no evidence that the firm is in business (i.e. none of their product seen in commerce) then place the firm OOB.

Attachment: Starting Your Food Business Guide

Revised March 7, 2002

FIELD OPERATIONS MANUAL

PROCEDURE III-03
Revised

SEAFOOD PEDDLERS

In order to more uniformly regulate those persons who sell seafood from the back of trucks, etc., please use the following guidelines:

a. All seafood peddlers must have adequate means to refrigerate their products.
b. Seafood products must be adequately protected from possible contamination. No open display of raw product.
c. Seafood peddlers who do not have adequate cleaning equipment and hand washing facilities can sell the following:
    - Whole uncleaned fish.
    - Prepackaged units of seafood products.
    - Oysters in the shell from approved sources.
    - Live Crabs.
    - Unshelled bulk raw shrimp.

    They may not:
    - Dress or fillet fish.
    - Dip oysters.
    - Shuck oysters.
    - Handle unpackaged peeled and de-veined raw or cooked shrimp.
    - Handle or sell unpackaged fish fillets.
d. Seafood peddlers who process seafood must have on board their vehicles the same general sanitary facilities as are usually found in retail seafood markets, i.e. hot and cold running water, equipment sink, handwashing facilities, proper drainage and wastewater holding facilities. They must have convenient access to a functional rest room facility.
e. All seafood peddlers who deal in prepackaged products must meet the customary labeling requirements of the Virginia Food Laws.
f. Dressed fish or headed raw shrimp can be sold unpackaged, if it is procured from their vendor in that condition. If the product is processed in a home operation, IN HOME MANUFACTURING OPERATIONS, FOM III-02 will apply.

NOTE: Outdoor cooking (ie: crab steaming) associated with roadside seafood operations would fall under the jurisdiction of VDH.

These guidelines are to be used as an aid in interpreting the Virginia Food Laws as they apply to seafood peddlers. If any unusual circumstances are encountered, please discuss them with your Regional Manager.

Revised December 2010

FIELD OPERATIONS MANUAL

PROCEDURE III - 04
Formerly 001

SWOLLEN CANS

If you encounter swollen canned food products, you should:

1) have them voluntarily destroyed
or
2) seize and sample them

It is preferable to have the product voluntarily destroyed since laboratory analysis does not always reveal the cause of the abnormality. Swollen canned food products should never be consumed, since they indicate improper processing and/or handling. Such improper processing or handling could allow the formation of *C.botulinum* toxin.

During inspections of any establishment if multiple cases of swollen canned food products are encountered, or if you encounter a canned food product that has had a repeated history of being found in a swollen condition, the following information should be obtained:

1) The name and identification of the product.

2) The name and address of the manufacturer or distributor.

3) The code/codes of the products.

4) The approximate date of when the products were received.

This information is necessary so that the FDA can follow up at the manufacturer/distributor.

Revised November 17, 1999

FIELD OPERATIONS MANUAL

PROCEDURE III-05
Formerly 020

RETAIL STORE INSPECTION CRITERIA

To promote uniformity in the conduct of retail store inspections, the attached list of inspection criteria has been developed. The criteria are based on the requirements of the Virginia Food Laws and related regulations and are the basis for our on-the-job retail store training. The order of department is not meant to mean that the departments are to be inspected in the order listed in this FOM.

Meat/Delicatessen Departments

1) General state of repair of meat processing equipment and utensils and the sanitation of the same.

2) Rodent activity in the meat area.

3) Insect activity in the meat area.

4) Cleanliness and state of repair of food contact surfaces, general work surfaces and storage surfaces.

5) Daily thorough cleaning of processing equipment and cleanliness of same.

6) Condition of floors, walls and ceilings and cleanliness of same.

7) Adequate refrigerated holding facilities maintaining proper temperatures.

8) Avoidance of time-temperature abuses of potentially hazardous products.

9) Proper facilities for maintaining correct temperatures for hot serve foods.

10) Proper protection of raw product from possible contamination in storage.

11) Avoidance of cross contamination of prepared product by raw

product such as beef by pork or chicken.

12) The intentional adulteration of raw product with fillers such as pork spleens in ground beef.

13) Potable water supply.

14) Hot and cold running water available for cleaning.

15) Proper hand-washing facilities and necessary soap and towels.

16) Proper equipment cleaning facilities.

17) Proper plumbing.

18) Proper drainage of meat room and meat walk-in cooler floors.

19) Protective covering on overhead lights.

20) Proper cleaning of cooling equipment, fans, guards and grills.

21) Correct use of rodenticides and insecticides.

22) Correct use of cleaning agents.

23) Correct use of food additives and the detection of the use of illegal food additives.

24) Compliance with applicable food product standards, such as maximum % fat in ground beef.

25) Smoking, eating or drinking in food processing areas.

26) Adequate employee hygiene.

27) Proper hair restraints.

28) Clean clothing.

29) No infections, diseases, or skin conditions.

30) Proper labeling and packaging.

31) Truthful advertising.

Bakery Department

1) General sanitation of floors, walls, ceilings, utensils and equipment.

2) Insect or rodent contamination of raw ingredients.

3) Proper use of food and/or color additives.

4) Proper use of rodenticides and insecticides.

5) Adequate cleaning of equipment and utensils and adequate cleaning facilities.

6) Proper handling and refrigeration of bakery products containing ingredients which support rapid microbial growth.

7) Proper employee practices including frequent hand washing, proper hair restraints and clean clothing.

8) Adequate hand washing facilities properly serviced.

9) Proper labeling of pre-packaged items.

Produce Preparation Area

1) General sanitation of floors, walls, ceilings and equipment in the produce preparation area and all produce coolers.

2) Proper cleaning and storage of produce preparation utensils.

3) Daily removal of all waste materials subject to decomposition and fermentation.

4) Rodent and/or insect activity.

General Stockroom Area

1) Rodent and/or insect defiled products.

2) Rodent and/or insect activity.

3) Rodent and/or insect entry points along walls, doors and receiving docks.

4) General sanitation of floors, walls, ceilings and shelves.

5) Springers, swells or leakers in canned goods.

6) Proper storage of merchandise off the floor and away from walls.

7) Broken or damaged product spilling onto floors or other product.

8) Segregation of toxic or hazardous products away from food products.

9) Storage of animal feeds away from human foods which are susceptible to insect attack.

10) Orderly morgue (also called reclaims and/or returns)area maintenance and procedures.

11) Adequate pest control practices and proper use of insecticides and/or rodenticides.

12) No domestic animals present.

13) Adequate and convenient washrooms and toilet separate from areas used to manufacture and store foods.

14) Proper waste and trash storage and disposal.

Dairy and Egg Products Storage Cooler

1) General sanitation of cooler floor, walls, ceiling, shelves and refrigeration units.
2) Maintenance of proper storage temperatures.

Walk-in Freezer Storage

1) Proper temperatures for frozen products.

2) No build-up of ice on products, floors, freezer unit.

Retail Sales Area

1) General sanitation of floors, walls, shelves, refrigerated display cases.

2) Check grain products for possible insect infestation.

3) Check canned products for leakers, swells and flippers.

4) Check produce areas for roaches, fruit flies and other pests.

5) Check dairy display for proper temperature and leakers.

6) Check prepackaged meat display for proper temperatures, swells, blown vacuums, off color or off odor products.

7) Check frozen foods display for proper temperature, defrost cycle problems, freezer burn and load limit abuses.

8) Check infant formula for outdated product.

9) Check prepackaged products for proper labeling.

10) Check to ensure that hazardous or toxic products are displayed away from human foods.

11) Candle soft drinks for the presence of mold, foreign material.

12) Check bulk displayed products for actual contamination, proper protection from contamination, proper rotation and adequate customer handling utensils.

Exterior of Store

1) Check for possible rodent and/or insect entry points.

2) Check for weed growth and other potential rodent harborage.

3) Check for adequate trash storage and removal.

Miscellaneous

1) Sleeping quarters separate and apart from food manufacturing, storage and sales area.

Inspection Criteria for Food Service Operations in Retail Food Stores

1) Check to see that sanitizing solutions are being used at least once a day on equipment, utensils and work surfaces used in the preparation, storage, and sale of potentially hazardous ready to eat food products and in every instance where there is a change from raw, unprocessed product to ready to eat food products.

2) Check to see if sanitizing solutions are being used properly:

2/1	Hot water	- 170□F	-	30 seconds
2/2	Chlorine	- 50 ppm	-	1 minute
2/3	Iodine	- 12.5 ppm	-	1 minute
2/4	Quaternary ammonium	- 200 ppm	-	1 minute

2/5 Any other sanitizer recognized by public health authorities as being safe and effective.

3) Check to see if refrigeration facilities are holding product at an internal temperature of 45 degrees F. or below and are equipped with an accurate thermometer.

4) Check to see if management has a stem type thermometer available and uses it to check the internal temperatures of hot and cold potentially hazardous, ready to eat food products.

5) Determine if self-service displays of unpackaged or unwrapped foods, other than unprocessed raw fruits and vegetables, are equipped with sneeze guards or other suitable devices which protect the food from contamination.

6) Determine if all self-service displays of unpackaged or unwrapped food products, other than unprocessed raw fruits and vegetables, are equipped with appropriate serving utensils which eliminate consumer contact with

the food product and are stored in a manner which prevents contamination of the food contact surface of the utensils.

7) Determine if self-service displays of unpackaged or unwrapped foods, other than unprocessed raw fruits and vegetables, are being monitored continuously by a store employee.

8) Check salad bars to determine if sulfite is being used to preserve the produce by either the retailer or the packer of the produce. If sulfite is being used, make sure a placard declaring its use is at point of display.

INSPECTION CRITERIA FOR FOOD HANDLING PRACTICES

1) Where applicable determine if frozen potentially hazardous food is being properly thawed by one of the following methods;

1/1 Placed in a refrigerator at 45 degrees F or below for a length of time sufficient to thaw the product.

1/2 Immersed in cold running water for a time sufficient to thaw the product.

2) Check to see that potentially hazardous cold foods are held at 45 degrees F or below during storage and display.

3) Check to see that potentially hazardous hot foods are handled properly in that:

3/1 Hot foods are placed directly from cooking operations into a pre-warmed display case and held at an internal temperature of 140 degrees F.

3/2 Hot foods which are to be stored for use later are removed from cooking operations or the display case and rapidly cooled in shallow vessels to 45 degrees F or less. Cold foods to be displayed hot are reheated to at least 165 F and then placed in a pre-heated hot display case.

In no instance is the display case to be used to reheat foods.

4) Check to ensure that potentially hazardous foods being processed in the retail store by cooking are cooked to heat all parts of the food to at least 140 degrees F except that:

4/1 Poultry, poultry stuffings, stuffed meats and stuffings containing meat are cooked to heat all parts of the food to at least 160 degrees F.

4/2 Pork and pork products are cooked to heat all parts of the food to at least 150 degrees F.

CRITICAL ITEM INSPECTIONS **HACCP**

"Critical Item Inspections" (CII) are HACCP type inspections done in retail establishments. An inspector should evaluate several key factors concerning the firm before doing this type of inspection. Some of these key factors are as follows:

1. inspectional history
2. management
3. employee turnover
4. turnover of food in the store
5. store temperature (air conditioned or not)

If during **your** evaluation of these or any other factors **you** believe there could be problems in the store then **you** should decide on how detailed **you** want to make the inspection. However, if **your** evaluation indicates no problems then **you** may want to do a critical item inspection.

CII's are inspections where emphasis is placed on the critical areas of the store. Listed below are some examples of PRIMARY and SECONDARY areas of concern. Some of these areas could switch from secondary to primary and visa versa depending of the **store's situation**.

PRIMARY	**SECONDARY**
ALL PROCESSING AREAS	PRODUCE
PERIMETER OF THE STOCKROOM	EGGS
ALL REFRIGERATION AND FREEZER UNITS (retail and backroom)	CAN GOODS
RESTROOMS	ALL PACKAGED BEVERAGES (soft drinks, juices, beer, wine, tea, coffee, etc.)
INFANT FORMULA	CONDIMENTS/DRESSINGS
BAKERY INGREDIENTS (flour, corn meal, mixes, etc.)	PASTA
GRAIN PRODUCTS/DRIED BEAN AND FRUIT	BREADS
REDUCED/QUICK SALE	CEREAL
SPECIALTY ITEMS	COOKIES/SNACK FOOD
	ANIMAL FEED

If anytime during a critical item inspection you find evidence that there could be problems in secondary areas of the store then you should make a more detailed inspection.

Revised November 17, 1999

Procedure III-06: Vacuum Packaging Systems in Retail Establishments

The adoption of vacuum-packaging systems (otherwise known as a reduced oxygen system) by food establishments have caused concern over the monitoring and maintaining of critical controls that would prevent the growth of *Clostridium botulism* and other pathogenic organisms within vacuum-packaged food products. Since vacuum-packaging of foods produces an environment conducive to the growth of such organisms, constant monitoring of the adherence to these controls is essential to assure the production of safe and wholesome food products. Consequently, we have adopted the following guidelines (recommended by the U.S. Food and Drug Administration) to be enforced in retail food establishments where vacuum-packing systems are in use.

In addition, since vacuum-packaged food products are "food in packaged form", they must bear the information required by the labeling provisions of the Virginia Food Laws. This would include the name of the product, a list of ingredients in descending order of predominance, the net weight declaration, and the name and address of the responsible firm.

ENFORCEMENT PROVISIONS

Whenever vacuum-packaging violations are encountered, they should always be listed on the inspection report as objection-able conditions. In many cases, vacuum-packaging violations may not be serious enough to justify taking direct or immediate regulatory action. In these cases, the violations will be taken into consideration along with any other objectionable conditions in order to determine the classification of the inspection. However, some violations may be serious enough so that immediate corrective action will be necessary. Following are guidelines to assist inspectors when serious vacuum-packaging violations are encountered:

Violation	Action To Be Taken
Foods that are unacceptable for vacuum-packaging.	Vacuum-packaging of these foods should be discontinued immediately. The products should be removed from sale and the firm should be requested to voluntarily destroy the products. If they refuse, the products should be seized and sampled for pH and Aw. (SEE NOTE C BELOW)
Products that are held or offered for sale past the acceptable expiration date (see control step 4 in this FOM procedure to determine acceptable expiration date).	Products should be removed from sale and the firm should be requested to voluntarily destroy the products. If they refuse, the products should be seized and sampled to verify the expiration date. The samples should be sent directly to your regional manager along with any necessary documentation to verify the violation. After verification, the firm will be notified in writing that the product will be destroyed. (SEE NOTE C BELOW)

Temperature abuse has been documented.	Temperature abuse should never exceed 4 hours. If it does, the products should be removed from sale and the firm should be requested to voluntarily destroy the products. If they refuse, the products should be seized and sampled for bacteriological analyses, to include Listeria monocytogenes analysis. (SEE NOTE C BELOW)
Inadequate processing guidelines or failure to follow proper processing guidelines.	If processing has been inadequate to the point that finished products may be harmful or injurious to health, vacuum-packaging should be discontinued until proper processing guidelines can be established and/or implemented, and the products should be removed from sale. The firm should be requested to voluntarily destroy the products; if they refuse, the products should be seized and sampled for pH, Aw, and bacteriological analyses, to include Listeria monocytogenes. (SEE NOTE C BELOW)
Untrained/unknowledgeable operators.	Vacuum-packaging should be discontinued until trained operators are available.
Inadequate processing conditions (i.e. general insanitary conditions; inappropriate location of vacuum-packaging operation such as in a stockroom, or packaging ready-to-eat products in a raw meat cutting area; etc.)	Vacuum-packaging should be discontinued immediately until this condition is corrected. Products should be removed from sale and the firm should be requested to voluntarily destroy the products. If they refuse, the products should be seized and sampled for pH, Aw and bacteriological analyses, to include Listeria monocytogenes (SEE NOTE C BELOW)

NOTE C - If it is necessary to seize and sample any of these products, the samples, including any collected and sent directly to your regional manager, must be official samples.

A food establishment that packages potentially hazardous food (Time/Temperature Control for food safety) using a vacuum-packaging system shall have a HACCP Plan that:

(1) Identifies the food to be packaged;

(2) Except as specified under (C) and (E) and as specified in (D) of this section, requires that the packaged food shall be maintained at (41°F) or less and meet at least one of the following criteria:

(a) Has an AW of 0.91 or less,

(b) Has a PH of 4.6 or less,

(c) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact package, or

(d) Is a food with a high level of competing organisms such as raw meat or raw poultry;

3-502.12 VACUUM PACKAGING SYSTEMS CRITERIA.*

(A) Except for a food establishment that obtains a variance as specified under 3-502.11 and except as specified under (C) and (E) and as specified in (D) of this section, a food establishment that packages potentially hazardous food (time/temperature control for food safety) using a reduced oxygen packaging method shall ensure that there are at least two barriers in place to control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*.

(B) A food establishment that packages potentially hazardous food (time/temperature control for food safety) using a reduced oxygen packaging method shall have a HACCP Plan that contains the information specified under 8-201.14(D) and that:

(1) Identifies the food to be packaged;

(2) Except as specified under (C) and (E) and as specified in (D) of this section, requires that the packaged food shall be maintained at (41°F) or less and meet at least one of the following criteria:

(a) Has an Aw of 0.91 or less,

(b) Has a pH of 4.6 or less,

(c) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact package, or

(d) Is a food with a high level of competing organisms such as raw meat or raw poultry;

(3) Describes how the package shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(a) Maintain the food at (41oF) or below, and

(b) Discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;

(4) Limits the refrigerated shelf life to no more than 14 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(5) Includes operational procedures that:

(a) Prohibit contacting food with bare hands,

(b) Identify a designated work area and the method by which:

(i) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination, and

(ii) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, and

(c) Delineate cleaning and sanitation procedures for food-contact surfaces; and

(6) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:

(a) Concepts required for a safe operation,

(b) Equipment and facilities, and

(c) Procedures specified under Subparagraph (B)(5) of this section and 8-201.14(D).

FISH

(C) Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method.

COOK-CHILL OR SOUS VIDE

(D) Except as specified under (C) of this section, a food establishment may package food using a cook-chill or sous vide process without obtaining a variance if:

(1) The food establishment implements a HACCP plan that ontains the information as specified under 8-201.14(D);

(2) The food is:

(a) Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the bagged product to another business entity or the consumer,

(b) Cooked to heat all parts of the food to a temperature and for a time as specified under 3-401.11,

(c) Protected from contamination after cooking as specified under Part 3-3,

(d) Placed in a package or bag with an oxygen barrier before cooking, or placed in a PACKAGE or bag immediately after cooking and before reaching a temperature below 135°F,

(e) Except for frozen food that is not shelf life restricted, cooled to 41°F in the package or bag as specified under 3-501.14 and then cooled to 34°F or less within 48 hours of reaching 41°F, and:

(i) Held at 34°F and consumed or discarded within 30 days after the date of preparation, or

(ii) If removed from a storage unit that maintains a 34°F food temperature, held at 41°F or less for no more than 72 hours before consumption.

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily,

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and

(h) Labeled with the product name and the date packaged; and

(3) The records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP Plan, are maintained and are:

(a) Made available to the regulatory authority upon request, and

(b) Held for 6 months; and

(4) Written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section are implemented.

Cheese

(E) A food establishment may package cheese using a reduced oxygen packaging method without obtaining a variance if it:

(1) Limits the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;

(2) Has a HACCP plan that contains the information specified under ¶ 8-201.14(D);

(3) Except as specified under Subparagraphs (B)(2), (B)(3)(b), and (B)(4), complies with ¶ (B) of this section;

(4) Labels the PACKAGE on the principal display panel with a “use by” date that does not exceed 30 days or the original manufacturer’s “sell by” or “use by” date, whichever occurs first; and

(5) Discards the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.

CHEESE

A food establishment may package cheese using a vacuum packaging system (reduced oxygen packaging method) without obtaining a Variance if it:

(1) Limits the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;

Hard Cheese	Pasteurized Process Cheese	Semisoft Cheese
Romano	Pasteurized Process American Cheese	Muenster
Gjetost	Pasteurized Process Gruyere Cheese	Port du Salut
Cheddar	Pasteurized Process Swiss Cheese	Primost
Colby	Pasteurized Process Limburger Cheese	Monterey Jack
	Pasteurized Process	

Gouda	Cheddar Cheese	Mozzarella
Provolone	Pasteurized Process Swiss Cheese blended with American Cheese	Bleu
Swiss (Emmentaler)	Pasteurized Process Brick Cheese	Gorgonzola
Gruyere	Pasteurized Process Mozzarella Cheese	Roquefort
Edam		Stilton

(2) Has a HACCP Plan

(3) Except as specified under Subparagraphs (B)(2), (B)(3)(b), and (B)(4), complies with(B) of this section;

(4) Labels the package on the principal display panel with a “use by” date that does not exceed 30 days or the original manufacturer’s “sell by” or “use by” date, whichever occurs first; and

(5) Discards the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.

12-02-05

FIELD OPERATIONS MANUAL

PROCEDURE III-07
Formerly 025 & 36

RETAIL APPLE and APPLE CIDER INSPECTIONS

Packages should be conspicuously marked with: (1) the grower or packer's name and address, (2) correct variety, (3) one of official standard grades (4) correct size, and (5) net contents. The Virginia Apple Marking Law requires this information to be conspicuously marked on each package "in plain words and figures on the outside, or a durable stuffer within and readily readable from the outside"; however, if the tie closure on bagged apples list part of this information it will be acceptable. Any placards or signs advertising bulk or packaged products should be factual, or removed.

A statement on the Inspection Report will list the number and type of packages which are in violation, the reason(s) for the failure, as well as the approximate net weight. If the packages are not packed by the store, the name and address of the packer should also be included to allow for follow-up at the packer level, if deemed necessary. Violations that are corrected will be so indicated on the Inspection Report.

Example (a): 65/3 lb. bags of apples marked, "Peaks of Otter Orch., Bedford, VA 24523, Red Delic., 2 1/4 in. min." were misbranded and offered for sale in the retail area as they did not indicate a grade.

Example (b): 20 various weight packages of apples were misbranded and offered for sale in the retail area, in that no packer's name, variety, grade or size shown.

APPLE JUICE/APPLE CIDER - Proper Washing of Apples to Remove E.coli 0157:H7

Processors of apple juice and apple cider should be inspected regularly, in accordance with our inspection frequency of food manufacturers. During these inspections, you should observe the apple washing procedures to insure that they are effective. Regulatory authority to require the washing of raw ingredients

containing soil exists in CFR Part 110 - Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food. (Subpart E, Section 110.80, paragraph (a) Raw Materials and Other Ingredients.)

Check the washing of apples to insure that the procedure is sufficient to remove soil. This is especially important in processors who produce unpasteurized cider and juice. Also be sure to ask the processor if they are using dropped apples in their product. If they do, make note of this practice so we can include it in the firm file.

Water used in the washing of apples should come from a potable supply and water used in a common wash should be of adequate sanitary quality. If the washing operation itself is not sufficient to remove all soil from the apples brushing may be necessary. Raw apples should be thoroughly examined to make sure all soil and soil residue is removed. If the firm is not washing their apples, urge them to do so, citing the dangers of unwashed product and the dangers of E.coli 0157:H7. If you observe soil present on apples that are to be pressed and processed into apple products, document this condition on your inspection report as an objectionable condition with a reinspection date of two weeks. When you reinspect the firm, if they are still not adequately washing their apples, classify the inspection as OAI, collect a sample of the finished product, and have it analyzed for E.coli 1057:H7. The product should be shipped in a refrigerated condition since competing organisms may suppress E.coli. Of course pasteurization is highly recommended for any apple cider products. ***If the apple cider product is NOT pasturized, you must collect a sample of the product for E. coli 0157:H7 (laboratory code 226-74 XMECOLIH7). THIS IS MANDATORY!***

Thereafter, we will handle the matter administratively under our voluntary compliance guidelines. (ie: Letter of Warning, etc.)

Revised November 17, 1999 Edited April 5, 2000

FIELD OPERATIONS MANUAL

PROCEDURE III-08
REVISED

HOT AND COLD HOLDING TEMPERATURES

The failure to hold potentially hazardous foods (time/temperature for safety [TCS] foods) at proper temperatures has been identified as one of the top five risk factors responsible for foodborne illness outbreaks. Proper temperature control is a fundamental element of food safety in limiting the growth of disease causing bacteria. Hot and cold holding temperatures, time/temperature control, as well as cooling time and temperatures, of potentially hazardous foods should be thoroughly checked during each inspection.

The center of a product is usually the point of measurement for product temperatures particularly when checking cold holding temperatures.

Hot holding temperatures may need additional measurements taken at points farthest from the heat source, e.g., near the product surface for food held on a steam table. In large holding units, e.g. salad bars and steam tables, inspectors should take the temperatures of foods in various locations to ensure that the equipment is working properly. If improper holding temperatures are noted, it is important to take extra steps to find out whether the problem is the result of equipment failure or whether a breakdown in a process such as cooling or reheating is the reason for the problem.

It is important that Inspectors calibrate their thermometers on a regular basis. The following method is effective in calibrating a probe food thermometer:

- Insert sensing area into a cup of ice slush.
- Allow indicator to stabilize.
- Adjust calibration nut to 32°F while in ice.
- Digital thermometer and thermocouple units can be checked for accuracy by assuring they read 32°F while in ice using this method.

REHEATING

One on-site correction used in the field is reheating. A common misconception is that reheating is a "magic step" for eliminating hazards resulting from improper holding or cooling. If a ready-to-eat, potentially hazardous food is improperly held or cooled, the potential for spore- or toxin-forming bacteria growth increases. If items are found "reheating" on the steam table, further inquiry is needed to assess whether the equipment in question is capable of reheating the food to the proper temperature (165°F) within the allowable time limit.

COOLING

The requirement for cooling cooked potentially hazardous foods (time/temperature control for safety foods), is that the food must be cooled from 135F to 41F or less in 6 hrs provided that the food is cooled from 135F to 70F within the first 2 hours. For example, if a facility cools chili from 135F to 70F in 1.5 hours; they then have 4.5 hours to get it from 70F to 41F of less (or to 45°F or less if existing refrigeration equipment does not support the 41°F temperature requirement – see note below).

.

NOTE: For cold holding of PHF's, foods may be held at 45°F or between 45°F and 41°F in existing refrigeration equipment that is not capable of maintaining the food at 41°F or less if:
1. The existing equipment is already in place and in use in the food establishment; and
2. Before January 1, 2012, the equipment is upgraded or replaced to maintain food at a temperature of 41°F or less.

CORRECTIVE ACTION

Cold Holding Temperatures:
Greater than 55°F for **more than 4 hours**---destroy
Greater than 55°F for **less than 4 hours**---refrigerate
41° (45°)-55°F---refrigerate

Hot Holding Temperatures:
130°F-135°F----reheat to 165°F*****
Less than 130°F, **greater than 4 hours**---destroy
Less than 130°F, **less than 4 hours**---reheat to 165°F*****
***** *It is acceptable for the firm to elect to rapidly chill the product to 41°*(45°) *or below within six (6) hours.*

Improper Product Cooling:

Cooked hot food may be reheated to 165 ºF for 15 seconds and the cooling process started again using a different cooling method if the food is:

- Above 70 °F and two hours or less into the cooling process; and
- Above 41 °F (45°) and six hours or less into the cooling process.

Cooked hot food should be discarded immediately if the food is:

- Above 70 °F and more than two hours into the cooling process; or
- Above 41 °F (45°) and more than six hours into the cooling process.

Frozen Foods:

Thawed frozen foods are generally a **quality** issue, not a food safety matter. Destruction of thawed product is not generally necessary. However, if the product falls within the parameters for cold foods, take the appropriate action indicated above. The disposition of the affected foods is a "***judgement call***".

Time as a Public Health Control:

Our Retail Food Establishment Regulations section 2VAC5-585-850 allows potentially hazardous food (time/temperature control for safety food) that is ready-to-eat to be stored without temperature control for up to 4 hours, after which it must be discarded or consumed or for up to 6 hours for refrigerated food, if the food is 41 °F when initially removed from temperature control, and as long as the food temperature does not exceed 70 °F.

Refer to 2VAC5-585-850 Time as a Public Health Control for more detailed information on the requirements. *Please note that firms will no longer need to submit a written HACCP plan to the office prior to using time as a public health control.*

CLASSIFICATION

Inspections will generally be given an "**NAI"** designation unless the firm needs to be monitored for compliance. The decision as to whether an establishment should be given a **"VAI"** designation for monitoring purposes will depend on a number of factors (i.e. product temperature, amount of product out of temperature, assessment of firms desire to comply). If the Food Safety Specialist feels that the firm needs to be monitored then they should classify the inspection "VAI" and request that a *temperature informational letter* be sent to the firm. This letter will indicate the dangers of holding potentially hazardous foods at inappropriate temperatures and will request the firm to initiate corrective action.

An "OAI" designation should only be given in circumstances where there have been repeated violations.

Revised August 2010

FIELD OPERATIONS MANUAL

PROCEDURE III-09
Formerly 027

SELF-SERVE POTENTIALLY HAZARDOUS FOODS

If a retail food store wishes to offer ready to eat potentially hazardous foods on a self-serve basis, they should be informed that they take on added risks and responsibilities and these operations are evaluated on a case by case basis. The parameters used in evaluating these operations include the monitoring of product temperatures, a sanitary method of dispensing the product, and a proper display that will discourage consumers from touching and/or contaminating the product. The display should also be conducive to constant monitoring of these operations by store personnel to insure that utensils and dispensers are properly used and that food is not contaminated by consumers. Equipment and display facilities should be designed, constructed, installed and maintained consistent with good public health principles.

Raw foods of animal origin, such as meat, chicken, or seafood, usually contain pathogens. By offering these foods for consumer self-service (typically found in imported food stores), a consumer could cross contaminate other foods stored in the same display or in nearby displays. Because raw animal foods are assumed to be contaminated and provide an ideal medium for growth of pathogenic organisms, they shall not be available for consumer self-service. Cross contamination of other foods in the store would be a serious violation of the Virginia Food Laws.

If you encounter raw foods of animal origin being offered for consumer self-service, insist that the firm discontinue this practice. Instead, the firm must place these foods behind a counter or in a glass case so that only qualified employees within the establishment have access to these products. These employees should package the product and hand it to the consumer in a manner that would prevent contamination of other foods in the same display or in nearby displays. Additionally, stress that employees should use clean utensils and dispensers and practice proper hand washing procedures when handling raw foods of animal origin.

Document the situation on your inspection report as an objectionable condition. If the firm does not comply, request that your Regional Manager send a Raw Meat and Seafood Letter of Information to the firm.

NOTE: FROZEN SHRIMP AND LOBSTER will be permitted for consumer self service. In the case of raw/uncooked frozen shrimp, the product should be displayed in a method that will not contaminate other food products. The product should be displayed high enough to discourage children from touching it and a sanitary scoop should be available to dispense the product. The display equipment should be capable of maintaining the product in a frozen state and should be placed in an area that is conducive to constant monitoring by employees. **All other raw/uncooked potentially hazardous food products shall not be offered for sale as self-service.**

FOR REFERENCE ONLY - FOOD CODE 3-306.13

Revised 7-3-03

Procedure III-10: Mushrooms, Cultivated and Wild Harvested

CULTIVATED/FARM-RAISED

At present, there is no regulatory inspection in place for producers of mushroom cultures and/or mycelium plugs. Furthermore, mushroom cultures must be pure in order to achieve growth under ideal conditions. When a "farmer" sells whole, fresh, uncut produce directly to retail establishments, a VDACS Food Safety inspection is not typically required for the raw agricultural produce. With this longstanding policy in mind, when mushrooms derived from commercially available mycelium plugs are cultivated and harvested from a farm and then provided to local retail establishments, they shall be considered an approved source.

When considering whether or not to place a mushroom cultivator under inspection, you must first determine whether or not the products will be sold as raw, unprocessed, agricultural commodities or as processed, finished products being offered in a consumer-size retail package.

1. **If offered as a raw, unprocessed, agricultural commodity**, the firm will NOT be placed under inspection, regardless of whether the growing and cultivating takes place indoors or outdoors. An example of an outdoor growing operation would be growing shiitake mushrooms on logs. In these cases, growers typically purchase "plugs" that have previously been inoculated with fungi (usually shiitake), and insert them into holes that have been drilled into the logs. Then, as environmental conditions allow, the mushrooms begin to grow directly on the logs and are then picked, by hand. In these cases, VDACS will provide guidance and assistance pertinent to food safety, upon request. When growing mushrooms in this manner, the firm should be able to provide written verification as to the origin/supplier of the mycelium or inoculated "plugs."

   Indoor mushroom growing operations should be treated in the same manner, as long as the products are being offered as raw, unprocessed, agricultural commodities. For these types of operations, the commodities will typically be offered bulk or sold at a Farmer's Market in baskets or open paper bags.

2. **If offered as processed, finished goods in retail packages**, mushroom growing and processing operations WILL be placed under inspection by the VDACS Food Safety Program. Field personnel shall use the applicable laws and regulations when conducting inspections of these types of operations. Some examples of post-harvest processing by growers are washing, slicing, cutting, chopping, drying, heating, canning and/or packaging. Any type of further secondary processing would also require an inspection. When conducting these inspections, field personnel are advised to ensure that Good Manufacturing Practices are being followed, as well as the requirements of food labeling, as outlined in Title 21 CFR Parts 110 and 101, as well as all other applicable federal regulations.

WILD HARVESTED

In Virginia, there are over 200,000 wild mushroom species of which about 200 are edible and 25 of culinary value that are normally sold. However, mushrooms picked in the wild and sold to a consumer that haven't been verified as safe by an individual with adequate training, could result in illness and/or death.

If/when encountering an individual whom offers for sale wild mushrooms as raw, unprocessed, agricultural commodities, inspection personnel are advised to inform the individuals of the need to have met the following requirements as set forth by the department.

The following requirements must be met for foragers/harvesters of edible wild mushrooms:

1. Prior to sale of wild harvested mushrooms, harvesters shall make a request in writing by completing and submitting the "Wild Mushroom Harvester Application" found on the VDACS website at: http://www.vdacs.virginia.gov/services-forms.shtml

2. The harvester shall describe their qualifications and training in writing or otherwise be able to demonstrate knowledge to VDACS for approval.

3. Harvesters shall keep records with the names of the Food Establishments where wild mushrooms were sold, including dates/species/quantities. In addition the package/container of mushrooms should have a label/tag stating the following:

    - Common name and scientific name of mushroom species
    - Name and address (city, state, zip code) of the harvester
    - Location/county of harvest
    - Dates of harvest
    - An accurate net weight

The intent of this requirement is to help establish record-keeping and traceability to assure safety of wild harvested mushrooms.

Approved Wild Mushroom Harvesters

The "Wild Mushroom Harvester Application" submitted by the harvester requesting approval will be received by Betty Ragsdale in the Richmond Office and reviewed by the Food Technical Specialist. Approved applications will be saved on the LAN for future reference and the operation will be placed on file by creating a new firm in VIPRS. Food manufacturer will be selected for the business type and "Wild Mushroom Harvester" will be selected for Specific Business Information. However the firm will be marked as exempt from Annual Fee and Inspection and an inspection will not be conducted.

If wild harvested mushrooms are offered as processed, finished goods in retail packages, the operation WILL be placed under inspection by the VDACS Food Safety Program. Field personnel shall use the applicable laws and regulations when conducting inspections of these types of operations. Some examples of post-harvest processing are washing, slicing, cutting, chopping, drying, heating, canning, packaging, or use of the mushrooms in other recipes. Any type of further secondary processing would also require an inspection. When conducting these inspections, field personnel are advised to ensure that Good Manufacturing Practices are being followed, as well as the requirements of food labeling, as outlined in Title 21 CFR Parts 110 and 101, as well as all other

applicable federal regulations. Harvesters may need to fill out the Application for a Home Food Processing Operation.

Additionally, edible wild mushrooms shall not be harvested from Federal, state, and local parks, forests and natural area preserves. The removal of edible wild mushrooms with the intent of retail sale from federal/state and/or local lands is prohibited. Individuals should contact the appropriate local or state authority responsible for management of the public lands to determine if mushroom harvesting is permissible and the permits those authorities may require. According to the Virginia Department of Conservation and Recreation, the picking of mushrooms for commercial use/profit is prohibited within Virginia State Parks, Natural Area Preserves and all other DCR lands.

> *4VAC5-30-50. Flowers, Plants, Minerals, Etc.*
>
> *No person shall remove, destroy, cut down, scar, mutilate, injure, take or gather in any manner any tree, flower, fern, shrub, rock or plant, historical artifact, or mineral in any park unless a special permit has been obtained for scientific collecting.*

Individuals intending to forage/harvest from someone else's property/land should obtain permission in writing from the landowner before removing any edible wild mushrooms with the intent of retail sale.

The following types of wild harvested mushrooms (mushrooms with tubes, spines and ridges and other mavericks) are considered approved by the regulatory authority (VDACS, Office of Dairy and Food, Food Safety Program) since they have clear identification marks and are easily identifiable in the field (fresh state) and there are no potentially poisonous look-a-likes:

- Hen of the Woods (Grifola frondosa) – Japanese name is "Maitake", a cluster of fan shaped overlapping caps
- Golden Chanterelle (Cantharellus cibarius), White Chanterelle (Cantharellus subalbidus), Blue Chanterelle (Polyozellus multiplex) – funnel shaped with ridges and cross-veins under cap
- Black Trumpet (Cantharellus tubaeformis) – trumpet shaped with ridges and a hole in the cap center, hollow stem
- Hedgehog Fungus (Hydnum repandum, Dentinum albidum, Dentinum repandum, Dentinum umbilicatum) – matte white to yellow brown with spines under the cap, wavy-edged cap
- Common Puffball (Lycoperdon perlatum) – white conical spines on the cap, net pattern when spines rubbed off, white uniform flesh
- Horn of Plenty (Craterellus cornucopioides) – wavy and out-rolled cap, funnel shaped
- Cauliflower Mushroom (Sparassis crispa) – cauliflower or sea sponge shaped, curved lobes
- Chicken of the Woods (Laetiporus sulphureus) – sulphur yellow to orange, grow in brackets, tubes present

- Lion's Mane or Bear's Head or Bearded Tooth (Hericium erinaceus) – spines present with what appears to be hanging, white "fur"
- Various bolete species to include: Queen Bolete (Boletus aereus), King Bolete or Cepe or Porcini (Boletus edulis), Manzanita Bolete (Leccunum manzanitae) – brown to red brown and spongy under the cap, no gills present
- Matsutake (Armillaria ponderosa, Tricholoma magnivelare) – tannish white cap with brown scales
- Blewit (Lepista nuda) – bluish lavender with notched cap and gills
- Morels (Morchella spp.) – sponge, pinecone or honeycomb shape with pits and ridges
- Oyster Mushroom (Pleurotus ostreatus) – white, tan or ivory with short gills connecting to an off-center stem
- Shaggy Mane or Lawyer's Wig (Coprinus comatus) – long, white cylindrical cap with shaggy, upturned brown scales
- Coral Fungi (Clavariaceae) – appear as branching stems pointing upward similar to coral
- Truffles (Tuber aestivum, Tuber magnatum) – black to gray and brown/white, irregular round shape

If the harvester wishes to sell wild harvested mushroom not listed on this document then they must provide rationale for consideration of approval by VDACS. All types of wild harvested mushrooms approved for sale will be noted on the reviewed application.

SALES OF WILD HARVESTED MUSHROOMS AT RETAIL FOOD ESTABLISHMENTS

The 2016 Retail Food Establishment Regulations state:

2VAC5-585-320. Wild mushrooms.

A. Except as specified in subsection B of this section, mushroom species picked in the wild shall not be offered for sale or service by a food establishment unless the food establishment has been approved to do so.[P]

B. This section does not apply to:

1. Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation; or

2. Wild mushroom species if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

The following requirements must be met for retail food establishments that sell, use or serve wild harvested mushrooms:

1. Prior to the sale of wild mushrooms, food establishments shall make a request in writing by completing and submitting the "Wild Mushroom Retail Sales Application" found on the VDACS website at: http://www.vdacs.virginia.gov/services-forms.shtml

2. Once the application is approved by VDACS, the food establishments shall keep records or invoices that include the following:

    a. Name and contact information of the person who identified the mushroom and/or the mushroom seller
    b. Common name and scientific name of mushroom species
    c. Location/county of harvest
    d. Dates of harvest
    e. Date of purchase from harvester
    f. An accurate net weight

3. The mushrooms should remain in the container in which they were received and be accompanied with a tag or label with the information above.

The records shall be retained for at least 90 days from the date the container is emptied. This retention period accounts for potentially long asymptomatic latent periods (that can be up to 14 days from consumption), diagnosis and investigation timeframes that can be up to 3 weeks, and already existing record retention timeframes specified in the FDA model Food Code for other foods. Commingling of wild harvested mushroom lots is not permitted as it serves to confound traceback or foodborne illness investigations and could hinder efforts to remove implicated product from the food chain.

If field personnel encounter a situation that is not addressed in this guidance document they should contact their Field Supervisor or Regional Manager for assistance.

Approved Food Establishments

The "Wild Mushroom Retail Sales Application" submitted by the Food Establishment requesting approval will be received by Betty Ragsdale in the Richmond Office and reviewed by the Retail Food Technical Specialist. Approved applications will be saved on the LAN for future reference.

Other Points of Concern that can be Discussed with the Harvester and/or Retail Establishment

- Mushroom caps with gills (oyster, shiitake, etc.) should be avoided by beginner harvesters because they can be confused with others in the same group that are poisonous and deadly.

- Wild harvested mushrooms should be thoroughly cooked and never consumed raw.

- Wild harvested mushrooms should not show any signs of spoilage (rotten, soggy, mushy, slimy, moldy) and/or insect infestation.

- Mushrooms need to breathe and the packaging should have air holes or be made of a breathable material.

- Any other types of wild mushroom species found offered for sale that were not approved with the application would be out of compliance with this FOM and as a result, they may be subject to regulatory action.

References and Resources

- Schwab, Alexander. *Mushrooming Without Fear: The Beginner's Guide to Collecting Safe and Delicious Mushrooms*. Skyhorse Publishing Inc., 1996.
- Lincoff, Gary. *The Complete Mushroom Hunter: An Illustrated Guide for Finding, Harvesting, and Enjoying Wild Mushrooms*. Quarry Books, 2010.
- Kuo, Michael. *100 Edible Mushrooms*. The University of Michigan Press, 2007.
- National Audubon Society. *Field Guide to Mushrooms of North America*. Chanticleer Press Inc., 1981.
- National Audubon Society. *Field Guide to Trees of Eastern Region North America*. Chanticleer Press Inc., 1980.
- Dr. Kathy Hodge, Cornell University
- Mr. Steve Haas, Haas Shrooms
- North American Mycological Association (NAMA) www.namyco.org
- The American Mushroom Institute (AMI) www.americanmushroom.org
- The International Mycological Association (IMA) www.ima-mycology.org

Procedure III-11: Risk-Based Approach to Territory Management

As with most governmental programs, the Food Safety Program is faced with an ever increasing workload and limited resources. In an effort to focus resources on establishments with the greatest food safety risk, Food Safety Specialists will utilize a risk-based approach when managing their territorial workload. The Food Safety Program has developed this guideline to be used in determining the best approach to managing your territory.

Risk Categories and Inspectional Frequencies

A firm has the potential to fall into one of three risk categories based on the types of operations that take place within the establishment. All firms will be rated as high, medium, or low risk. Each category has a corresponding inspectional frequency range. To determine the risk category and the inspection frequency of a firm, use the risk assessment questionnaire (Appendix A or B).

Type of Establishment Operation and Risk Category

In order to decide whether a firm is high, medium or low risk, you must look at the establishment's operation. Types of operations include, preparing foods that require time/temperature to maintain safety, preparing foods requiring a variance or HACCP plan, reheating and hot holding ready-to-eat items or simply offering prepackaged food items. Sometimes a firm may have several operations that would cause the firm to fall into different risk categories (i.e. a market with a produce department and deli). In those situations, the overall risk category will correspond to the highest risk operation in that establishment.

Please note that the inspectional frequencies indicated by the risk assessment are target frequencies for our program. In certain instances, such as larger inspectional inventory, etc., you may not be able to achieve these frequencies. However, keep in mind that the general pattern with regards to risk should always be followed with high risk firms being inspected more frequently than medium or low risk firms. Please note that the stated frequencies are for those firms with a good compliance history. If a firm's inspection indicates poor compliance and/or unusual situations, then consider increasing the frequency of inspection.

Full Risk Based Inspections

A full risk based inspection is an inspection based on the five foodborne illness risk factors. These risk factors are:

1) Food obtained from unapproved sources,
2) Improper cooking of raw animal or plant foods,
3) Improper holding of time/temperature control for safety food,
4) Contaminated food contact equipment and surfaces, and
5) Poor personal hygiene of food employees.

A risk based inspection should focus on violations and observations pertaining to these five risk factors. The inspector should focus efforts on areas of the establishment where food is being prepared, cooked, cooled, hot or cold held, and stored. Also consider activities that are static vs. active. Static operations would be cold holding or date marking, whereas active operations would be activities such as cooking raw animal food, hot holding, and reheating. If there is an opportunity to observe an active operation, do so over a static operation, leaving the static operation for later. Minimal attention should be given to grocery aisles of prepackaged non-TCS foods (example: only spot check infant formula dates or grain/pet food for signs of pest activity). In addition, FSS may choose to scan the retail aisles for uninspected products at his/her own discretion. Focus your efforts on areas of the firm where foodborne illness risk factor violations are most likely to occur.

Limited (specific) Inspections

A limited inspection is an inspection of an establishment conducted to observe only specific objectionable conditions. Limited inspections should only be conducted for compliance follow up inspections when a single item or issue was in violation or possibly for a specific complaint in which the firm was recently inspected. An example would be if the hot water was not working at the hand sink in the deli area of a retail store, which caused the inspection to be classified as VAI. When you return for the follow up inspection, it would not be necessary to re-inspect the entire store. A simple check to see that the hot water was restored at the dysfunctional sink would be all that was necessary.

Firms Not Routinely Inspected but Not Classified as Exempt

In order to focus resources on establishments with the greatest food safety risk, Food Safety Specialists will not routinely inspect the following types of establishments:

- Beer and Wine Stores that sell pre-packaged beverage products but do not have food or beverage service. Examples include Total Wine and More
- Drug Stores that sell pre-packaged food products, including infant formula, but do not have food or beverage service. Examples include CVS, Rite Aid, Walgreens
- Farmers Markets
- Health Food Stores that sell pre-packaged food/dietary supplement items but do not have food or beverage service. Examples include GNC, The Vitamin Shoppe, Vitamin World
- Ice Vending Machines
- Pre-Packaged Only Food Stores that sell infant formula and/or unwrapped produce. Examples include Dollar General, World Market, K-Mart, Roses
- Produce Stands that sell whole, uncut produce and/or pre-packaged items from approved sources

However, if any of the above firm types call for a pre-opening inspection, an initial inspection will be conducted. These firms will be marked in VIPRS under Billing Exemption as “Routine Inspection.” However, this shall not diminish the authority of the Department under §3.2-5102 of the Virginia Food Laws. The Department will still inspect these establishments if complaints are received or if any other reason warrants an investigation/inspection. Firms included in the category above that request a pre-opening inspection in an unreasonable amount of time, will be made aware that they may open without inspection with the understanding that on their next inspection, they will be marked out of compliance for not receiving an inspection prior to opening. As their schedule allows, but not more than 30 days, the FSS will conduct the inspection of the establishment. If there is a question as to whether or not a firm should be marked exempt as Routine Inspection, the Food Safety Specialist should contact their Regional Manager.

NOTE: The Virginia Food Laws define “food” as “….intended for human consumption and introduction into commerce.” Therefore, food banks or other establishments that do not introduce food into commerce will be marked as exempt from annual fee and inspection in VIPRS.

Tips for Effectively Managing Territory

Food Safety Specialist should attempt to inspect past due firms using a risk-based approach. When conducting routine inspections, Food Safety Specialists shall inspect firms on their Past Due list first, not their monthly workplan. Use the Reporting feature in VIPRS to access your Past Due list. Filter out firms that are marked as

"Annual Fee and Inspection" and "Routine Inspection." Prioritize firms following the below guidance (highest priority listed first):

1) Inspect firms that are overdue for a VAI or OAI follow up inspection
2) Inspect firms that do not have a designated risk category in VIPRS
3) Inspect firms that are high risk, then medium risk, and then low risk
    - Consider whether the firm is a dual jurisdiction firm and therefore also inspected by VDH. If yes, then priority should be given to non-dual jurisdiction firms.
    - Consider the compliance history of the firm. Priority should be given to firms with previous VAI or OAI inspections.
4) Group inspections in the same county/city/zip code/street to eliminate excess driving time.

This list is not all inclusive. Food Safety Specialists shall use sound judgement in order to prioritize establishments with the highest food safety risks.

Retail Risk Assessment and Inspection Frequency Questionnaire
Annex A

Low

1) Pre-packaged food only:	YES ☐	NO ☐
2) Beverage service only:	YES ☐	NO ☐
3) Firms not considered to be high risk or medium risk:	YES ☐	NO ☐

Medium

4) Food processing for same day service. May involve hot and cold holding of TCS foods after preparation or cooking:	YES ☐	NO ☐
5) Handling, cutting, grinding raw meat products:	YES ☐	NO ☐
6) Cutting/slicing ready-to-eat meats and cheese:	YES ☐	NO ☐
7) Ready-to-eat foods with extensive food handling, e.g. sandwiches:	YES ☐	NO ☐

High

8) Complex processing including cooking, cooling and reheating for hot holding involving TCS foods:	YES ☐	NO ☐
9) Conduct specialized processes, e.g., smoking and curing; acidified foods; reduced oxygen packaging that require a variance:	YES ☐	NO ☐
10) Using time as a public health control:	YES ☐	NO ☐
11) Preparing TCS food from raw animal ingredients:	YES ☐	NO ☐
12) Situations where a high potential exists for cross-contamination:	YES ☐	NO ☐
13) Processing unpasteurized ciders or juices:	YES ☐	NO ☐
14) A food salvage operation:	YES ☐	NO ☐

To determine risk category:

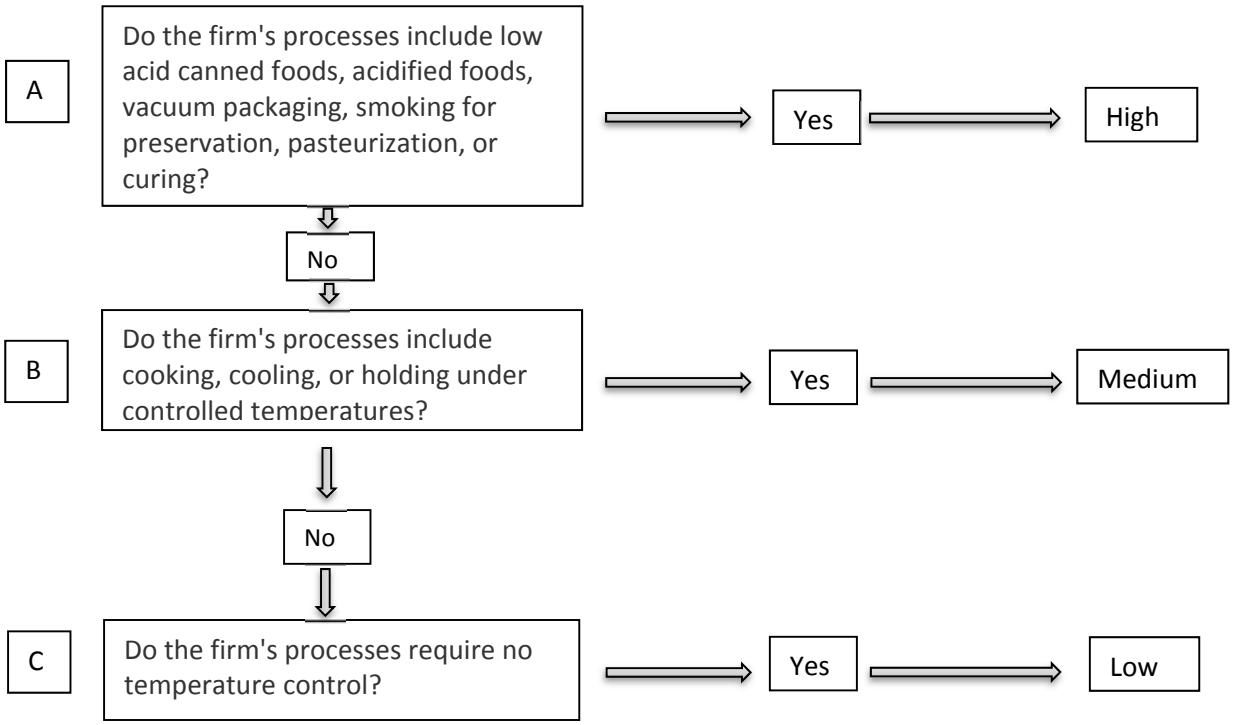
- If Yes is selected to any questions 1-3, and no is selected for all questions 4-14, the risk is low.
- If Yes is selected to any questions 4-7, and no is selected for all question 8-14, the risk is medium.
- If Yes is selected to any questions 8-14, the risk is high.

Low: 1-36 months
Medium: 1-18 months
High: 1-12 months

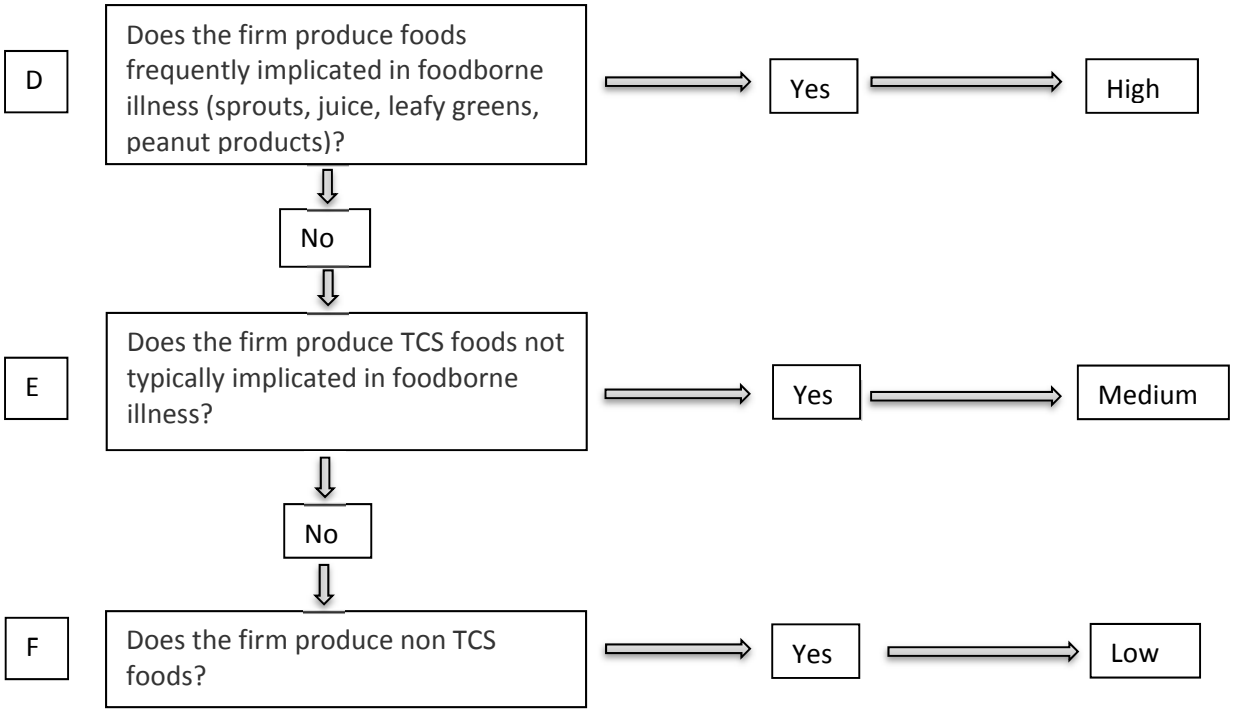
GMP Risk Assessment and Inspection Frequency Questionnaire

Annex B

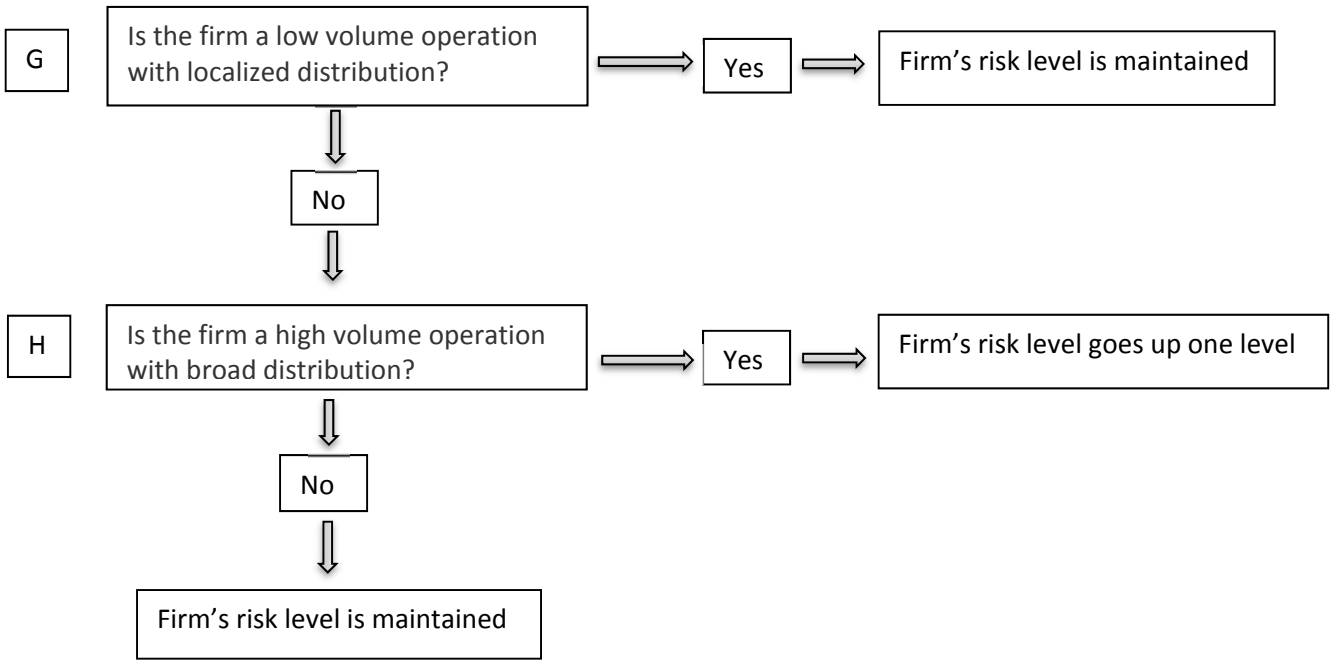
Question Set 1:



Question Set 2:



Question Set 3:



To determine risk

1. Answer questions in question sets 1, 2 and 3, following arrows on the GMP Risk Assessment and Inspection Frequency Worksheet
2. Determine risk to be low, medium, or high and use the reference (below) to determine inspection frequency. Enter this data onto the GMP inspection report on page 4
3. This document does not need to be saved. It is intended to be used as a guide and does not have to be submitted with the inspection report.

Examples:

a. If you answer question A" Yes", then the risk is high and there is no need to go further with the flow chart.
b. If you answer question A "No", but question B "Yes", you must continue with the flow chart.
c. If you answer question A "No", question B "Yes", but question "C" "Yes" or "No", you must continue with the flow chart.

To determine inspection frequency:

Low risk 1-36 months
Medium risk 1-14 months
High risk 1-10 months

FIELD OPERATIONS MANUAL

Procedure III-12
New

FOODS, INCLUDING "PIES" ACCEPTABLE FOR UNREFRIGERATED RETAIL DISPLAY

Some food products and especially pies, e.g. pumpkin, sweet potato, custard type pies etc., traditionally, due to formulation, have been classified as "potentially hazardous" food products requiring refrigeration. However, some manufacturers, again, by formulation, have made their product "shelf stable" and can no longer be considered as potentially hazardous.

For a questionable food product, by any manufacturer, including home operators, to be considered "shelf stable", they must submit the appropriate data to the Food Safety Central Office for review and acceptance. When their product is accepted as "shelf stable", the product will be included in the attached table.

Note: Our agency does not "approve" food products. We only "accept" the product/process.

January 31, 2000

1 February 18, 2000

Name / Address	Pie Type / Shelf Life / Code	Other Information
American Products Co., Inc 101741 Miller Rd. Dallas, TX 75236	Pumpkin Pie, Pecan Pie, Chocolate Chess Pie, Lemon Chess Pie - 5 day shelf life Buttermilk Chess Pie - 3 day shelf life	Labeled "Refrigerate After Purchase" "SSP" - on bottom of pie tin
Best Foods Baking Co. 30 Inez Drive Bay Shore, NY 11706	Entenmann's Deluxe French Cheesecake Entenmann's Pumpkin Pie: 3 day shelf life	Labeled "Sell By" Y umpkin pie may also be sold under the label "General Foods Corporation 250 North St. White Plains, NY 10625."
Blue Bird Baking Company 521 Kiser Street Dayton, OH 45404	Pre-baked Pumpkin Pies: 22 oz and 32 oz sizes	3 day shelf life. May also be labeled with Holmes Apple Farms or Family Secret Labeled "Refrigerate after opening"
Bonerts Slice of Pie 3144 West Adams Street Santa Ana, CA 92704	Sweet Potato pie and No Sugar Added Pumpkin Pie: 5 day shelf life	NOTE: 8" Egg Custard and 8" Coconut Custard Pies are not shelf stable.
CGI Desserts, Inc. 5065 Westheimer, Ste. 700 Houston, TX 77056 phone: 713-439-1000 Sold at Food Lion	7" Layer - 5 day shelf stable Black Forest Cake, Carrot Cake, Sinfully Chocolate, Red Velvet Cake, Coconut Delight, Sinfully White, and Golden Vanilla Cake	CAKES THAT ARE NOT SHELF STABLE: Irish Mist, German Chocolate, Carmel Apple Cheese Tart, Candy Mountain with Reese's Peanut Butter Cups, Vesuvius.

Country Home Bakers **302 28th ., S.E.** **Grand Rapids, MI 49548**	Pumpkin Pie: 3 day shelf life Sweet Potato Pie: 2 day shelf life (post bake) Note: Both pies sold raw, cooked at store and sold in store containers. Prebaked pumpkin pies: 3 day shelf life	Also sold under Jessie Lord, Readi-Bake, and Sanders Labeled "Refrigerate After Opening" coded: JLCHB on bottom of pie tin
Davis Bakery, Inc. **1600-C Roseneath Road** **Richmond, VA 23230**	Lemon, Pecan, and Chocolate Fudge Pies	
H. C. Brill Co., Inc **1912 Montreal Rd.** **Tucker, GA 30084**	Ready-to-use Fillings: Bavarian Cream, Lemon, Chocolate, Key Lime, and Powdered Meringue Mix	All fillings are acidified foods NOTE: The meringue mix must be prepared in accordance to the labeled instructions
Kyger's Bakery, Inc. **3825 Street Road 38 E.** **P.O. Box 4731** **Lafayette, IN 47903**	Lemon, Banana, Butterscotch, Coconut, and Chocolate Filling and Meringue Pies	
M. L. Dessert Corporation T/A **Michele's Family Bakery** **7746 Dungan Road** **Philadelphia, PA 19111**	Pre-baked Pumpkin Pie: 3 day shelf life	Side of box has "REG. PENNA. DEPT. AGR (MLD)" and "CONN. LIC. 1662" Pies found mostly in Safeway Stores, Inc in Northern VA
Mrs. Smith's Bakeries, Inc. **2900 Flowers Industrial Way** **Suwanee, GA 30024**	Coconut, Chocolate, and Lemon Meringue Pies Pumpkin Pie and Sweet Potato Pie: coded on bottom of tin "CT3934" Pre-baked Pumpkin pie: 3 day shelf	Also sold under Pies, Inc. and Our Special Touch Bakeries, Inc. NOTE: Sweet potato and Pumpkin pies

	life after thawing	
Pies Incorporated **300 Lake Hazeltine Drive** **Chaska, MN 55318**	Pumpkin Pie: 3 day shelf life	Must be packaged in Pies, Inc. labeled container
Plush Pippin Corporation **21331 88th Place South** **Kent, Washington 98031**	Pumpkin Pie: 8" pre-baked code -44214 9" pre-baked code -24214 10" pre-baked code -54514 8" un-baked code -43214 9" un-baked code -23214/ 51214 10" unbaked code -58514 Lemon Meringue Pies: 8" pre-baked code -42340 9" pre-baked code -22340	First five digits on bottom of pie tin are the manufacturer's code 33764. The last five digits are the codes listed to the left of this column. Lemon Meringue and Pumpkin pies have a 4 day shelf life.
Rich Products Corporation **1150 Niagara Street** **Buffalo, NY 14213**	Pumpkin pie: 5 day shelf life 8" pre-baked code -30390 10" pre-baked code -30453 8" un-baked code -04482 10" un-baked code -14760 Buttercreme: 7 day shelf life	Label may not contain Rich Products as manufacturer therefore look for the code listed to the left of this column.
Sara Lee Bakery / Country Commons **3727 Ventura Dr.** **Arlington Heights, IL 60004**	Sweet Potato Pie: 8" un-baked code -5827 10" un-baked code -5870 8" pre-baked code -5826 10" pre-baked code -5834 Pumpkin Pie: 8"un-baked code -5302 9"un-baked code -5835 10" un-baked code -5804 8" pre-baked code -5301 10" pre-baked code -5805 8" Pre-baked "no sugar added" Pumpkin Pie: code on bottom of tin NPH-AT-3 0652	All pies will have the following on the bottom of the tin: NPH-AT-3 + four digit number NPH = non potentially hazardous AT = ambient temperature display and sale 3 = shelf life AND the UPC code will display the four digits listed

Sarsfield Foods Limited **P.O. Box 368** **15 Roscoe Drive** **Kentville, N.S. B4N 3X1** **Canada**	Pumpkin Pie: 8" ; 24 oz Code 16123 9" ; 37 oz Code 47923 10" ; 44 oz Code 61223	All pies will have the following on the bottom of the tin: NPH-AT-3 + five digit number NPH = non potentially hazardous AT = ambient temperature display and sale 3 = shelf life
Western Country Pies **250 West Crossroads Sq.** **Salt Lake City, UT 84115**	Pumpkin, Sweet Potato, Lemon Meringue, Chocolate Meringue, Coconut Meringue Pies	Coded with "WCP S/S" on the bottom of tin WCP = firm name S/S = shelf stable

PRODUCTS, OTHER THAN PIES, THAT HAVE BEEN TESTED
for pH and Aw, or other documentation has been received concerning shelf stability of the product

Dawn Food Products, Inc.	Ruhl Fondant	Product used as a glaze or an ingredient in icing and contains > 90 sugars pH: 0.79 Aw: Undetermined due to the nature of the product.
Unilever (Lipton)	“Country Crock Churnstyle Spread”	Product maybe unrefrigerated, but is labeled with a conservative “Keep Refrigerated” to maintain quality.

4 February 18, 2000

5 February 18, 2000

FOODS, INCLUDING "PIES" ACCEPTABLE FOR UNREFRIGERATED RETAIL DISPLAY

Some food products and especially pies, e.g. pumpkin, sweet potato, custard type pies etc., traditionally, due to formulation, have been classified as "potentially hazardous" food products requiring refrigeration. However, some manufacturers, again, by formulation, have made their product "shelf stable" and can no longer be considered as potentially hazardous.

For a questionable food product, by any manufacturer, including home operators, to be considered "shelf stable", they must submit the appropriate data to the Food Safety Central Office for review and acceptance. When their product is accepted as "shelf stable", the product will be included in the attached table.

Note: Our agency does not "approve" food products. We only "accept" the product/process.

January 31, 2000

FIELD OPERATIONS MANUAL

PROCEDURE III-13
NEW

EXPIRATION DATES – INFANT FORMULA AND GRADE A DAIRY PRODUCTS

With the exception of infant formula and fluid milk products, the Virginia Food Laws (adopted regulations) do not require sell-by dates on food products. This is a voluntary practice utilized by industry as a means to maintain product quality. **Product dating is a food quality issue not a food safety issue.** As long as the product is wholesome and fit for human consumption it can be sold regardless of the product date.

INFANT FORMULA

Each and every time you find outdated infant formula (or infant formula without an open code date) being offered for sale, list this noncompliance as an objectionable condition on the inspection report indicating both the number of containers involved and the actual dates on the containers. In addition request and witness the voluntary destruction of the violative containers. If the firm refuses to voluntarily destroy the infant formula place it under seizure. List the pounds destroyed or seized on the data entry section of the inspection report.

Example: Five/13 oz. cans of Similac Infant Formula were observed outdated (1 NOV 2011) and being offered for sale on the retail shelf.

GRADE A DAIRY PRODUCTS

The Virginia Dairy Services regulations prohibit the sale of grade “A” dairy products after their pull date. 2VAC5-490-40(2)(q) of the Regulations Governing Grade "A" Milk states, “No person may sell or offer for sale any packaged grade A pasteurized milk, grade A pasteurized milk product, or milk product after the date of the ‘pull date’ on the package.” Grade “A” dairy products include, but are not limited to**,** whole milk, skim milk, nonfat milk, buttermilk, chocolate milk and similar products, half and half, table cream, sour cream, cottage cheese and yogurt.

To address this regulation, Food Safety Specialists are to incorporate a check of grade “A” dairy products as part of their retail store inspection. If you find outdated product, list it as an

objectionable condition on the inspection report and have it removed from sale. It will not be necessary to have the product destroyed.

It is important to point out that there is no public health concern with the consumption of pasteurized dairy products after their code date has expired. Pasteurization is a process that completely eliminates all pathogens from dairy products during processing. Pull dates are established with an allowance of time after the date has expired to give the consumer time to consume the product after purchase. For fluid products like whole milk the product should maintain its quality for four days after the expiration date. For cultured products like yogurt the time is more likely a couple of weeks.

June 2012

FIELD OEPRATIONS MANUAL

PROCEDURE III-14
New

RETAIL EGG INSPECTION

The inspection of eggs on the retail level is to be incorporated into your routine inspection of retail establishments. Three lots of eggs will be inspected at each firm, several cartons of each lot. The inspection will consist of temperature check and visual examination of the eggs for checks, loss eggs. (dirty eggs and leakers).

If the eggs are not refrigerated at less than 45 degrees F., you should have the firm refrigerate the eggs immediately.

If you encounter a problem with dirty eggs and/or leakers in excess of 2%, or with checked eggs in excess of 9%, management should be notified and given an opportunity to re-work the eggs. If this can not be done by the time the inspection is completed, the eggs will have to be seized until the inspector has an opportunity to return to the establishment to re-inspect the eggs. If the firm does not wish to re-work the eggs, the lot should be removed from sale and returned to the processor for re-working. Actual candling of eggs is not necessary except in situations where it could assist in the determining a violation involving check eggs. (i. e. When checks are approaching 10%).

In all instances where violations are encountered, documentation on the Inspection Report should include a description of the violation, the number of dozens of eggs in violation and the producer’s name or P-number.

Revised August 99 Edited April 5, 2000

Originally drafted by JAM

FIELD OPERATIONS MANUAL

PROCEDURE III-15
NEW March 30, 2015

GAME ANIMALS and NON-AMENABLE SPECIES

The following guidance document has been developed to assist inspection personnel in regards to VDACS Office of Dairy and Foods regulatory approach to operations that slaughter commercially raised, non-amenable species of meat and/or poultry.

Currently, USDA Food Safety and Inspection Service list amenable species as:

1. **Meat** – Beef, swine, sheep, goat, and equines

2. **Poultry** – Chickens, turkeys, ducks, geese, guineas, ratites (emu, ostrich, rhea), and squab.

Any species of meat and/or poultry that do NOT appear on the lists above are considered to be **non-amenable**, and therefore are not subject to USDA/OMPS regulations. Nor are they included in the USDA/OMPS inspection process. As a result, finished products of these species are not required to, *nor may they* bear the federal or state mark of *mandatory* inspection, when introduced into commerce. They include animals such as reindeer, elk, deer, antelope, buffalo, bison, rabbits, pheasant and quail. Processors of non-amenable species may elect to go under voluntary inspection with OMPS/USDA.

NOTE: The Virginia Department of Game and Inland Fisheries has regulations regarding the sale of wild game. In general, it is unlawful to buy or sell wild game for human consumption. See www.dgif.virginia.gov of call 804-367-1000 for more information.

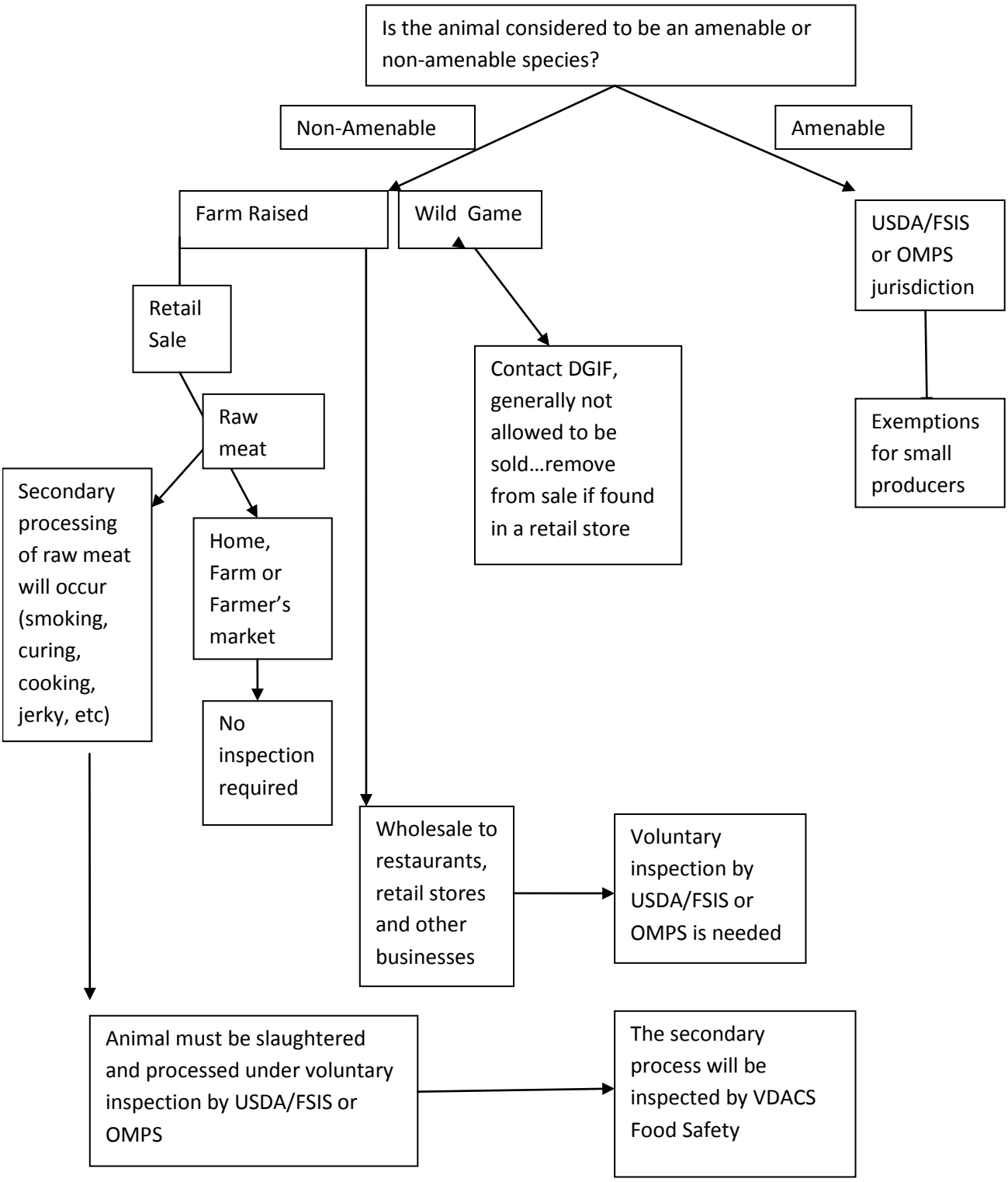
Sales to or at Retail Establishments/Restaurants: Vendors/processors who wish to slaughter, process, and sell the meat of non-amenable species at or to restaurants or retail stores must apply for voluntary inspection by the Office of Meat and Poultry Services (804-786-4569). *FSSP personnel will not conduct any inspections related to the safe and sanitary slaughter of these non-amenable species for these purposes.*

Sales from the Home or Farmer's Market: For vendors/processors who wish to sell the raw, cut meat of non-amenable species from their home or at farmer's markets directly to the end consumer, VDACS Food Safety and Security Program will not put these processors under inspection. If the operator wants to engage in a secondary process (i.e. smoking, curing, sausage-making, cooking, salting, or preparing jerky) using non-amenable game animal meat, the slaughter of that meat must be overseen by OMPS or USDA through voluntary inspection. The secondary process (curing, smoking, jerky, cooking) will be inspected by the Food Safety and Security Program. Although VDACS Food Safety and Security Program will not routinely put primary processors on file (those who slaughter, cut, and sell raw meat), these operations are

still subject to the Virginia Food Laws and GMPs and we reserve the right to investigate complaints, collect samples, and enforce the Food Laws on a case-by-case basis.

Wild Game: Wild non-amenable species that can be legally hunted under Federal or State regulatory authority cannot be sold, but can be harvested for personal consumption. The Office of Meat and Poultry Services and USDA do not offer voluntary inspection for wild-caught game. Wild-caught game would only be able to be sold during the hunting season (according to the Department of Game and Inland Fisheries provisions in §29.1-536) and may only be sold directly to the consumer from the farm or at a farmers market (if one is in operation during the hunting months.) Therefore if any wild game is found in a retail store it shall be removed from sale.

DECISION FLOW CHART



FIELD OPERATIONS MANUAL

Procedure III-16
Revised

PRELIMINARY INSPECTIONS OF PROPOSED WATER BOTTLING SITES

Whenever you are requested to conduct a preliminary inspection of a proposed water bottling operation (i.e. inspection of a spring site for approval/disapproval as a water source) you should first obtain as much information as possible concerning the proposed operation to assure that the operation will be within our area of jurisdiction. If the proposed operation is within our jurisdiction, you should then contact the appropriate Field Office of the Virginia Department of Health-Office of Drinking Water (ODW) for the particular county where the water source is located (see http://www.vdh.virginia.gov/drinking water/contacts/). You should arrange a joint visit with the ODW district engineer to the site of the proposed operation. The district engineer will make recommendations on whether the site will be acceptable as a water source, and will advise us on source protection (i.e. how to build the spring cistern to prevent surface water contamination, how far down in the ground to place the sides of the spring box to preclude surface water seeping into the supply, should the ground be sloped away from the spring box, etc.). These recommendations are advisory. However, these engineers have the expertise in protection of water sources, and it is unlikely that we would ever seriously modify these recommendations. In addition to these recommendations, the engineers may require that specific tests be performed, some of which may take a considerable amount of time, and they may recommend various treatments for the water supplies to be considered safe.

If it is determined that the site will be unacceptable for water bottling purposes, the person proposing the bottling operation should be informed of this decision. However, if the site is acceptable, the proposed operator should be informed of what modifications are necessary to properly protect the water source, and recommendations should be made for setting up the water bottling operation in compliance with the Virginia Food Laws and applicable regulations. To that end, you should review and leave with the operator CFR Parts 110, 129 and 165. Part 110 addresses good manufacturing practices, Part 129 addresses the construction of the water bottling operation and Part 165

deals with water quality standards. (Copies of these parts can be obtained from the office; in many cases, copies of these parts will have already been mailed to the proposed operators).

If the proposed site needs modification to be acceptable for bottling purposes, a water sample need not be taken until the modifications have been completed (it makes no sense to collect a sample of water for bacteriological analysis from an unprotected source). If the site does not need modification, a sample should be collected by the firm to determine the quality of water prior to treatment.

As with any visit, a memorandum should be completed to fully document these meetings and any recommendations that you make.

Revised September 25, 2007

FIELD OPERATIONS MANUAL

Procedure III-17
Revised

FILLING OUT THE SEIZURE/RELEASE FORMS

THE SEIZURE FORM SHOULD BE FILLED OUT ACCORDINGLY:

Date: Date the seizure was made.

Issued to: Name of the Person-in-Charge of the operation.

Title: Title of the Person-in-Charge of the operation.

Firm: Name of establishment.

Address: Address of establishment.

Product type: Select from the dropdown.

Product: Name of the product seized. The product code should be recorded here, if practical.

Estimated Amount: Estimated amount in pounds.

Product Manufacturer: Name of the manufacturer of the seized product.

Product Manufacturer Address: Address of the manufacturer of the seized product.

Seizure Reason: The reason for the seizure. Example: "The corn being ground contained rodent pellets."

Seizure Remarks: Any additional remarks regarding the seizure. If samples are taken, the sample numbers should be listed here.

Receipt Acknowledged By/Title: The name and title of the most responsible person involved in the operation. The person should sign on the signature line below.
NOTE: The refusal of the firm representative to sign the form does not negate the seizure. The referenced products are still under seizure.

Form delivered by Inspector: The Food Safety Specialist name should be typed and then signed on the signature line below.

If the product has to be released, a “Release” form will be filled out. This form is identical to the “Seizure” form and should be filled out using above information. The “Reason” section should state the reason for the release. (Example: Laboratory analysis reveals that the product complies with the Virginia Food Laws. This product is released from seizure.)

Revised June 2014

Field Operations Manual

Procedure III-18
NEW

INSPECTIONS OF FIRMS PRODUCING FOOD PRODUCTS SUSCEPTIBLE TO CONTAMINATION WITH ALLERGENIC INGREDIENTS

INTRODUCTION

Each year regulatory agencies receive reports of consumers who experienced adverse reactions following exposure to an allergenic substance in foods. Food allergies are abnormal responses of the immune system, especially the production of allergen-specific IgE antibodies to naturally occurring proteins in certain foods that most individuals can eat safely. The food protein fragments responsible for an allergic reaction are not broken down by cooking or by stomach acids or enzymes that digest food. These proteins can cross the gastrointestinal lining, travel through the bloodstream and cause allergic reactions throughout the body. Some foods can cause severe illness and, in some cases, a life-threatening allergic reaction (anaphylaxis) that can constrict airways in the lungs, severely lower blood pressure, and cause suffocation by the swelling of the tongue or throat.

Frequently such reactions occur because the presence of the allergenic substance in the food is not declared on the food label. Current regulations require that all added ingredients be declared on the label, yet there are a number of issues that have arisen in connection with undeclared allergens that are not clearly covered by label regulations.

There is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies: Peanuts, Soybeans, Milk, Eggs, Fish, Shellfish, Tree nuts and Wheat.

If you are requested to do a follow-up investigation involving an allergic reaction, which appears to be caused by an undeclared food other than the eight foods listed above, contact your Field Supervisor or Regional Manager for further guidance.

OVERVIEW

The purpose of this guide is to provide the Food Safety Specialist with guidance in the area of inspectional methods, techniques and procedures to use during on-site inspections. This guide covers the following problem areas:

1. Products that contain one or more allergenic ingredients, but the label does not declare the ingredient in the ingredient statement;

2. Products that become contaminated with an allergenic ingredient due to the firm's failure to exercise adequate control procedures, e.g. improper rework practices, allergen carry-over due to use of common equipment and production sequencing, inadequate sanitation;

3. Products that are contaminated with an allergenic ingredient due to the nature of the product or the process; i.e., use of common equipment in chocolate manufacturing where interim wet cleaning is not practical and only dry cleaning and product flushing is used;

4. A product containing a flavor ingredient that has an allergenic component, but the label of the product only declares the flavor, e.g., natural flavor. Under current regulations, firms are not required to declare the individual components of flavors, certain colors, and spices. However, firms are encouraged to specifically label allergenic components/ingredients that are in spices, flavors, and colors;

5. Products that contain a processing aid that have an allergenic component, but the label does not declare it. Processing aids that contain allergenic ingredients are not exempt from ingredient declaration under the incidental additives regulation 21 CFR 101.100(a)(3), and therefore, must be declared.

   Note: Processing aids are generally considered to be substances that are added to a food for their technical or functional effect during processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food. See 21 CFR 101.100(a)(3) for more information.

INSPECTION PROCEDURES

PRODUCT DEVELOPMENT

Determine whether the firm identifies potential sources of allergens starting in the product development stage. For example, do they identify for each product all ingredients, ingredient components, processing aids, rework, processing steps, environmental conditions, and product carry over due to use of common equipment? Are potential sources of allergen contamination identified at each step?

Determine whether the products contain allergenic ingredients. For the most frequently produced products, request formulas. If formula information is refused, construct formulations by observing production.

Determine if the firm has assessed whether the packaging material used in direct contact with the product contains an allergen; e.g., foil coated with wheat ingredient as releasing agent.

Does the firm use processing aids in the manufacture of the food? If so, do the processing aids contain allergenic ingredients? If so, what are the allergenic ingredients?

Does the firm use spices, flavors, or colors contain allergenic components? If so, do these spices, flavors or colors contain allergenic ingredients? If so, what are the allergenic ingredients?

RECEIVING
Determine whether the firm uses allergenic ingredients.

Determine how these allergenic ingredients are handled at receiving and how they are identified and/or segregated in raw material storage.

Determine if the firm stores any of these allergenic ingredients in bulk tanks. If yes, how are the contents of the bulk tanks identified?

Determine what the firm's procedure is for receiving ingredients into the bulk tank and what controls are in place to ensure proper product identity at all times.

Determine if the firm receives any raw materials that are labeled with a statement, such as "this product was processed on machinery that was used to process products containing (allergen)" or "may contain (allergen)". If so what ingredients? How are such statements reflected on the label of the firm's finished product?

Determine whether a label from each incoming lot of finished product labels is visually checked, either upon receipt or during production, to ensure the ingredient statement is correct for the intended product and that it is not a carton of mixed labels.

EQUIPMENT
Try to inspect the equipment before processing begins and document the adequacy of clean up. For example, is there a build up of residual materials or pockets of residue in corners that may contain an allergen from previous runs? What is the condition of the conveyor belts? Is there any product build-up above processing zones? Also observe whether the firm checks the processing lines for cleanliness prior to production and whether they maintain a record of the check. Is this simply a visual check or does the firm use another method?

Determine whether the firm uses a Clean-In-Place system for cleaning fixed lines, e.g. pipelines and tanks. If so, how do they ensure that the interior surfaces of the welds in the lines are smooth and will not entrap material during operation? Are the pipes free from dents?

Determine if equipment is cleanable, e.g. stainless steel, accessible for cleaning.

Determine if the firm has a written procedure for cleaning. Does the cleaning procedure include how to clean and at what frequency the equipment is cleaned? Describe procedure.

Determine if equipment and production lines are shared to process different products.

Determine if shared equipment is cleaned in between production of a product that contains allergens and one that does not, e.g. full clean-up with detergent and water.

PROCESSING

Determine what control measures, if any, are used by the firm to prevent the contamination of products that do not contain allergens? What control measures does the firm employ? At what steps in production are the control measures instituted?

Determine how the firm separates the production of those products that contain allergens from those that do not contain such ingredients. Is cross-contact likely to occur, e.g., airborne food particles, dust, allergen product residues from equipment, etc.?

Determine if unpackaged, exposed product on the processing line is handled in a way that protects it against contamination.

Determine if shared processing lines (equipment) are used. If yes, is allergen-containing product processed first or last?

Determine what is done with the portion of the product that is a mixture of the non-allergen product and allergen product, e.g., is it sent to waste or for animal feed or reworked?

Determine whether the firm reworks product, and if they only rework like products. How is rework controlled? Is rework inventory reconciled at the end of the day?

Determine how product to be reworked is stored and identified. Are rework containers clearly labeled?

Determine how such rework holding vessels and containers are cleaned and stored.

FINAL PRODUCT TESTING

Determine if the firm performs final product testing for the presence of allergens in products not intended to contain allergens. If so, for which allergens, and how is the testing documented?

Determine what method of analysis is used and the sensitivity of that method.

Determine if the testing is routine or periodic.

LABELING

Determine if finished product label controls are employed, e.g., how are labels delivered to the filling and/or packaging area?

Determine if product labels with similar appearances but different ingredients are controlled to ensure that the correct label is applied to correct product.

Determine if finished product packages are inspected prior to distribution to ensure that an allergen containing product is labeled properly, or that labels are inspected during production. Is that inspection documented?

Determine if secondary ingredients are incorporated in the final product ingredient statement, e.g. the raw material mayonnaise, which contains eggs, oil and vinegar.

Determine if the firm uses a statement such as "this product was processed on machinery that was used to process products containing (allergen)" or a statement such as "may contain (allergen)" if the firm uses shared equipment for products that contain and products that do not contain allergens. Any other such statement? Ask the firm why they believe they have to use the precautionary statement.

Determine if the finished product label reflects any precautionary statements that were on the raw material labels, e.g., "this product was processed on machinery that was used to process products containing (allergen)".

Determine if the firm has a system to identify finished products made with rework containing allergenic ingredients. Does the final product label identify the allergens that may have been in the reworked product?

SUMMARY

Allergens may be unintentionally added to food as a result of practices such as improper rework addition, product carry-over due to use of common equipment and production sequencing, or the presence of an allergenic product above exposed product lines. Such practices with respect to allergenic substances may be insanitary conditions that may render the food injurious to health and adulterate the product.

Therefore, it is extremely important that the inspector attempt to fully identify or demonstrate the likely sources of and possible routes of contamination of the product with undeclared allergen ingredients. The critical points in the food manufacturing operations should be identified and special attention given to those areas.

Questions that arise should be directed to your Field Supervisor and/or Regional Manager for resolution. If needed, additional information on allergens can be found at the FDA (www.fda.gov) and National Food Processors Association (www.nfpa-food.org) web sites.

Issued new March 7, 2002

FIELD OPERATIONS MANUAL

Procedure III-19
NEW

FOOD LABELING GUIDE

Introduction
The VDACS-Food Safety Program is responsible for assuring that foods sold in Virginia are safe, wholesome and properly labeled. The purpose of our labeling program is twofold, to prevent the economic deception of the consumer and to provide the consumer the necessary information to make an informed choice. Food manufacturers (including home operations) must provide full and complete labeling.

It is impractical in this guide to address every food label question that might arise. When you encounter a problem you may submit a label to the Regional office for review, call the office if immediate assistance is needed, or check the FDA computer web site at: www.cfsan.fda.gov/dms/lab-cat.html

The following Food Label requirements must be met in accordance with FDA Code of Federal Regulations and Virginia Food Laws 3.1-396 (e):

A) Identity Statement (Name of food) – 21 CFR 101.3
- Must be on principal display panel (front of container)
- Must be an accurate description of product (common or usual name)
- Must be one of the principal features on the label (prominent on the label)
- If sold in optional forms (whole., sliced, etc.) must be part of identity statement or visible through container
- Must be LARGEST TYPE on principal display panel

B) Ingredient Statement - 21 CFR 101.4
- Required if food is fabricated from 2 or more ingredients.
- Must be declared by common or usual name (ie: sugar instead of sucrose)
- Colorings, Additives, Preservatives must be declared (common or usual name)
- Must be in descending order of predominance by weight.
- Type size must be at least 1/16 of an inch.
- May be on principal display or information panel.
- Ingredients that are fabricated from 2 or more sub components must list the sub-components.

**Allergens - A complete breakdown of ingredients will be necessary if the product contains an allergen (such as peanuts, tree nuts, milk, soy, shellfish, fish, and wheat).

C) **Net Weight /Quantity of Contents –** All inspection reports should contain the following statement:

> **For information on the declaration of the net weight or content, please contact the Department of Weights & Measures at 804/786-2476.**

D) Name & Address of Manufacturer, Packer or Distributor – CFR 101.5

- May be on principal display panel or information panel.
- Must be conspicuous.
- Unless the name given is the actual manufacturer it must be accompanied by a qualifying phase. For example: "manufactured for" or "distributed by."
- Street address if the firm's name/address are not listed in a current city directory or telephone book.
- City or town, state and zip code.

LABELING OF SPECIFIC FOOD PRODUCTS

Eggs – See Virginia Egg Law

- All egg cases or retail containers in which eggs are kept for the purpose of sale, or offered or exposed for sale shall be marked (labeled) according to one of the grades and sizes, or marked ungraded.
- The labeling shall appear on the principal display panel of the package.
- The retail containers shall bear the name and address of the packer or distributor when the eggs are kept, offered, or exposed for sale or sold at any place other than on the premises where packed.
- The grade and size, or ungraded status shall be spelled out in full.
- When loose eggs are on display for sale, a sign shall be attached showing the grade and size, or the ungraded status, in lain view to the public.
- Safe Handling Statement - Effective September 4, 2001 all shell eggs that have not been treat to destroy salmonella must bear the following statement:

SAFE HANDLING INSTRUCTIONS: To prevent the illness from bacteria; keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly. Statement must appear on the principal display panel (PDP), information panel, or inside portion (top lid) of egg carton.

Ground Beef

If the firm elects to voluntarily put a sell-by date on any packaged meat, poultry or seafood product they **can not** remove, alter, destroy or obscure the original sell-by date. If the product is repackaged, the replacement label shall bear the original sell-by date. One note, this does not apply to meat, seafood or poultry that is canned or cured.

When qualifying terms (ie: lean, extra lean, premium,…) are used in the advertising/labeling of ground beef products it is necessary to state the maximum %fat in

the product. This information can either be stated on the product label or on a placard in reasonable proximity to the ground beef display.

Apples - See Virginia Apple Law

Marking (labeling) – Each closed package shall be marked in a conspicuous manner on the outside thereof, or upon a durable stuffer placed within, but readily readable from the outside, with the information hereafter listed:

- The correct size of apples;
- The minimum quantity of apples;
- The correct variety or varieties of apples;
- The official grade of apples; and
- The name and address of the grower or packer.

Organically Grown Foods

For information regarding Organic Food Labeling and/or 3rd party certification please contact Tom Smith @804/786-3549.

Sell-By dates on packages

With the exception of infant formula and fluid milk products, the Virginia Food Laws do not require sell-by dates on food products. This is a voluntary practice utilized by industry as a means to maintain product quality. **Product dating is a food quality issue not a food safety issue**. As long as the product is wholesome and fit for human consumption it can be sold regardless of the product date.

Issued new March 8, 2002

FIELD OPERATIONS MANUAL

Procedure III-20
NEW

Nutrition Labeling and Education Act – (NLEA)

The Nutrition Labeling and Education Act requires most foods to bear nutritional labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements. Suggest firms interested in NLEA contact FDA at:

Office of Food Labeling
HFS-810
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
301/436-2373

Nutrition Facts Panel 21 CFR 101.9 (d)

May be placed on Principal Display Panel or Information Panel and must meet specific requirements.

Mandatory Nutrients Needed on Nutrition Facts Panel 21 CFR 101.9 (d) (7) (ii)

- Calories
- Total Fat
- Cholesterol
- Total Carbohydrates
- Sugars
- Vitamin A
- Calcium
- Calories from Fat
- Saturated Fat
- Sodium
- Dietary Fiber
- Protein
- Vitamin C
- Iron

Percent Daily Values (DV) based on a 2,000 calorie diet
(not required on foods for children less than 4 years of age)

Voluntary Nutrients

- Calories from Saturated Fat,
- Polyunsaturated Fat, Potassium
- Insoluble Fiber
- Other Carbohydrates.
- Monounsaturated Fat
- Soluble Fiber
- Sugar Alcohol

Serving Size 21 CFR 101.12

1) Based on Reference Amounts
2) Common Household Measurements
3) Discrete Units.

Nutrition Label Formats 21 CFR 101.9

Several different formats can be used and is based on available package space and size of package.

Nutrient Claims – Must be approved by FDA & Listed Below

If a nutrient content, health or implied claim is made on a label then Nutritional Labeling is mandatory and the firm loses their exemption. A claim directly or by implication characterizes the level of a nutrient in the food (ie: lowfat).

Nutrient Content Claims – General Requirements 21 CFR 101.54 (a)

- Calories - 21 CFR 101.60
- Sodium - 21 CFR 101.61
- Fat, Fatty Acids - 21 CFR 101.62 (b)
- Fatty Acids - 21 CFR 101.62 (c)
- Cholesterol - 21 CFR 101.62 (d)

Core Descriptors (Approved by FDA)

- High – 21 CFR 101.54 (b)
- Fiber - 21 CFR 101.54 (d)
- Lean - 21 CFR 101.62 (5) (e)
- Reduced/Less -21 CFR 101.62 (4)
- More/Added - 21 CFR 101.54 (e)
- High Potency - 21 CFR 101.54 (f)
- Good Source - 21 CFR 101.54 (c)
- Low -21 CFR 101.62 (b) (2)
- Extra Lean - 21 CFR 101.62 (5)(e)
- No Fat - 101.62 (b)
- Light/Lite – 21 CFR 101.56

Synonyms For Core Descriptors (Approved by FDA)

- Free – No, zero, without, trivial source of, insignificant source of, negligible source of
- Low – Little (few for calories), contains a small amount of, low source of
- High – Rich in, Excellent Source of
- Good Source – Contains, Provides

****Please note: Companies that manufactured/processed foods under brand names that used terms that were undefined prior to 10/25/89 are exempt and allowed to use those undefined terms (ex – Diet Coke - Diet is not on the list approved by FDA)****

Health Claims General Requirements - 21 CFR 101.14

Authorized by Regulation 21 CFR 101.71

- Dietary Saturated Fat & Cholesterol and Coronary Heart Disease 21 CFR 101.75
- Dietary Fat and Cancer - 21 CFR 101.73
- Sodium and Hypertension – 21 CFR 101.74
- Calcium and Osteoporosis - 21 CFR 101.72
- Sugar Alcohols and Dental caries – 21 CFR 101.80
- Soy protein and Coronary Heart Disease (CHD)
- Soluble Fiber from whole oats or psyliium and CHD – 21 CFR 101.81
- Fruits, Vegetables, and Grain Products for cancer - 21 CFR 101.76
- Fruits, Vegetables, and Grain Products for CHD – 21 CFR 101.77
- Folate and Nueral Tube Defects - 21 CFR 101.79
- Sterol/stanol esters and Coronary Heart Disease **(TENTATIVE – Interim Rule)**

Implied Claims - 21 CFR 101.65

An implied claim is one that suggests that a nutrient or ingredient is absent or present in a certain amount or claims about a food that suggests a food may be useful in maintaining healthy dietary practices. The requirements for labels with health symbols (vignettes) is considered the same as making an implied claim (EX. - heart shape symbol).

Exemptions to Nutritional Labeling - 21 CFR Part 101.9 (j)

These exemptions deal only with the necessity of having the "Nutrition Facts" panel, and has no effect on the mandatory labeling information (i.e., common name of product, net contents, ingredient statement, name and address of responsible firm).

EXCEPTION - If any nutrient content claim (e.g., "low fat") or health claim is made, the exemption is not applicable.

Automatic Exemption

Establishments **are not required to apply/file for a Small Business Exemption** if they have less than < 10,000 units sold and less than < 10 employees.

Small Business Food Labeling Exemptions

Under 21 CFR 101.9(j)(1), a business may be exempt from the requirement of including a "Nutrition Facts" panel on its food packages. This exemption is based on number of employees and number of product units sold.

Currently, a business must apply with FDA for a Small Business Exemption.

The exemption includes businesses with fewer than 100 employees and annual sales of less than 100,000 units. No exemption may be taken if a company has more than the number of employees listed regardless of number of units produced.

The exemption also applies to retailers with annual gross sales of less than $500,000, or with annual gross sales of food to consumers of less than $50,000. The number of employees is based on the average number of full time equivalent employees.

1) A "product" is a food with the same brand name and statement of identity.
2) A "unit" is a package or, if unpacked, the form in which the product is offered for sale.
3) "Company" includes domestic and international affiliates.

Businesses must file an annual notice with FDA that they are claiming an exemption based on number of employees and units of product. The web site available to find information regarding Small Business Exemptions and the necessary forms is: **www.cfsan.fda.gov/dms/sbel.html**

Other Exemptions - Nutritional Labeling - 21 CFR Part 101.9 (j)

Foods served for immediate consumption.

1) Restaurants, delis, bakeries, etc. with facilities for immediate consumption.
    a) Situations where food is consumed immediately or while customer walking away.
    b) Ready-to-eat foods not for immediate consumption.
    c) Primarily prepared on-site.
    d) Not offered for sale outside that location.

Probably the biggest area of concern will be in deciding whether a R-T-E food not for immediate consumption was primarily processed/prepared on-site.

Administratively, it is impossible to identify each type of food sold and the exact amount of processing or preparation that would be needed to say that the food was "processed and prepared primarily" on site. Circumstances at the retail level must be the deciding factor.

To provide guidance in this area:

When food is processed or prepared (including portioning) primarily on premises and sold there, as in the prepared food sections of supermarkets, nutritional labeling is not required. Therefore, nutritional labeling would not be required on bread that is shaped, filled, decorated, assembled or customized and baked in the retail establishment. Cheese that is sliced and portioned according to directions given by the consumer and pudding that is portioned according to directions given by the consumer need not be nutrition labeled.
Conversely, if the food arrives at a store in a form to be sold directly to the consumer (ie: it is standardized) then nutritional labeling must be required. In this situation, preparation or processing of the food is accomplished primarily at another establishment and the same food is then shipped to a retail food store in a form that requires minimal or no further processing (ie: thawing the product).

Donated foods- NLEA covers "food offered for sale" only.

Foods shipped in bulk form – 21 CFR 101 .24, 101.100

1) Used in the manufacture of other foods.
2) To be processed, labeled, or repacked at another site.

Raw fruit, vegetable and fish - 21 CFR 101.42, 101.43, 101.44, 101.45

1) Voluntary nutrition labeling program.

Nutritional Labeling of Dietary supplements - 21 CFR 101.36

1) Require Supplement Facts Panel.

Foods of no nutritional significance (ex: coffee beans, tea leaves) 21 CFR 101.100

1) All nutrients must be at a level that allows a declaration of "zero".
2) Incidental Additives.
   A) Incidental additives are substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.
3) Processing Aids.
   A) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.
   B) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.
   C) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food. (iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives.

Issued new March 8, 2002

Procedure III-21: Food Manufacturing Inspection Procedures

In order to maintain a uniform inspection program, this procedure describes practices Food Safety Specialists (FSS) shall follow when conducting manufacturing inspections. The criteria in the training protocol are based on the requirements of the Food and Drug Administration's (FDA's) Manufactured Food Regulatory Program Standards (MFRPS) Inspection Program.

Definitions

- CFR: Code of Federal Regulations
- FALCPA: Food Allergen Labeling and Consumer Protection Act
- FOM: Field Operations Manual
- FSP: Food Safety Program
- HACCP: Hazard Analysis and Critical Control Points
- NLEA: Nutritional Labeling and Education Act
- ORAU: Office of Regulatory Affairs University
- SSOPs: Sanitation Standard Operating Procedures
- VIPRS: VDACS Inspection Program Reporting System

Considerations before Conducting an Inspection

Training of Personnel

FSS shall only lead inspections for which they are qualified, in accordance with the Procedure I-23 VDACS Training Manual.

Basic manufacturing inspections may only be conducted by FSS who have completed prerequisite online ORAU course requirements and basic field training which consists of completing at least 10 joint trainee-led inspections with a qualified trainer and receiving a minimum of two (2) "Acceptable" ratings.

Advanced/Specialized manufacturing establishments are those that produce commodities specifically associated with a federal regulation that has been adopted by the state of Virginia. These include firms that fall under Seafood and Juice HACCP regulations, and Acidified or Low Acid regulations. These specialized inspections can only be performed by FSSs who have successfully completed the following requirements as described in Procedure I-23 VDACS Food Safety Program Training Manual:

- Participate in two joint field training inspections.
- Completion of the specific Advanced Food Inspection Curriculum Coursework.
- After successful completion of the course participate in one evaluation or field inspection audit that is found to be acceptable by a qualified field inspection trainer or qualified field inspection auditor prior to conducting independent inspections.
- Within one year after being released to do specialized food inspections complete a second evaluation or field inspection audit that is found to be acceptable by a qualified field inspection trainer or a qualified field inspection auditor in the area of specialty.

Advanced/Specialized Inspections
Special considerations should be taken when conducting inspections of establishments that fall under industry-specific codes of federal regulation including Seafood HACCP, Juice HACCP, Acidified Foods, Low Acid Canned Foods, and Dietary Supplements.

For Seafood and Juice HACCP inspections, the "Fish and Fishery Products Hazards and Controls Guide" or the "Juice HACCP Hazards and Controls Guide", respectively, must be used to identify and evaluate the hazards associated with the highest risk product/process.

In addition to a review of the firm's hazard analysis and HACCP plan, the FSS shall conduct their own hazard analysis and compare it to the firm's, review applicable monitoring, verification, and corrective action records. Deficiencies shall be noted on the relevant code-specific inspection report available in VIPRS. The FSS shall assess deficiencies in the firm's monitoring and sanitation procedures during the walkthrough of the facility.

The FSS must assess and document the Seafood or Juice HACCP firm's sanitation monitoring for the applicable eight key areas of sanitation on the applicable specialized inspection report.

In general, FSSs should review the course manual and other materials they receive at the FDA courses that are relevant to the specialized inspection to re-familiarize them with documentation or record-keeping that is required, special monitoring regulations, etc. For example, when conducting an Acidified Foods inspection, materials provided in the FD202 course should be reviewed. The firm must be able to produce a Better Process Control School certificate. Other documentation required for acidified food processors include scheduled processes for each acidified product, filing those processes with FDA, and monitoring records. This list is not all-inclusive, but the inspection shall cover all of the citations in the applicable CFR.

FDA Contract Inspections
The Commonwealth of Virginia enters into an annual contract with FDA to perform inspections of and obtain samples from manufacturing firms, warehouses, and distribution centers in Virginia that fall under FDA jurisdiction. In order to fulfill this function, the FSS must be able to use the FDA's Product Code Builder. In addition, the FSS must be trained in FALCPA and NLEA regulations to perform comprehensive labeling reviews to satisfy contract requirements.

Information concerning the Reportable Food Registry and FDA User Fees shall be distributed to all firms that fall under FDA jurisdiction.

Protective Clothing (See FOM Procedure I-12 Dress Code for additional information)
Each FSS has been issued lab coats and an annual allowance of $100 for steel-toed boots. Other personal protective equipment may be necessary when conducting an inspection. Follow the firm's GMP safety procedures. If an injury or accident occurs while on the job, the FSS shall immediately report the incident to their Regional Manager.

Conducting a Manufacturing Inspection

<u>Inspection Preparation</u>

Document Review
Before conducting a manufacturing inspection, FSS shall review the Virginia Food Laws and CFRs that are applicable to the operation (please see Appendix 1 at the end of this document for a list of Virginia-adopted

CFRs). Any additional laws that may be useful for conducting an inspection (i.e. NLEA and FALCPA) may also be reviewed. In addition, FSS should review FOMs that are relevant to the inspection; this may include procedures related to sampling, complaints, recalls, etc.

The FSS shall review the establishment file including previous inspection reports, consumer complaints, and any previous compliance action using the online VIPRS system and/or paper files. Sometimes it may be necessary to consult additional materials depending on the commodity being inspected (for example: FDA guidance exists for sprout producers and should be reviewed prior to inspecting a sprout processor.)

Equipment Review
Before conducting an inspection, FSS shall verify that all supplies and equipment are available for use and working properly and calibrated, when necessary. Supplies and equipment include inspection forms, lab coat, hair net (or equivalent), probe type thermometer, temperature sensitive tape for verifying hot water warewashing final rinse temperature, sanitizer test strips, flashlight, alcohol swabs, coolers, ice packs, sample seals, laptop computer and printer, and digital camera.

Equipment Verification
FSS should refer to the procedure on verifying the accuracy of thermometers and pH meters. FSS are responsible for ensuring equipment has been verified according to that procedure prior to conducting an inspection of a manufacturing facility.

See FOM Procedure II-05 Equipment Verification/Calibration for additional information.

Introduction and Record Review

Proper Identification
The FSS shall introduce himself/herself to the most responsible person in charge at the firm at the beginning of the inspection and include their full name and agency. The FSS shall confirm that the person to whom they are speaking is the most responsible person in charge at the firm and is able to answer questions during the walkthrough. The name and title of the most responsible person of the firm (even if they are not present during the inspection) shall be entered into the "Attention To" field on the inspection screen in VIPRS. VDACS has jurisdiction over all manufacturing firms in the state of Virginia regardless of whether or not they engage in interstate commerce.

Establishing FDA jurisdiction
If the inspection is an FDA contract inspection, the FSS shall state that they are conducting an inspection on behalf of FDA and ensure that the firm both wholesales product and engages in interstate commerce. In addition the FSS will mark "FDA Contract" field "YES" in the Inspection Screen in VIPRS. FSS shall also present FDA credentials, in addition to state credentials and issue the firm a Form 482 – Notice of Inspection. The firm may make note of the FSS's badge number if necessary, however credentials shall never be allowed to be photocopied.

State the purpose of the visit (Routine, Visit, Complaint, Follow-Up, Recall Check, FDA Contract, etc)
The FSS shall announce the intent to conduct an inspection and state the reason for inspection. The extent and purpose of inspection are required fields in the inspection screen in VIPRS and must be filled out in order to generate/issue an inspection report.

Refusals (See FOM Procedure I-04 Refusal to permit entry, inspection or sampling)
If an FSS is refused entry to the firm or permission to collect samples, they must explain to firm management that the Commonwealth of Virginia grants this authority via the Virginia Food Laws. Read 3.2-5102 followed by 3.2-5126(A)(5) and (B) of the Virginia Food Laws to the person refusing the request. If the FSS is still denied permission to inspect, the Regional Manager shall be contacted immediately. FSS must document any refusals (refusal to collect samples or conduct an inspection, refusal to provide records required by law, etc) in the "Refusals" section of the Inspection Screen. This section will display on any new inspections entered into VIPRS on May 5, 2015 and going forward. Note: refusal to sign the inspection report is not a "refusal," but can be mentioned in the additional remarks section that the "firm did not sign per company policy."

FSS will not ask for complaint records unless the inspection is a complaint inspection or a recall effectiveness check. The firm is not legally obligated to share complaint records with the FSS.

Adherence to the company's polices
The FSS must exercise caution in all activities in the firm. Follow the firm's GMP/sanitation program for employees: wash and sanitize hands, shoes, and equipment as indicated by the firm's policies. Restrict unnecessary movement between various areas in the firm and when possible, complete your activities in one area before moving to the next.

Initial Interview
When conducting the initial interview, the FSS must identify and/or verify firm and management information such as business address, mailing address if applicable, phone number, and legal name of the business. In order to describe the individual responsibilities of key personnel, FSS must document the name and title of the person to whom the report is going to be issued. For non-contract state inspections, corporate officers do not need to be identified and the legal status of the firm can be verified by inquiring if the firm is an LLC, corporation, individual, or partnership. This information will be documented in the "owner" screen of VIPRS. Any significant changes since the last inspection may be documented in the additional remarks section of the report.

The FSS shall determine the facility layout and the type of products manufactured prior to beginning the walkthrough. A review of the company's records which may include preventive controls plans, HACCP plans, pest control records, employee health and/or allergen policies, water source records, SSOPs, or other records must be conducted. If the firm is willing to share food safety related complaints, the FSS may want to focus inspection on sanitation or HACCP deficiencies that could have led to the complaint. FSS shall ask for the firm's recall plan and if any recalls have occurred since the last inspection.

Facility Registration
The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires most domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. *The Bioterrorism Act covers both interstate and intrastate firms.* Home-operations are not required to register, however, if the processing takes place in a separate building on a person's property, they must register with FDA. Facilities may register electronically at http://www.access.fda.gov. The firm must re-register every two years on even years (e.g. 2012, 2014, 2016) for compliance. Failure to register under the BT Act does not make the food product(s) violative. *DO NOT record the firm's Bioterrorism number and DO NOT record the failure to register as an objectionable condition on the inspection report*.

Conducting the Inspection

Walkthrough

Evaluate the methods, facilities, and controls used in manufacturing, storage and distribution of foods. If there are several products being prepared at once, do not try to cover the entire operation during one inspection. Select the product with the greatest potential for bacterial contamination or which poses the greatest risk.

To choose the highest risk product, consider these factors:

- the number of steps involved;
- if temperature control is required;
- if the finished product is ready-to-eat;
- if a HACCP plan is used;
- if the product has been implicated in foodborne illness outbreaks or recalls

Each inspection will be different, but the techniques for gathering evidence will be the same. Follow the selected processing line, to the extent possible, from beginning to end to identify and observe potential sanitation problems. To reduce the risk of contaminating finished product with raw, some firms will insist that the inspections be conducted "backwards"—that is, to follow the production from the end of the production line to the start. This is acceptable, and shows that the firm is thinking about food safety.

Observe employee sanitary practices and other activities that are critical to the safe and sanitary production and storage of food. Provisions used for assessing these activities can be found in 21 CFR Part 110.10: disease control, cleanliness, education/training and appropriate supervision.

These basic observations shall be made for every firm:

(a) Procedure(s) regarding employee cleanliness and sanitation.
(b) Flow of employee traffic: entrance(s) to the processing area, location of locker rooms(s) and bathrooms, locations of different work stations, raw product areas vs. finished product areas, employee movement into different processing areas, and any other areas that may affect the safe and sanitary production and storage of food.
(c) Employees' uniform and dress: shirts, pants, jackets, lab coats, shoes, jewelry, hairnets, gloves, and any other piece of clothing that could contribute to product contamination
(d) Employees' actions: hand washing, cross contamination of food contact surfaces with nonfood contact surfaces, and good hygienic practices.
(e) Documentation of employee training regarding sanitary practices.
(f) Oversight and routine monitoring of proper employees practices.
(g) Documentation that the firm is following its own standardized processes based on records (HACCP, Risk Control, SSOPs, etc) that the FSS has reviewed.

Assess the likelihood that conditions, practices, components and/or labeling could cause product to be adulterated or misbranded.

(a) Use the principles of HACCP during your inspection to identify: hazards specific to the selected product, critical control points in the process, and potential areas for contamination or adulteration related to product handling and the processing environment.

(b) Observe the processing of the product selected for the inspection focus. Place emphasis on the risk factors related to the processes and controls for the specific products observed. See 21 CFR 110.80 for processing control requirements and 21 CFR110.35 for sanitary operations.
(c) Connect observations made to potential product adulteration. A single observation may be only "part of the story."
(d) Identify routes of potential cross-contamination between allergen and non-allergen ingredients.
(e) Observe the condition of the labeling area, labeling equipment and conveyor equipment.
(f) Evaluate labels for accurate declarations of ingredients by reviewing the formula and raw material labeling and by observing ingredients being staged and/or batched/mixed during production. Reference the NLEA and FALCPA for more information regarding labeling as needed.
(g) If new ingredient suppliers are used, verify that labels are still accurate. Pay special attention to new allergens.
(h) Written observations must record specific areas or situations that would lead to instances of actual or *potential* adulteration of food products.
(i) If the firm allows it, speak with employees doing the work on both current and past practices, conditions and circumstances.

Distinguish between significant vs. insignificant observations and isolated incidents vs. trends:

(a) Determine which observed violations are significant, i.e. those closely linked to a public health risk and/or product adulteration.
(b) Have the firm take appropriate intervention measures and/or onsite corrective actions for each significant observation that is determined to be out of compliance.
(c) Examples of significant vs. insignificant observations: Focusing on areas where cross-contamination of cooked and raw products might occur shall be addressed *before* addressing a food employee chewing gum and wearing nail polish; or, emphasizing RTE salad processing and handling before addressing soiled non-food contact surfaces.
(d) Examples of isolated incident vs. trends observations: Identify patterns in documentation over time rather than focusing on single incidences that were corrected and not repeated; observe employee handling practices across different products that create potential for contamination and indicate deficiencies with monitoring of employee practices; identify sanitation deficiencies in similar areas of production related to facility construction or layout.

Interviewing Personnel

No one knows a firm's procedures, processes, and routines better than the firm's own staff. Therefore, good communication skills are essential to getting all the information an inspector needs. Here are some suggestions for good interviewing techniques:

(a) Actively engage in dialogue with the firm's owner(s) and employees.
(b) Be very specific when asking questions and requesting information from the firm.
(c) Use common language which is familiar to the firm.
(d) Ask open-ended questions and follow-up questions (questions that cannot be answered with "yes" or "no").
(e) Reconcile discrepancies in information provided by firm employees.
(f) Be respectful of peoples' time during the inspection.
(g) Inform the person accompanying you during the inspection of the deficiencies at the time they are observed.
(h) Explain the public health significance associated with each deficiency.

(i) Avoid giving specific recommendations for desired corrective actions. There may be many ways for the firm to comply and/or the recommendation may not achieve desired compliance. It is appropriate to offer a suitable solution, but it is the firm's responsibility to make the final decision.
(j) Point out positive examples and areas of improvement from the previous inspection.

Collection of Evidence
Examples of evidence that supports significant violations could include:

(a) Copies of invoices regarding ingredient supply and/or product distribution will be necessary in the event of a traceback.
(b) Copies of records noting deficiencies in monitoring of critical limits i.e., pH, temperatures. If the records are confidential, the firm must mark the document as such. Otherwise, it can be copied and uploaded onto the LAN.
(c) Photographs of insanitary food contact surfaces or processing environment must be representative of conditions observed during inspection. The scope of the photographs shall be identified through the variation of close up photographs and large encompassing views per FOM Procedure I-09 Digital Camera-Use & Mounting of Photographs.
(d) Samples – raw material or finished product must be collected according to FOM Procedure IV-02 Identification and Preparation of Samples.

FSS shall offer payment to the firm for all product samples and ask if the firm requires a companion sample.

(e) Packaging or photographs of product labeling may be collected to support misbranding observations.

Verify that corrections have been made to the deficiencies identified during the previous inspection.

(a) Review all previously identified deficiencies during the current inspection.
(b) If the previous deficiencies have not been corrected, note it as a "repeat" violation on the GMP Inspection Report.

Immediate Corrective Actions
Certain violations require immediate action in order to avert a serious public health hazard. The FSS must alert the firm's appropriate management when an immediate corrective action is necessary and in some instances may need to contact their supervisors when such a situation is encountered to discuss how to remediate the problem. When a violation is corrected in the FSS' presence, the FSS shall still note the violation on the report and also check the corrected on site (COS) button to document firm compliance.

For information related to the seizure and release of food products, see FOM Procedure I-00 Compliance and Enforcement Procedures and Inspection Classification as well as Procedure III-17 Seizure & Release Forms.

A firm may voluntarily denature and dispose of adulterated or misbranded products. FSS shall oversee denature or disposal of such products and document information including the type of product, amount of product, and reason for destruction on the inspection screen. In addition, FSS shall document in the corrective actions field of the inspection report when the firm voluntarily chooses to reheat, refrigerate, or pull products from sale, and shall document the amount and type of product in question. The firm's signature on the final inspection report indicates that they voluntarily completed these actions.

Make every reasonable effort to discuss all observations with the management of the establishment as they are observed to minimize surprises, errors, and misunderstandings when the Inspection Report is issued. This discussion must include those observations, which may be written on the Inspection Report and those that will

only be discussed with management during the closeout meeting. Industry may use the opportunity to ask questions about the observations, request clarification, and inform the inspection team what corrections have been or will be made during the inspection process.

Completing the Inspection Report

Assigning Risk
The business information screen in VIPRS requires a risk category and inspection frequency be keyed into the system prior to submitting an inspection report. Manufacturers inspected by the FSP will be categorized into three levels of risk – high, medium, and low. Inspection frequencies are delineated in month increments and are inversely proportional to the level of risk. See FOM Procedure III-11 Risk-Based Approach to Territory Management.

Business Specific Information
FSS shall enter as much business specific information on the business information screen as possible to aid in subsequent inspections. Check to ensure that if processes have changed at the facility the corresponding commodity-specific boxes are marked in VIPRS. Again this information is required before the inspection report can be generated.

Business Distribution
FSS shall enter information regarding the firm's distribution on the business information screen in VIPRS. This section was implemented into the VIPRS system on May 5, 2015. Information such as the percentage of ingredients received from out of state suppliers; percentage of products sold to out of state customers; and percentage of products sold wholesale are required fields that must be filled out before the inspection report can be generated.

Information in the Inspection Screen
Before the inspection report is printed and submitted, the FSS must review the firm's quality assurance program (if the firm has one) and complete the Quality Assurance Review section in the Inspection Screen. This section will display on any new inspections entered into VIPRS on May 5, 2015 and going forward. The firm's quality assurance program must be in writing and must include the risks associated with the firm's products/processes and the controls. "YES" shall be marked if the firm has a written quality assurance plan that addresses the risks associated with the firm's products/processes and the controls for those risks. "Firm does not have a quality assurance program" shall be marked if the firm does not have a written quality assurance program and/or the program they have does not include the risks associated with their products/processes and the controls. "NO" shall be marked if the firm states they have a quality assurance program but it is inaccessible for whatever reason and therefore unable to be reviewed. If "NO" is marked, the Quality Assurance Description field must be filled out with an explanation of why the quality assurance program was not reviewed. FSS may also choose to provide additional comments on the firm's quality assurance program if "YES" or "Firm does not have a quality assurance plan" is marked.

In addition, if the FSS took any pictures during the inspection or has any additional attachments related to the inspection, "YES" should be selected in the Pictures Taken/Additional Attachments section in the Inspection Screen. If there are additional attachments or pictures related to the inspection these will be uploaded to the LAN. The FSS must also obtain the firm's signature either electronically on the Inspection Screen in VIPRS or on the paper inspection form if VIPRS is unavailable. The firm's signature indicates that the inspectional findings and violations were discussed with the most responsible person at the firm at the time of the inspection and this person was given the opportunity to respond.

Marking Items IN/OUT/NA

After completing a full inspection, all items on the GMP report (#1-46) must be filled in with "IN" for items in compliance, "OUT" when violations are observed, or "NA" when the item is not applicable to the facility or the product observed during the inspection. When an item is marked "OUT" of compliance, FSS must choose the applicable CFR citation and copy that citation into the text box before writing out a narrative sentence of what was observed. Code Reference Guidance documents are available for FSS on the Network, if needed.

Reportable observations will be written succinctly, accurately and clearly. Conditions listed shall be significant and relate to an observed or potential problem with the facility, equipment, processes, controls, products, employee practices, or records. Observations must be factual, objective, and free of commentary. "Potential problems" shall have a reasonable likelihood of occurring based on observed conditions or events. Observations which are listed shall be significant and correlate to regulated products or processes being inspected noting possible causes of contamination. Observations of questionable significance shall not be listed on the Inspection Report, but will be discussed with the firm's management so that they understand how uncorrected problems could become a violation. If the same violation was noted on the previous inspection report, the "R" must be marked on the current report indicating this is a repeat violation.

Critical Violations vs. Non-Critical Violations

Although the CFR does not designate critical and non-critical violations, VDACS FSP has determined the following violations to be considered "critical." The printed inspection report given to the firm will NOT show whether a violation is critical or not. The designation of violations as either critical or non-critical is for internal tracking purposes ONLY. When an item is marked "OUT," it will automatically be checked as either critical or non-critical when the specific violation code is selected.

GMP Inspection Critical Violations:

#1 – Personnel with sores, infections, etc restricted from food processing areas; report such health conditions to supervisors

#3 – Hands properly washed and/or sanitized; good hygienic practices

#6 – Responsibility for disease control and employee hygiene is clearly assigned to competent supervisory personnel

#21 – Insects, rodents, and other pests not present; insecticides and rodenticides used and stored so as to prevent contamination of food

#22 – Food contact surfaces are cleaned and sanitized at intervals frequent enough to avoid contamination of food products; non food contact surfaces of equipment clean

#23 – Water from approved source and adequate in quantity for its intended use; water temperatures and pressure maintained at suitable levels for its intended use

#24 – Plumbing carries sufficient quantities of water; plumbing adequately designed, installed, and maintained in a manner to prevent contamination including backflow and cross-connection; proper floor drainage

#36 – Responsibility for firm sanitation assigned to one individual; Chemical, microbiological, or extraneous material testing procedures used to identify sanitation failures or food contamination, if necessary

#37 – Raw materials, other ingredients, and rework are adequately inspected for adulteration and stored to prevent contamination; ingredients washed or cleaned as necessary

#38 – All manufacturing operations are conducted in a way that prevents contamination of food contact surfaces, minimizes growth of microorganisms, and minimizes contamination or adulteration of food.

#39 – Refrigerated foods maintained at 45 degrees F or below as appropriate for particular food involved; frozen foods frozen; hot foods maintained at 140 degrees F or above

#46 – Pre-operational inspection conducted

Additional Remarks
FSSs are encouraged to provide educational materials to firm employees as necessary. When provided, FSS's shall enter a description of field-level compliance actions meaning all materials provided to the firm in the additional remarks section of the inspection report.

FSS may also use the additional remarks section to document other noteworthy actions.

Close-Out the Inspection

Review the Inspection Report
After completion of the inspection report, two (2) copies shall be printed in order to leave a copy with the firm and one to keep for the FSS' records. Meet with the most responsible person-in-charge possible to discuss your findings and observations. Additionally, encourage the firm to invite management personnel from all the relevant sections of the firm to share in the discussion.

During the discussion, be frank, courteous and respectful towards management. Point out that the observations listed on the inspection report are of objectionable conditions found during the inspection. Then, explain the significance of each one. Try to relate each listed condition to the applicable sections of the regulations. Answer any questions that firm management may have related to your inspectional observations and provide any additional information that may be appropriate to discuss.

Provide courteous customer service by providing prompt/timely responses to client requests. Avoid using jargon and acronyms without explanation. Use interpreters, drawings, demonstrations, or diagrams to overcome language barriers. A telephonic interpreter is available to FSS. If you require a translator and do not have the information for launching the service, please contact your regional office or see the network at H:\(F-o-o-d S-a-f-e-t-y and Security Program)\(Food Inspect)\(Code Reference Guidance Documents)\Telephone Interpreter Service.

Do not be overbearing or arbitrary in attitude or actions. Do not argue if management voices a different view of the observation or of your opinions. Make clear the prime purpose of the discussion is to call attention to objectionable practices or conditions which must be corrected.

Determine management's intentions regarding correcting objectionable conditions. If the inspection is an FDA contract, the FSS must confirm and document how many days the firm will need to implement a corrective action for each violation. The firm may propose corrections or procedural changes and ask the FSS if this is satisfactory. If this involves areas where the FSS' knowledge, skill, and experience are such that it is known the change will be satisfactory, the FSS can so advise management. But FSS shall not assume the role of an authoritative consultant. In areas where there is any doubt, the FSS must explain to management that an endorsement of the proposed corrections cannot be made. Concentrate on what needs to be done rather than how to do it.

Signature
VIPRS inspection reports automatically populate with the signature of the FSS who is logged into the system and any secondary inspectors who are chosen from a drop-down menu in the inspection screen.

If signing the report is against firm policy, document in the additional remarks section of the inspection form that the firm refused to sign and inform the person that refusal to sign does not negate the findings of the inspection. Signing does not denote agreement with the findings, only an acknowledgement that the findings

were discussed with the most responsible person at the firm at the time of the inspection and that the person was given the opportunity to respond.

Classify the Inspection

There are three basic classifications to identify establishment conditions that will establish the need for follow-up inspections or regulatory actions. Follow-up inspections will be based on VDACS criteria and timelines.

For state (non-contract) inspections, the classifications are NAI, VAI and OAI.

NAI – No Action Indicated

Establishment has no or limited objectionable conditions and is considered in substantial compliance with the Virginia Food laws and applicable regulations. Next Routine Inspection varies depending on the firm's risk assessment.

VAI – Voluntary Action Indicated

Objectionable conditions were found during the inspection that, if left unchecked, could create a public health nuisance or concern. Further regulatory action could result if conditions are not corrected. Follow-Up Inspection: 1-3 months. There may be instances when a follow-up inspection may not be necessary and follow-up can be completed via email, fax, or by phone.

OAI – Official Action Indicated

This classification is used when violations are critical and conditions could support criminal charges. Follow-Up Inspection: 30 days.

For FDA contract inspections, the classifications are NAI, VAI, or OAI, but are determined using different parameters from state inspections and have different follow-up procedures.

NAI – No Action Indicated

No objectionable conditions or practices were found during the inspection, or the objectionable conditions found do not justify further action.

VAI – Voluntary Action Indicated

Significant objectionable conditions and practices were observed, but the objectionable conditions do not meet the threshold for regulatory action. Any corrective action is left to the establishment to take voluntarily.

OAI – Official Action Indicated

Objectionable conditions were found and regulatory action will be recommended.

Inspection classification criteria are large in number and scope. Numerous factors are taken into consideration when determining inspection classifications. Determine if a re-inspection or follow-up inspection is necessary. Please see **FOM Procedure I-00 Compliance and Enforcement Procedures and Inspection Classification** for more information.

Completing the Paperwork

See **Procedure I-06 Computer Software (APEX) and Paperwork Submission Criteria** regarding the timelines for submitting inspection reports.

Additional Relevant FOM Procedures Not Previously Mentioned

- Procedure II-01 Foodborne Illness Complaint Investigations
- Procedure IV-12 Service Samples
- Procedure II-07 Recall Audit Check Procedure

APPENDIX 1

VDACS ADOPTED CFRS – Available at:
http://lis.virginia.gov/cgi-bin/legp604.exe?000+reg+2VAC5-600-10

2VAC5-600-10. Adoption by reference.

A. Regulations from Title 21, Chapter 1, Subchapter A, Code of Federal Regulations. The Board of Agriculture and Consumer Services hereby adopts the following provisions of Chapter 1 of Title 21, Subchapter A of the Code of Federal Regulations (Rev. April 1, 2010) as regulations applicable in the enforcement of the Virginia Food Act by reference:

Part 73, Listing of color additives exempt from certification, Subpart A - Foods.
Part 74, Listing of color additives subject to certification, Subpart A - Foods.
Part 81, General specifications and general restrictions for provisional color additives for use in foods, drugs and cosmetics.
Part 82, Listing of certified provisionally listed colors and specifications, Subpart B—Foods, Drugs and Cosmetics.
B. Regulations from Title 21, Chapter 1, Subchapter B, Code of Federal Regulations. The Board of Agriculture and Consumer Services hereby adopts the following provisions of Chapter 1 of Title 21, Subchapter B of the Code of Federal Regulations (Rev. April 1, 2010) as regulations applicable in the enforcement of the Virginia Food Act by reference:
Part 100, General.
Part 101, Food labeling.
Part 102, Common or usual name for nonstandardized foods.
Part 104, Nutritional quality guidelines for foods.
Part 105, Foods for special dietary use.
Part 109, Unavoidable contaminants in food for human consumption and food-packaging material.
Part 110, Current good manufacturing practice in manufacturing, packing, or holding human food.
Part 111, Current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements.
Part 113, Thermally processed low-acid foods packaged in hermetically sealed containers.
Part 114, Acidified foods.
Part 120, Hazard analysis and critical control point (HACCP) systems.
Part 123, Fish and fishery products.
Part 129, Processing and bottling of bottled drinking water.
Part 133, Cheeses and related cheese products.
Part 136, Bakery products.
Part 137, Cereal flours and related products.
Part 139, Macaroni and noodle products.
Part 145, Canned fruits.
Part 146, Canned fruit juices.
Part 150, Fruit butters, jellies, preserves, and related products.
Part 152, Fruit pies.
Part 155, Canned vegetables.
Part 156, Vegetable juices.
Part 158, Frozen vegetables.
Part 160, Eggs and egg products.
Part 161, Fish and shellfish.
Part 163, Cacao products.
Part 164, Tree nut and peanut products.

Part 165, Beverages.
Part 166, Margarine.
Part 168, Sweeteners and table sirups.
Part 169, Food dressings and flavorings.
§ 170.19, Pesticide chemicals in processed foods.
Part 172, Food additives permitted for direct addition to food for human consumption.
Part 173, Secondary direct food additives permitted in food for human consumption.
Part 174, Indirect food additives: General.
Part 175, Indirect food additives: Adhesives and components of coatings.
Part 176, Indirect food additives: Paper and paperboard components.
Part 177, Indirect food additives: Polymers.
Part 178, Indirect food additives: Adjuvants, production aids, and sanitizers.
Part 179, Irradiation in the production, processing and handling of food.
Part 180, Food additives permitted in food or in contact with food on an interim basis pending additional study, Subpart B—Specific requirements for certain food additives.
Part 181, Prior-sanctioned food ingredients.
Part 182, Substances generally recognized as safe.
Part 184, Direct food substances affirmed as generally recognized as safe.
Part 186, Indirect food substances affirmed as generally recognized as safe.
Part 189, Substances prohibited from use in human food.

C. Regulations from Title 21, Chapter 1, Subchapter L, Code of Federal Regulations. The Board of Agriculture and Consumer Services hereby adopts the following provisions of Chapter 1 of Title 21, Subchapter L of the Code of Federal Regulations (Rev. April 1, 2010) as regulations applicable in the enforcement of the Virginia Food Act by reference:
§ 1240.61, Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.

D. Regulations from Title 40, Chapter 1, Subchapter E, Code of Federal Regulations. The Board of Agriculture and Consumer Services hereby adopts the following provisions of Chapter 1 of Title 40, Subchapter E of the Code of Federal Regulations (Rev. July 1, 2010) as regulations applicable to the enforcement of the Virginia Food Act by reference:
Part 180, Tolerances and exemptions for pesticide chemical residues in food.

Statutory Authority
§ 3.2-5101 of the Code of Virginia.
Historical Notes
Derived from VR115-05-13 § 1, eff. October 28, 1991; amended, Virginia Register Volume 8, Issue 7, eff. December 5, 1991; Volume 16, Issue 20, eff. May 31, 2000; Volume 17, Issue 9, eff. December 14, 2001; Volume 27, Issue 14, eff. February 22, 2011.

FIELD OPERATIONS MANUAL

PROCEDURE III-22
New

Inspection of Sprout Processors

Raw sprouts present unique food safety problems because conditions under which they are produced—growing time, temperature, water activity, pH, and nutrients---are ideal for the rapid growth of bacteria.

All parties involved in the production of sprouts -- seed producers, seed conditioners and distributors, and sprout producers -- should be aware that seeds and sprouted seeds have been recognized as an important cause of foodborne illness. Sprouts have been identified as a special problem because of the potential for pathogen growth during the sprouting process. If pathogens are present on or in the seed, sprouting conditions may favor their proliferation. There is no inherent step in the production of raw sprouts to reduce or eliminate pathogens. Contaminated seed is the likely source for most reported sprout-associated outbreaks. Research has been initiated on methods to reduce or eliminate pathogenic bacteria on seeds and sprouts and some treatments show promise. However, to date, no single treatment has been shown to completely eliminate pathogens under experimental conditions used.

To counter this risk, FDA guidance recommends seed disinfection combined with microbial testing of used irrigation water from each batch or production lot to determine whether the pathogens Salmonella and E. Coli 0157:H7 are present.

Sprout-Associated Outbreaks

In 1997, an outbreak of 108 cases of *E. coli* O157:H7 in Michigan and Virginia was epidemiologically associated with sprouts. Traceback revealed that all implicated alfalfa sprouts were produced at a single sprouting facility in each state. Sprouts grown by the Michigan sprouter at the time of the outbreak came from two lots of seeds; one from Idaho and the other from Australia. The Virginia sprout manufacturer used the same lot of Idaho seeds as one of the lots used in Michigan. Cultures from this seed lot did not yield *E. coli* O157:H7.

Further investigations revealed that seed may have been contaminated at the farm where the alfalfa was grown. On the alfalfa farm in Idaho where the seeds were harvested, several possible sources of contamination from cow and deer manure were noted. Some fields were irrigated with water drained from neighboring fields where manure was applied and some alfalfa fields were directly adjacent to cattle feed lots.

Some alfalfa was grown next to a deer refuge, and deer were observed in these fields daily.

Outbreak investigations identified several factors that affect the microbial safety of sprouted seeds. To date, contaminated seeds have been the likely source for most, if not all, outbreaks. Seed contamination could have occurred at the farm, seed processor, or sprouting facility. The processes used for the production of sprouted seeds offer ample opportunity for cross contamination from a few seeds or sprouts to the entire production lot. Most seeds used for sprouting are not grown for human consumption. The seeds are generally grown, milled, and stored under conditions where contamination can readily occur. Frequent failures to isolate pathogens from implicated seeds suggest that seed contamination may be intermittent, at very low levels, or unequally distributed within seed lots. However, even low levels of pathogens are a concern. Conditions during sprouting (time, temperature, water activity, pH, and nutrients) are ideal for growth of pathogenic bacteria such as *Salmonella* and *E. coli*.

In recent outbreaks, investigations have attempted to determine the extent to which certain practices, such as seed disinfection treatments, are being used by sprout producers associated with an outbreak. In general, facilities associated with recent outbreaks often did not apply seed disinfection treatments, applied treatments inconsistently, or used disinfectants at relatively low levels. Conversely, facilities that traceforward investigations have identified as having used seed from the same lot as an implicated facility, but that have not been associated with any reported illnesses, appear to have been consistently using seed disinfection treatments, such as 20,000 ppm calcium hypochlorite, to disinfect seed prior to sprouting. While there may be other mitigating factors (such as product volume and amount of implicated seed used) these observations support the efficacy of seed disinfection treatments as a means to reduce the potential of sprout-associated foodborne illness outbreaks.

Requirements:

The following requirements identify the preventive controls that should be taken immediately to reduce the risk of raw sprouts serving as a vehicle for foodborne illness and ensure sprouts are not adulterated. Failure to adopt effective preventive controls can be considered unsanitary conditions which may render food injurious to health. Food produced under such conditions is considered adulterated. VDACS will consider enforcement actions against any party who does not have effective preventive controls in place, in particular, microbial testing.

These requirements are based on the information provided by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1999).

Seed Production:
Contaminated seed is the likely source for most, if not all, reported sprout-associated outbreaks. Seeds for sprout production should be grown under good agricultural

practices (GAPs) in order to minimize the likelihood that they will contain pathogenic bacteria.
There are multiple opportunities during seed production and harvest by which contamination with foodborne pathogenic microorganisms can occur. Once present on seeds, these pathogens are likely to remain viable for extended periods.

Seed Conditioning, Storage, and Transportation: Seeds that may be used for sprouting should be conditioned, stored, and transported in a manner that minimizes the likelihood that the seeds will be contaminated with pathogens. For example, seed should be stored in closed or covered containers in a clean dry area dedicated to seed storage. Containers should be positioned off the floor and away from walls to reduce the possibility of contamination by rodents or other pests and to facilitate regular monitoring for pest problems.

Sprout Production: While seeds have been identified as the primary source of food borne pathogens on sprouted seeds, the procedures and practices used by sprout producers have a substantial impact on the likelihood that pathogenic bacteria will survive and proliferate in sprouts. Sprouters should implement appropriate practices to ensure that sprouts are not produced under unsanitary conditions which may render the product injurious to health. Facilities with poor sanitation can significantly increase the risk of product contamination. Inadequate water quality and poor health and hygienic practices can all increase the risk of food becoming contaminated with pathogens. Sprouters need to adhere to 21 CFR Part 110 which sets forth good manufacturing practices (GMPs) in manufacturing, packaging, or holding food for human consumption.

Seed Treatment: A number of treatments have been shown to reduce levels of pathogenic bacteria present on seeds, but none have totally eliminated pathogenic microorganisms. Their routine use is likely to reduce the level of contamination, if present, and in turn, decrease the risk for food borne disease with sprouted seeds.

Seeds for sprouting should be treated with one or more treatments (such as 20,000 ppm calcium hypochlorite) that have been approved for reduction of pathogens in seeds or sprouts. Some treatments can be applied at the sprouting facility, while others will have to be applied earlier in the seed production process. However, at least one approved antimicrobial treatment should be applied immediately before sprouting. Sprouters should carefully follow all label directions when mixing and using antimicrobial chemicals.

Testing for Pathogens: Because currently approved antimicrobials have not been shown to be capable of eliminating all pathogens from seed, sprout producers should conduct microbiological testing of spent irrigation water from each production lot to ensure that contaminated product is not distributed. Because testing for pathogens can be done with irrigation water as early as 48 hours into what is generally a 3 to 10 day growing period, producers who plan accordingly can obtain test results before shipping product without losing product shelf-life. Testing, whether done by the producer or

contracted out, should be performed by trained personnel, in a qualified laboratory, using validated methods.

Traceback: Traceback cannot prevent a foodborne illness outbreak from occurring. However, being able to trace a food back to it's source quickly can limit the public health and economic impacts of an outbreak, if it occurs. Information gained in traceback investigations may also help prevent future outbreaks. Sprout producers, seed producers, conditioners, and distributors should develop and implement systems to facilitate traceback and recalls in the event of a problem. All parties should test their systems in advance of a real problem.

Inspection Report Documentation & Classification:

Non-compliance with the above requirements should be documented as objectionable conditions on the inspection report. Significant deviations from the subject requirements (such as failure to conduct microbiological testing of spent irrigation water) as well as other accompanying sanitary deficiencies may result in an OAI designation.

Identifying "Healthy" Sprouts

While it is impossible to tell if sprouts are free of pathogens by looking at them with the naked eye, there are some tips in identifying sprouts that are less likely to cause foodborne illness. Check to see if the roots are clean. The stems should appear white or cream in color. Fresh sprouts should have a clean, fresh aroma. Look for the ISGA-certified grower's seal on packaged sprouts. This seal certifies that the grower follows the sprout sanitation and growing recommendations of the International Sprout Growers Association.

Issued new July 2, 2003

Field Operations Manual

Procedure III-23
New

Dietary Supplements

Overview

In October 1994, the Dietary Supplement Health and Education Act (DSHEA) was signed into law. This law created a new regulatory framework for the safety and labeling of dietary supplements. Under DSHEA, dietary supplements fall under the general umbrella of “foods”, not drugs, and require that every supplement be labeled a dietary supplement. In response to DSHEA, the state of Virginia moved to regulate dietary supplements as food products. Unfortunately, some dietary supplements have been shown to cause harm in some consumers and therefore, there is some concern regarding the consumption of certain dietary supplements. Thus, it is important that you include as part of your normal inspection routine a brief examination of the dietary supplement section of the retail food store. If labeling deficiencies, products of concern, or other problems are noted with dietary supplements, they should be documented as objectionable conditions on your inspection report. If you come across a questionable product or a labeling issue that you are unsure as to whether or not it is in violation of the Virginia Food Laws and related regulations, attach a separate memo to your Regional Manager but do not document it on your inspection report.

Currently, there are no FDA regulations that are specific to the manufacturing of dietary supplements. At present, the manufacturer is responsible for establishing its own manufacturing guidelines to ensure that the dietary supplements it produces are safe and contain the ingredients listed on the label.

It should be noted that the labeling regulation (CFR Part 101) is applicable to dietary supplements.

What is a dietary supplement

Dietary supplements are any products taken by mouth that contain a so-called “dietary ingredient” intended to supplement the diet. The dietary ingredients in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, as well as substances such as enzymes, organ tissues, metabolites, extract or concentrate. Dietary supplements can be found in many forms such as tablets, capsules, gelcaps, liquids, or powders. Alcohol based herbal tinctures are also considered to be dietary supplements.

All homeopathic products are considered drugs and are therefore not regulated as dietary supplements.

Product statements (claims)

Overview

Under DSHEA, dietary supplements may bear “structure/function” claims---statements that describe the effect a dietary supplement may have on the structure or function of the body---without prior FDA review. It is acceptable to make a structure/function claim, provided that the claim is backed by scientific evidence.

Disease claims, that is, claims to diagnose, cure, mitigate, treat, or prevent disease may be made only for approved drug products. A dietary supplement shall not claim to diagnose, treat, cure, or prevent any disease.

There is a fine line between an acceptable structure/function claim (such as, promotes urinary tract health) and an unacceptable disease claim (such as, prevents urinary tract infection), therefore, use discretion when reviewing product labels, focusing on the blatantly obvious disease claims (i.e. will cure cancer, etc*.).*

If disease claims or false structure function claims are made, document them on your inspection report as an objectionable condition.

- **What is a structure/function claim**

Structure/function claims describe the role of a nutrient or dietary ingredient affecting a structure or function in humans, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity," or they may describe general well-being from consumption of a nutrient or dietary ingredient.

The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not approved by FDA. For this reason, the law says that if a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim.

- **What is a disease claim**

A statement is a disease claim if it mentions a specific disease or class of diseases. For example, “reduces the pain and stiffness associated with arthritis” or “will prevent heart disease”, etc

.

A statement also is a disease claim if it **implies** that it has an effect on a specific disease or class of diseases by using descriptions of the disease-state. Some claims imply disease treatment or prevention because they are so closely tied to a disease. For example, “reduces cholesterol” is a characteristic symptom associated with stroke and cardiovascular disease so that any claim about it would be an implied disease claim.

- **Can symbols/pictures be used on the label**

In general, any picture or vignette or other symbol can be used if it doesn’t imply a disease. For example, pictures of healthy organs would constitute an appropriate structure/function claim while a picture of an abnormal tissue or organ would be an implied disease claim. In addition, the heart symbol and EKG tracings are considered implied disease claims because they are strongly associated with heart disease.

Labeling—

1. The words “dietary supplement” must appear on the principal display panel. *Note: At this time, certain variations are permitted. If the term “dietary supplement,” “herbal supplement,” “supplement,” etc., is reasonably legible and is anywhere on the product container, we will not need to issue a report that the products are misbranded. You should, however, discuss the labeling deviation with the establishment manager and indicate that corrections should be made within a reasonable time frame*.

2. A statement of identity (ex: “ginseng”) is required.

3. An ingredients statement of all other ingredients in the product is required.

4. The net quantity of contents (ex: “60 capsules”) should be displayed on the label.

5. The name and place of business of the manufacturer, packer, or distributor is required.

6. Directions for use (ex: “take one capsule daily”).

7. A “Supplement Facts” panel, which lists the serving size, amount of dietary ingredients per serving, and the active ingredient, should appear on the label. *Note: If the container has a surface area of 12 square inches or less and the container label bears no nutrient or structure/function claims, then it is exempt from the requirement to include a supplement facts panel on the label. However, these containers MUST include an address or telephone number*

that a consumer can use to obtain the required supplement or nutrition information (ex: "for nutrition information, call…").

8. The assertion, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease" must appear on all dietary supplements that make a structure function claim, such as "promotes strong bones".

If you encounter establishments that are, in fact, manufacturing dietary supplements, please send a memo to your Regional Manager indicating the name and address of the establishment, the nature of the establishment (i.e. wholesale supplement manufacturer, manufactures products as part of a retail sales operation, etc.), the products produced, and the processes utilized to manufacture those products. You and your Regional Manager will decide when and if the operation should be inspected.

Products/Ingredients Determined to be Unsafe—

1. **Gamma Butyrolactone (GBL), Gamma Hydroxybutyric Acid (GHB), and 1,4 Butanediol (BD).** These agents can cause dangerously low respiratory rates, unconsciousness/coma, vomiting, seizures, bradycardia, and death. These substances increase the effects of alcohol and are even more dangerous when consumed with other central nervous system depressant drugs. These products are often listed as "party drugs" on internet sites, are advertised in muscle building magazines, and are sold in health food stores as dietary supplements. FDA considers these products to be unapproved new drugs and have conducted seizures to prevent sales to consumers. GHB, which is legally available in the U.S. only as an investigational new drug for specified purposes (thus, it cannot be legally marketed), has been implicated as a "date rape" drug.

   GBL, when ingested, rapidly metabolizes into GHB. Some of the suspect products may list 1,4 butanediol, tetramethylene glycol, gamma butyrolactone, or 2(3H)-Furanone di-hydro on the label or have no label at all. Health authorities believe manufacturers are renaming their products and substituting BD for GBL, however, the effects of ingesting BD are as dangerous as those of GHB and GBL.

   GBL product names include: Longevity, Revivarant, GH Revitalizer, Gamma G, Blue Nitro, Insom-X, Remforce, Firewater, and Invigorate. Products that contain BD include Revitalize Plus, Serenity, Enliven, GHRE, SomatoPro, NRG3, Thunder Nectar, and Weight Belt Cleaner. FDA has warned consumers not to drink products named Cherry fX Bombs, Lemon fX Drops, and Orange fX Rush, as all of them contain BD.

   If products containing these ingredients are found, document it as an objectionable condition on your inspection report, seize them, sample them, and sent them in to the Richmond Office for further evaluation. Your Regional

Manager will need to contact the Office of Criminal Investigation, as this falls under their jurisdiction.

2. **Herbal Products for Diabetics.** There are several brands of Chinese herbal products that contain prescription drugs that could cause dangerous drops in blood sugar. Manufacturers of these products claim that they contain only natural Chinese herbs, however, it was discovered that the products also contain the prescription diabetes drugs glyburide and phenformin. Therefore, consumers of these products can receive a dangerously high amount of the drugs from the affected herbs, especially if they also take a regular diabetes medicine.

   The product brand names are as follows:
   1. Diabetes Hypoglucose Capsules, sold by Chinese Angel Health Products of Santa Monica, CA.
   2. Pearl Hypoglycemic Capsules, imported by Sino American Health Products Inc., of Torrance, CA, but also sold by Chinese Angel.
   3. Tongyitang Diabetes Angel Pearl Hypoglycemic Capsules & Tongyitang Diabetes Angel Hypoglycemic Capsules, sold by Sino American.
   4. Zhen Qi Capsules, sold by Sino American.

   If these products are found, document it as an objectionable condition on your inspection report, seize them, sample them, and send them in to the Richmond Office for further evaluation. Your Regional Manager will need to contact the Center for Drug Evaluation and Research, as they have jurisdiction over these "drugs".

3. **Triax Metabolic Acceleratory (Triiodothyroacetic acid).** FDA is warning consumers not to purchase or consume the product Triax Metabolic Accelerator, containing the active ingredient, tiratricol. The product has been marketed as a dietary supplement for weight-loss purposes by Syntrax Innovations, Inc. of Cap Girardeau, Missouri. FDA has determined, however, that the product is not a dietary supplement, but instead an unapproved new drug containing a potent thyroid hormone, which may cause serious health consequences, including heart attacks and strokes. The chemical name for the active ingredient in the product is triiodothyroacetic acid (TRIAC). The Center for Drug Evaluation and Research has jurisdiction over this product.

   If these products are found, document it as an objectionable condition on your inspection report, seize them, sample them, and send them in to the Richmond Office for further evaluation. Your Regional Manager will need to contact the Center for Drug Evaluation and Research, as they have jurisdiction over these "drugs".

4. **Aristolochic Acid.** Aristolochic acids are potent carcinogens and nephrotoxins that are present, primarily, in plants of the family Aristolochiaceae. There are at least 14 aristolochic acids known. While a product that contains a large amount

of one or more of these acids may result in the rapid onset of acute toxicity symptoms in a consumer using the product, a product containing a small amount could be used for years with no apparent adverse effects, until serious, irreversible effects, such as renal failure, have occurred. See the attached list of plants known to contain aristolochic acid and of plants which may become adulterated with Aristolochia spp.

Currently, there is an FDA Import Alert in place for this product, which should catch most imported products containing this ingredient. However, you may still encounter it in some domestic products.

If these products are found, sample them, and send them in to the Richmond Office for further evaluation. Because there has been some confusion with various types of this product and what is considered to be safe and unsafe, your Regional Manager will need to consult with FDA for additional analysis of the product before you seize the product. Do not document the situation as an objectionable condition on your inspection report.

5. **Comfrey.** Products containing comfrey are said to be beneficial in the treatment of a wide variety of serious diseases and health conditions and has been marketed for both internal and external treatment. However, the Federal Trade Commission (FTC) has found that comfrey contains toxic substances and, when taken internally, can lead to serious liver damage. It is commonly found in Indian ayurvedic products, which are similar to the Chinese yin and yang products.

   Comfrey may also be listed as “boneset” because it used to be used to mend bones. However, there is another harmless plant that is also sometimes referred to as “boneset”.

   If these products are found, document it as an objectionable condition on your inspection report, seize them, sample them, and send them in to the Richmond Office for further evaluation.

6. **Sodium Usniate/Usnic Acid.** Usnic acid or sodium usniate could cause liver damage. It is used as an antiseptic as well as an ingredient in weight loss products. It claims to increase a person’s basal metabolic rate and therefore cause them to lose weight. Some common names for Usnea are Old man’s beard, Beard lichen, and Tree hair. It is an ingredient in a weight loss product called Malibu Trim and is currently being investigated by the FTC, as this product claims to be “Safe”.

   If these products are found, document it as an objectionable condition on your inspection report, seize them, sample them, and send them in to the Richmond Office for further evaluation.

As mentioned previously, when you encounter unsafe products (i.e. comfrey, GBL, etc.), document it as an objectionable condition on your inspection report, seize them, collect an official sample, and send it to the Richmond Office for further review, with the exception of Aristolochic Acid—do not seize this product without being instructed to do so by your Regional Manager. Please note that in most instances, there will be no need to collect duplicate samples of products that have significant similarities.

Products of Concern—

1. **Ephedrine.** In some instances products containing ephedrine are sold as "over the counter" (OTC) drugs, such as a bronchodilator, in which case they are legal and acceptable. OTC products are not under our jurisdiction. However, products containing ephedrine and it's alkaloids (pseudoephedrine, norephedrine, and N-methyl ephedrine) can also be marketed and labeled as dietary supplements as an aid in weight loss, energy, "pep", performance enhancement, or as a substitute for illicit drugs, such as MDMA. These supplements are commonly labeled as "natural" or "herbal" and use common names for the source of the active ingredients (ma huang, Chinese ephedra, and sida cordifolia—another plant source with small amounts of ephedrine alkaloids). The usual recommended OTC dosage of ephedrine in bronchodilator products is 12.5 mg – 25.0 mg. Many dietary supplements contain more than 25.0 mg of ephedrine or its alkaloids per dose.

   Recently the RAND study, commissioned by the National Institute of Health, found limited evidence of an effect of ephedrine on sports performance enhancement or muscle building. In light of this information on these structure function claims, now determined to be false, FDA has issued warning letters to dietary supplement manufacturers who are placing such claims on their product labels. Examples of false or misleading claims include, "enhancing your body's own muscle-building", "strength supplementation", "supporting lean muscle mass growth", "train with ultra high intensity", etc. One of the firms who received a warning letter from FDA is located in Virginia. The name of the firm is GotSupplements.com, LLC and is located in Yorktown, VA. The products with labels making false claims were Dymetadrine Xtreme and Thermbuterol.

   If you encounter products containing ephedrine or its alkaloids that are making false structure function claims relative to sports performance enhancement and muscle building, document it as an objectionable condition on your inspection report, seize them, sample them, and send them to the Richmond Office for further evaluation.

   FDA has proposed a warning label for products containing ephedrine that would warn consumers about reports of serious adverse events after the use of ephedrine (including heart attack, seizure, stroke, and death). However, this label has not yet been approved.

The Food Safety Program will be following FDA's lead with regards to products containing ephedrine or its alkaloids. Therefore, if you encounter these products during your inspection, do not seize them, sample them, or document them as an objectionable condition on your inspection report, unless they are making the false structure function claims described above. Just be aware that there are risks associated with these products.

If you encounter a "unique" or questionable product that you are unsure as to whether or not it is in violation of the Virginia Food Laws and related regulations, collect an official sample, attach a separate memo to your Regional Supervisor, and do not document it on your inspection report.

Issued new July 18, 2003

FIELD OPERATIONS MANUAL

PROCEDURE III-24
Revised

NONPROFIT ORGANIZATIONS HOLDING ONE DAY SALES

The 2003 session of the Virginia General Assembly passed legislation that exempts nonprofit organizations holding one-day food sales from inspection. This legislation became effective July 1, 2003.

Note: The exemption holds for any type of food produced by the nonprofit organization to be sold during the one day event.

INTRODUCTION

Historically, the Food Safety and Security Program has not searched for nonprofit organizations (i.e. churches, fire departments, rescue squads, etc.) which raise funds for charitable purposes by holding food sales. It has always been believed that expending resources to attempt to locate such food sales is counter-productive and an unwise use of extremely limited food safety and security resources. This continues to be the position of the Food Safety and Security Program, relative to locating and inspecting any nonprofit organizations which raise funds for charitable purposes by holding food sales.

In situations where Food Safety Specialists are requested to provide food safety guidance to nonprofit organizations, the Food Safety and Security Program will continue to provide such guidance. Otherwise, the Program will continue its longstanding policy to deal with such organizations only when it has been determined that their operations pose a substantial risk to consumers. Additionally, persons who produce food products for sale by the nonprofit organizations will typically only be inspected if they produce food products on a regular and ongoing basis; those persons who only produce food products periodically and only for sale by the charitable organizations will typically not be inspected.

OBJECTIVE AND INTENT

This FOM is established to provide guidance associated with food establishments claiming exemption from the inspection and right of entry requirements, set forth in §§ 3.1-398.1 and 3.1-399 of the Code of Virginia, as nonprofit organizations holding one-day food sales.

DEFINITIONS

For the purposes of this FOM, the following definitions will be utilized:

Organization - A number of persons or groups united for a particular purpose.

Nonprofit Organization

An organization that is:

- Organized for some purpose other than to generate income or profit, and
- Accepted as nonprofit by any state or federal agency.

If an organization is not accepted as nonprofit by any state or federal agency, then it must

- Exist to benefit persons who are not members of the organization, and
- Be capable of documenting receipts and expenses, and
- Maintain documentation to show it is an organization, or can otherwise demonstrate that it is an organization, and
- Maintain a list of organization members.

One-day Food Sales

- Not conducted on any two consecutive days.
- Conducted on a limited basis, and although it may be a recurring basis, recurrence is no more than twice per month.
- A special occurrence, and not held in the ordinary course of events.

Administrative Procedures

Nonprofit organizations participating in one day sales will be sent an informational packet with some general food safety guidelines, along with a form requesting their contact information, a list of the products they are making, their intended point of sale, and the frequency of which they plan to hold their sales. In addition, they will be asked to submit documentation supporting their claim to be “nonprofit”.

If an organization can provide documentation that it is organized for a purpose other than generating income or profit and that it is accepted as a nonprofit organization by any state or federal agency, then it will qualify as a nonprofit organization for purposes of the exemption. If such documentation is not available, then the determination of exemption will be handled on a case-by-case basis. In order to maintain uniformity and consistency with this policy, such determinations shall be the responsibility of the Program Supervisor.

A copy of the information sent in will be forwarded to the inspector for that area. A letter will then be sent to the organization indicating to them that we have received their information, that we have them on file as a nonprofit organization participating in one day sales, and that they are exempt from an inspection by VDACS.

A nonprofit CFN will then be assigned to the firm. By issuing nonprofit organizations participating in one day sales a special CFN, this will ensure that these firms will not show up

on monthly inspector work plans, however, there will be a record of these firms on file, should there be questions regarding these organizations in the future.

Field Procedures

The Food Safety Specialist, when gathering information, should take precautions to ensure that they do not imply that a particular manufacturer/vendor does or does not qualify as a non-profit organization holding one-day food sales. If the Inspector encounters an 'unregistered' vendor who wishes to operate (or is operating) under this exemption, they should prepare a memo on an inspection report detailing the pertinent information about the business and forward it to their Regional Office. The memo should cover the same points as the form in the informational packet:

- Name, address and phone number for the vendor (i.e. contact information)
- Name of the nonprofit organization
- List of food products they intend to prepare
- Location(s) of sale
- Frequency of sales
- Documentation, as identified in the "definitions" section of this FOM, supporting their nonprofit claim
  - Include a copy of their documentation if available. If not, instruct the vendor to submit the documentation supporting their nonprofit claim to the Regional Office.
- Upon receipt of such information, the Regional Supervisor will review the information and forward that information to the Program Supervisor. A timely determination will then be made and communicated to the vendor/manufacturer.

<u>Inspection</u>

- No inspection will be necessary if the vendor has adequate on-site documentation of their non-profit status or you can reasonably determine that the vendor is a nonprofit entity or closely affiliated with a nonprofit organization.
- Inspect the firm if they cannot provide the necessary documentation of their nonprofit status or if you can not reasonably determine their affiliation with a nonprofit organization. Steps should be taken to inspect the processing location, as well.
  - The firm will be assigned a retail CFN and be under inspection until such time that they provide the necessary nonprofit documentation.
  - Once the nonprofit documentation is provided, the retail CFN will be placed out- of-business and the firm will be assigned a nonprofit CFN. The firm will be sent a letter indicating that they are exempt from inspection.

Attachments: Nonprofit registration information

Revised November 28, 2004

Dear Sir or Madam:

Thank you for your inquiry regarding your desire to operate as a nonprofit organization in a one-day food sale event. Nonprofit organizations preparing food for a one day sale event are exempt from Virginia Department of Agriculture inspection.

In order to be sure that you qualify for an exemption, please submit the following information to our office.

- Documentation verifying that you are a nonprofit organization. This may be a copy of the letter you received from the IRS referencing section 501(c)(3) of the IRS code indicating that you are qualified for an exemption or simply a letter from the nonprofit organization you are supporting.
- Completion of the attached registration form.

Please send your registration form and nonprofit documentation to:

VDACS-Office of Food Safety
P.O. Box 1163, Room 510
Richmond, VA 23219.

Once we have received your information, we will send you a letter indicating that you are on file with our office as a nonprofit organization preparing food for one day sale events and are exempt from our inspection.

In addition to the registration form, we have enclosed basic food safety information to help ensure that the food you prepare has been properly handled and is safe to eat.

If you have any questions regarding the registration process or about the attached food safety information, please do not hesitate to give our office a call at (804) 786-3520.

Sincerely,

Pam Miles
Regional Manager
Food Safety Program

Registration Form

Name

_____

Address

_____

_____

Phone # _____ (Daytime) _____ (Evening)

Name of Organization

_____

List of food products you intend to prepare for the event(s)

_____

_____

_____

_____

_____

Point(s) of Sale

_____

How often are these “one day sale” events held?

_____

_____

Do you plan to participate in each event?

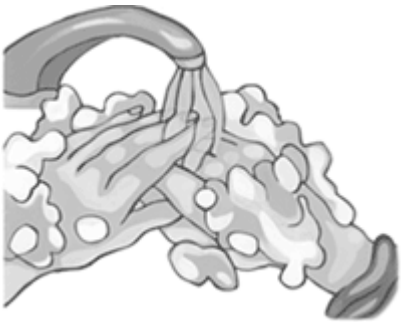
_____

Please submit this form, along with documentation supporting that you are a nonprofit organization to the address listed on the front page of this packet.

The “411” on Food Safety (Clean, Cook, Separate, Chill)*

CLEAN

Use these TIPS to keep your hands, surfaces, and utensils squeaky clean!



Wash Up!

- Make sure there is handwashing soap and paper towels or a clean cloth at every sink in your home.
- Wash your hands with hot, soapy water (for at least 20 seconds) *before* and *after* handling food and after using the bathroom, changing diapers, or handling pets. Thoroughly scrub hands, wrists, fingernails, and in between fingers. Rinse and dry hands with paper towels or a clean cloth.

Fruits & Veggies

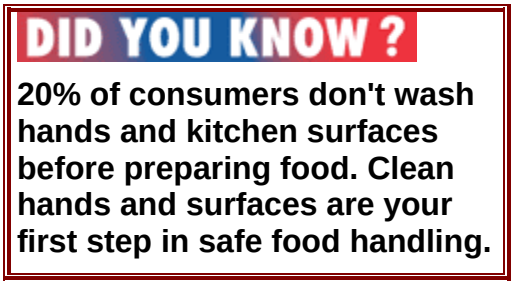
- Rinse raw produce under running water. Don't use soap, detergents, or bleach solutions. For thick or rough-skinned vegetables and fruits, use a small vegetable brush to remove surface dirt. Try to cut away any damaged or bruised areas on produce. Bacteria can thrive in these places.

Surface Cleaning

- Consider using paper towels to clean up kitchen surfaces and throw the germs away with the towels. If you use cloth towels, launder them often, using hot water. **Note:**

Don't dry your hands with a towel that was previously used to clean up raw meat, poultry, or seafood juices.

- Wash your cutting boards, dishes, utensils, and countertops with hot, soapy water after preparing each food item and before you go on to the next food. Periodically, kitchen sanitizers can be used for added protection against bacteria. You can also use one teaspoon of liquid chlorine bleach per quart of clean water to sanitize surfaces. The bleach solution needs to sit on the surface to be sanitized for about 10 minutes to be effective.
- Replace excessively worn cutting boards (including plastic, non-porous acrylic, and wooden boards). Bacteria can grow in the hard-to-clean grooves and cracks.
- In your refrigerator, wipe up spills immediately, clean refrigerator surfaces with hot, soapy water, and, once a week, throw out perishable foods that should no longer be eaten.
- Keep pets off kitchen counters and away from food.



COOK

Cooking food safely is a matter of degrees! Food safety experts agree that foods are properly cooked when they're heated for a long enough time and at a high enough temperature to kill harmful bacteria that cause foodborne illness. This temperature can vary from food to food, too.

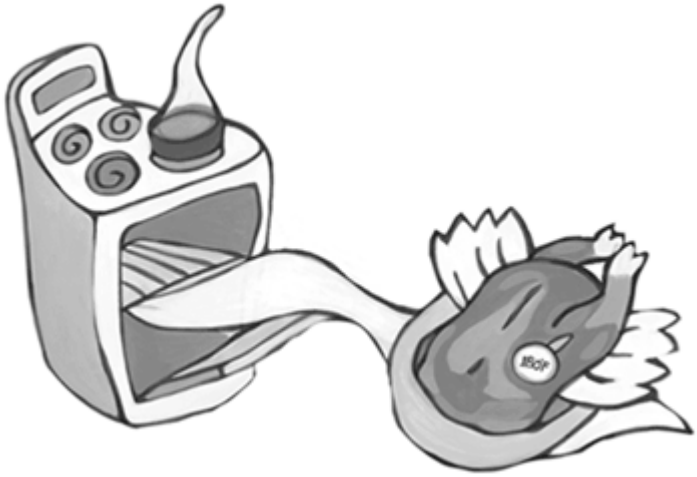
The best way to keep your food safe is to use these "hot" food safety TIPS.

Cook It Right . . .

Color is not a sure indicator of whether food is safe to eat. The only way to know that meat, poultry, casseroles, and other foods are properly cooked all the way through is to use a clean food thermometer.

Ground Beef

Oftentimes, when meat is "ground up" to make hamburger, bacteria that may have been present on the surface of the meat can end up *inside* the burger. When this happens, bacteria are less likely to be killed by cooking if the proper temperature is not achieved.



Cook ground beef to at least 160° F (71° C). Use a food thermometer to check. The Centers for Disease Control and Prevention link eating undercooked, pink ground beef with a higher risk of illness. If a thermometer is not available, do not eat ground beef that is still pink inside.

Meat and Poultry

Cook roasts and steaks to an internal temperature of at least 145° F (63° C). Whole poultry should be cooked to 180° F (82° C) - measure the temperature in the thigh. Chicken breasts should be cooked to 170° F (77° C).

Seafood
Cook fish until it's opaque and flakes easily with a fork.

Eggs
Cook eggs until the yolks and whites are firm. Don't use recipes in which eggs remain raw or partially cooked, unless you use pasteurized eggs.

Leftovers
Leftovers should be reheated to 165° F (74° C). Bring sauces, soups, and gravies to a boil.

Did you know that improper handling of raw meat, poultry, and seafood can set the stage for cross-contamination? As a result, bacteria can spread to food and throughout the kitchen.

SEPARATE

Here's how to prevent harmful bacteria from S-P-R-E-A-D-I-N-G!

Safely Separate

- Separate raw meat, poultry, and seafood from other foods in your grocery store shopping cart and in your refrigerator.

Take Two

- If possible, use one cutting board for raw meat products and another one for fresh fruits and vegetables.

Lather Up

- Always wash hands, cutting boards, dishes, and utensils with hot, soapy water after they come in contact with raw meat, poultry, seafood, eggs, and unwashed fresh produce.

Clean Your Plate

- Place cooked food on a clean plate. If you put cooked food on an unwashed plate that previously held raw meat, poultry, or seafood, bacteria from the raw food could contaminate the cooked food.

Seal It

- To prevent juices from raw meat, poultry, or seafood from dripping onto other foods in your refrigerator, place these raw foods in sealed containers or plastic bags.

Marinating Mandate

- Don't use sauce that was used to marinate raw meat, poultry, or seafood on cooked foods, unless it is boiled before applying. Never taste marinade or sauce that was used to marinate raw meat, poultry, or seafood.

Keep perishables in the refrigerator! At room temperature, pathogenic bacteria in food can double in number every 30 to 40 minutes. The more bacteria there are, the greater the chance you could become sick.

<u>CHILL</u>

Then, follow these COOL rules:

- Refrigerate food quickly because cold temperatures keep most harmful bacteria from multiplying. A lot of people think it will harm their refrigerator to put hot food inside, but it's not true. Hot food won't harm your refrigerator. More important, prompt refrigeration of foods will keep your food and you safer.
- Set your home refrigerator no higher than 40° F (4° C) and the freezer unit at 0° F (-18° C). Check the temperature occasionally with an appliance thermometer.
- Refrigerate or freeze perishables, prepared food, and leftovers within 2 hours.

- Divide large amounts of leftovers into shallow containers for quick cooling in the refrigerator.
- Marinate foods in the refrigerator.
- Don't pack the refrigerator too full. Cold air must circulate to keep food safe.
- At family outings or barbecues, use a cooler to keep perishable foods cold. Always use ice or cold packs and fill your cooler with food. A full cooler will maintain its cold temperatures longer than one that is partially filled.

For safe thawing, follow the THAW LAW:

- Never thaw foods at room temperature. You can safely thaw food in the refrigerator. 4 to 5 pounds of frozen food takes about 24 hours to thaw.
- You can also thaw food outside the refrigerator by immersing it in cold water. Change the water every half hour to keep the water cold.
- You can thaw food in the microwave, but if you do, be sure to cook the food immediately after it's thawed.

DID YOU KNOW?

23% of consumers' refrigerators are not cold enough! To discourage the growth of foodborne bacteria, your refrigerator should be set at 40° F (4° C).

**Information provided by FDA's Center for Food Safety and Applied Nutrition.*

FIELD OPERATIONS MANUAL

Procedure III-25
New

Use of the Blacklight in Identifying Rodent Activity

An ultraviolet light (i.e. blacklight) can be a useful tool for detecting rodent urine contamination on packaged products. However, the blacklight is not infallible. Many contaminants appear similar in color; therefore, much depends on the acquired skill and interpretation of the user. In addition, stains can vary in color depending on the type of bagging/packaging material.

The key to telling the difference between rodent urine and other substances that glow is the pattern of fluorescence. Look for the typical droplet pattern, since rodents commonly urinate while moving, in contrast to large patchy areas or uniformly spread out stains.

Because it can be difficult to determine that a particular substance that fluoresces is rodent urine, it is important support your findings by looking for other indications of rodent activity such as droppings, a strong urine smell, nesting material, gnawed product, etc. to confirm the presence of rodents.

As always, evidence of rodent activity is to be documented on the Inspection Report.

Note: In determining whether a product is adulterated due to rodent urine, it is important to remember the type of packaging material. A plastic liner would act as a barrier to urine contamination. Also, there can be several layers of paper that make-up the package. An Inspector should remove each layer and re-examine whether the layers have acted as a barrier in preventing product contamination (i.e. can you detect urine stains on the immediate product layer).

Fluorescent Properties Indicative of Rodent Activity:

- Wet, fresh, or continually wetted runs may fluoresce poorly (but should have a strong urine odor associated with them).
- Fresh, dry urine stains will fluoresce blue-white.
- Older urine stains will fluoresce a yellowish/white color.
- Rodent hairs will fluoresce as blue/white streaks.
- Many types of bagging and threading materials will fluoresce under the blacklight. However, the characteristic rodent stain can be identified by its yellowish color in contrast to the usual glow of chemical stains.

Because of either natural fluorescence or "quenching" of UV rays, it may be difficult to determine if rodent activity is present by use of the blacklight alone, even if they are contaminated, on the following food products:

Note: "Quenching" refers to a covering up or a decrease in the ability of a product to fluoresce.

High Gluten Flour (Natural)
Nut Meats (Natural)
Bean Flours (Natural)
Bran (Natural)
Pop & Field Corn (Natural)
Wheat (Natural)
Starch (Natural)
Spices (Natural or Quenching)

Issued New June 2, 2004

Field Operations Manual

Procedure III-26
New

Pre-packaged Food Exemption

Qualifying for an Exemption

The Virginia General Assembly passed legislation that went into effect July 1, 2004 that exempts **retail food stores** carrying only pre-packaged food items from routine inspection by our office and from payment of an inspection fee. In order to qualify for an exemption the firm must conform to the following criteria:

- They must be a retail establishment.
- They sell only food or beverages that are sealed in packaging by the manufacturer and have been officially inspected in the manufacturing process.
- They do not prepare or serve food.
- They do not offer beverage service (i.e. coffee counter, fountain drink machines).
- They do not sell infant formula.
- They do not sell salvaged foods.
- They do not sell unwrapped produce.
- The do not offer self service of unwrapped foods (i.e. bins of snack foods, donut cases, bulk health food bins, etc.).

Firms qualifying for the exemption are still obligated to comply with the Virginia Food Laws and will still be subject to surveys and complaint investigations. If complaint investigations reveal significant violations of the Virginia Food Laws, follow up inspections will be conducted until such time as voluntary compliance has been achieved or steps have been taken to force compliance.

Establishments qualifying for this exemption must certify in writing to our department that they are exempt. Exemption certification forms will be sent out during the inspection fee billing cycles each year. Establishments who feel that they meet the exemption criteria will submit a completed exemption form to the Richmond Office. Exemption forms will then be sorted by territory and sent to each inspector for verification that the firm is truly exempt.

Note: Exemptions will only be valid for one year. Exemption notices will be sent each year with the inspection fee invoices. Exemption forms will have to be completed each year by those firms wishing to be exempt from inspection. Exemption verification procedures will also need to take place each year.

Verification Procedures

Once you receive establishment exemption forms for your territory, you will need to visit those establishments and verify that the firm does in fact meet the necessary criteria to qualify for an exemption.

Note: If it is obvious that the firm does not qualify for an exemption (i.e. the firm is a warehouse, manufacturer, etc.) then it will not be necessary to visit the establishment. Retail firms should be visited as store operations can vary over time.

Exempt Firms. If you determine that the firm is indeed exempt, write **"EXEMPT"** in red ink at the top of the exemption form and create an inspection report memo documenting that the firm is exempt. **Give the firm a one year follow up date.** Attach the inspection report memo to the exemption form and return to your Regional Office so that the information can be keyed into the database. The exemption form will then be filed in the firm's establishment folder.

Non-exempt Firms. If you determine that the firm does not meet the exemption criteria, document why it does not meet the exemption on an inspection report memo and return both the exemption form and memo to the Richmond Office, Attention: Sandy Linkous. Sandy will then see that the firm is sent a letter explaining why they do not qualify for an exemption, along with their invoice for the inspection fee.

Note: If you perform an inspection/visit as part of the verification process you will need to send a copy of the Inspection Report to your Regional Office as well as the Richmond Office to get inspectional credit. Regional Offices do not need a copy of the exemption forms…they should be attached to the Inspection Report and submitted directly to the Richmond Office, Attention Sandy Linkous.

A list of firms that meet the exemption requirements will be created for each territory and sent out to the respective Inspector.

Notifying Firms of an Exemption

As previously stated, exemption application forms will be sent out to retail establishments during the inspection fee billing cycle each year. If a firm has been sent an exemption application and the application is not received by the Richmond Office via "returned mail", then the establishment is considered to have been notified.

If you visit a new firm that has not been notified of the exemption via an inspection fee billing cycle and you feel that the firm would qualify for an exemption (i.e. the firm opens after the exemption notices have been mailed for that fiscal year), proceed with inspecting the firm so that a file can be created for future visits, complaint investigations, etc. Give the firm a one year follow up date. The firm will be notified of the exemption legislation and be given the opportunity to apply for an exemption during the next inspection fee billing cycle.

If an establishment is notified about the exemption, qualifies for the exemption, and chooses not to file for an exemption, then they are still subject to our regular inspection.

Issued New November 2, 2004

Field Operations Manual

Procedure III-27
Revised

JURISDICTIONAL ISSUES

Convenience Store Jurisdictional Issues: Seating

Background
The 2004 General Assembly passed legislation effective July 1, 2004 that was intended to eliminate, to the greatest extent possible, any duplication of inspections in convenience stores and gas stations. This legislation has necessitated a modification of our current convenience store inspection protocol.

Law
§ 3.2-5130 of the Code of Virginia gives VDACS the responsibility of inspecting all establishments that manufacture, hold, or offer food products for sale. Title 35.1 of the Code of Virginia gives the responsibility for inspecting food service operations in restaurants to VDH. In addition, § 35.1-25 of the Code, as amended, exempts from VDH jurisdiction *convenience stores or gas stations that are subject to the Department of Agriculture and Consumer Services Retail Food Establishment Regulations for the Enforcement of the Virginia Food Laws or any regulations subsequently adopted and that (i) have 15 or fewer seats at which food is served to the public on the premises of the convenience store or gas station and (ii) are not associated with a national or regional restaurant chain*.

Definitions

Convenience store - A small retail food establishment with primary emphasis placed on providing the public a convenient location to quickly purchase from a wide array of consumable products, predominantly prepackaged foods or prepackaged foods and gasoline. Convenience stores may also offer food services including but not limited to coffee, iced and frozen drinks and prepared sandwiches and snack foods.

"Seating" will be defined as tables and chairs provided in locations on premises and intended to be used by customers as a dining area. This includes picnic tables and other seating located on the premises exterior to the establishment.

Standard booths or picnic tables will be counted as seating for four to six people based on size.

NOTE: If tables and chairs have price tags on them, but are still being used by customers as a dining area, then this seating will be counted.

Protocol
Some local health departments have adopted local ordinances that provide for inspection of convenience stores in addition to all restaurants. To provide a more uniform and consistent inspection program, VDACS will inspect the retail portion ***and*** the food service portion of ***all*** convenience stores or gas stations with food service operations containing 15 or fewer seats, provided that the food service operation is not associated with a national or regional restaurant chain. This includes independently owned food service operations/restaurants located within the convenience store or gas station.

If the food service operation located within a convenience store or gas station 1) has greater than 15 seats, or 2) is associated with a national or regional restaurant chain (regardless of the number of seats), then the health department will inspect the food service operation. Until otherwise notified, VDACS will continue to inspect the retail portion of these firms.

New Establishments & Food Service Additions
There will be instances where people will want to open a new convenience store or gas station that has a food service operation with 15 seats or less. In the past, the health department has given direction on what the requirements are for these firms regarding public restrooms and whether the capacity of the water supply and septic system was adequate.

With regards to restrooms, please direct the firm to their local city or county building inspector for the necessary requirements.

With regards to private water supplies and septic systems, VDACS will still defer to the health department to ensure that the firm meets the necessary requirements. The health department will determine whether or not the water supply and septic system is adequate for the proposed operation and supply this information to VDACS in writing. VDACS will enforce the determination given by the health department. If the firm is a new operation, ask the firm to supply you with a copy of their proposed menu so that the health department can use that as a guide in determining whether or not their water and septic systems are adequate.

If an existing firm is on a private water supply or septic system and they wish to modify their food service or add a food service operation with 15 seats or less, VDACS will still defer to the health department for an evaluation of their water and septic systems. VDACS will need to notify the health department of the proposed changes and have them evaluate the systems in place. Again, if you can obtain a proposed menu, this will aid the health department in their evaluation. The health department will provide VDACS with the results of their evaluation in writing, and VDACS will be responsible for enforcement of that evaluation.

Operational Changes Affecting Jurisdiction

There may be times during your inspections that you find that a firm that is currently under VDACS jurisdiction has modified their operation such that it should now be under the

jurisdiction of VDH. For example the firm now has greater than 15 seats; the firm is catering; the firm has removed many or all of the retail items and is now operating as a takeout or sit down restaurant; etc.

Protocol

If during an inspection of a VDACS establishment you observe something that may now put the firm under the jurisdiction of VDH, you must let the owner/operator know and you must inform them to contact VDH. This should be documented at the bottom of the inspection report. For example: "NOTE: The owner was informed that because the firm now has a total of 16 seats, the food service portion of the firm will fall under the jurisdiction of VDH. The owner was advised to immediately contact VDH." Another example may be "NOTE: The owner was informed that because all retail items have been removed from the store and the firm is now operating as a takeout restaurant, the store will fall under the jurisdiction of VDH. The owner was advised to immediately contact VDH."

After documenting this information on the inspection report, ***you will need to contact the appropriate VDH office/inspector promptly, ideally within 24-48 hours, but in no case should it exceed 5 business days***. You will need to document in writing that VDH was contacted. Submit a MEMO to your Regional Manager and place a copy of the MEMO in the firm folder and include any pertinent information including who you spoke with, what was discussed, etc. If an email was sent to VDH, submit the email chain to your Regional Manager and place a copy in the firm folder.

If the firm states that they will make changes so they will not fall under the jurisdiction of VDH, you will need to note this on the inspection report as well. For example: "NOTE: The owner was informed that because the firm now has a total of 16 seats, the food service portion of the firm will fall under the jurisdiction of VDH. The owner stated the seats would be removed immediately so the firm could remain under VDACS jurisdiction." You will need to classify the inspection report VAI and conduct a 30 day follow up inspection to assure that the firm is complying.

In some instances it may be necessary to conduct a joint visit with VDH to determine whose jurisdiction a firm will fall under. If a joint visit is conducted, a MEMO will need to be submitted to your Regional Manager and a copy placed in the firm folder. The MEMO should include any pertinent information including who was present during the visit, the results of the joint visit, and whose jurisdiction the firm will fall under.

Summary

- VDACS will inspect the retail portion *and* the food service portion of *all* convenience stores or gas stations with food service operations containing 15 or fewer seats, provided that the

food service operation is not associated with a national or regional restaurant chain (McDonald's, Blimpies, Subway, Burger King, etc).

- VDACS will inspect independently owned food service operations with 15 seats or less that are located within a convenience store or gas station.

- VDH will inspect the food service portion of convenience stores and gas stations with food service operations that contain greater than 15 seats or that are associated with a national or regional restaurant chain (regardless of the number of seats). VDACS will inspect the retail portion of these firms until otherwise notified.

- VDACS will defer to the health department for evaluations on all private water supplies and septic systems for new and existing firms wishing to install or modify a food service operation.

- VDACS will notify the firm owner if it appears the firm will now fall under the jurisdiction of VDH

- VDACS will notify VDH of any firms that now appear to fall under the jurisdiction of VDH

- VDACS will conduct a 30 day follow up inspection on all firms that state they will make the necessary changes to stay under the jurisdiction of VDACS

Revised May 2012

Field Operations Manual

Procedure III-28
New

VDACS Procedure for Inspections of Community Canneries

Background

Historically a community cannery has been a facility owned by a municipality for use by individuals in the surrounding areas who desired to process food for their personal use.

Many community canneries now have expanded the scope of operations from the individual canning food for their family to firms manufacturing foods for commercial sale.

If processors are manufacturing food items in community canneries we have an obligation to protect the consumer and therefore will need to inspect these operations as we become aware of them.

Please be aware that all foods (low acid, acidified, acid, etc.) processed must conform to the requirements of the Virginia Food Laws and associated regulations (i.e. CFR part 110, 113, 114, etc.). Please note that the actual process as well as the equipment itself must comply.

Processors should be provided with a "Starting a Food Processing Business in Virginia" packet and be encouraged to work with Va. Tech to ensure that the product is produced in a safe manner.

Administrative procedures

1) All food processors that manufacture food in a community cannery and sell product directly to the public (commercially) **MUST** be under inspection.

2) Individuals processing foods in a community cannery for their own use **WILL NOT** be inspected.

3) If non-profit organizations are manufacturing foods in a community cannery and offering the products for sale to the public they will **NOT BE EXEMPT** from inspection unless they meet the requirements of FOM III-24 - One Day Sales Events.

4) Acidified foods processes must be approved by an appropriate processing authority (such as Joell Eifert with Virginia Tech). Low acid food processes must also be approved. Remember to verify that the cannery in question is suitable to do low acid foods. Individuals producing acid foods should also have their process evaluated and should provide documentation to the office that their process is acceptable and will render their products safe as well as shelf stable.

5) Each processor will be given a CFN and placed on file.

Note: Please note that although will not be placing the cannery facility on file (i.e. no CFN) the cannery will still need to register with FDA.

Information regarding registration can be obtained by the cannery at the following website:

http://www.cfsan.fda.gov/~acrobat/frm2541.pdf

When the cannery registers this generates a unique number in the CFSAN system (FCE) which identifies the facility, it's physical location and the type of processing that occurs there (i.e. LACF or Acidified).

Processors that use the cannery to produce LACF or ACF products would then use the cannery's FCE number generated by CFSAN on their process filing forms (2541a). These forms are specific for each product manufactured at a specific location.

Information regarding registration can be obtained by the cannery at the following website:

http://www.cfsan.fda.gov/~acrobat/frm2541a.pdf

Inspection Procedures

The inspection of the Community Cannery will be conducted while the processor is manufacturing those food products being offered for sale to the public. The Food Safety Specialist should state on the inspection report during the first visit what commercially processed products they have been approved to process at that facility. The processor will be approved for selling those foods only.

1) Manufacturing equipment should be observed to determine if it is functioning as designed. If any of the manufacturing equipment is not suitable for commercial food processing then the processor should be notified they cannot manufacture products using that piece of equipment. Those products that could not be manufactured due to the inadequacy of the equipment should be listed separately from any approved products

that may be on the inspection report. It is the processor's responsibility to work directly with the Community Cannery personnel to ensure the equipment is acceptable and in good working order.

2) The processor should be provided with a copy of the pertinent laws and regulations that pertain to the foods being manufactured for commercial sale. (i.e. Acidified Foods-CFR Part 114, Low Acid Foods-CFR Part 113, etc).

   In addition, the owner/operator responsible for the operations of the Community Cannery should be informed by the Food Safety Specialist that the facility may be subject to FDA inspection. They should also be informed of the need to meet the regulatory requirements as set forth for those foods being processed

3) The inspection report should be provided to the processor only**.** The name and address information needed on the inspection report should be as follows:

   <u>The physical location and mailing address of the processor</u>

   EX. - Primary/Billing address (home residence): 3322 McFister Lane

   <u>The physical location of the community cannery</u>

   EX. - Processing Address: (Community Cannery): 2121 Old Farley Lane

   Please include both of these addresses in the address section of the inspection report.

4) Food labels should show the name and address of the processor and not the community cannery.

Personnel

All operators of processing and packaging systems used to produce acidified or low-acid foods must be under the operating supervision of a person who has attended a specialized school (i.e. Better Process Control School).

This requirement can be met by either the actual operator attending the Better Process Control School or the operation being supervised by a cannery employee who has had the requisite training.

Note: If a Food Safety Specialist is not properly trained to evaluate the equipment their Regional Manager should be contacted for further assistance.

DEFINITIONS

PROCESS AUTHORITY

The person or organization that scientifically establishes thermal processes for low-acid canned foods or processing requirements for acidified foods. The processes are based on scientifically obtained data relating to heat or acid resistance of public health and spoilage bacteria and/or upon data pertaining to heat penetration in canned foods. The process authority must have expert scientific knowledge of thermal and/or acidification processing requirements and have adequate experience and facilities for making such determinations.

Better Process Control School requirement for Acidified Food Manufacturers 21 CFR 108.25(f)

All plant personnel involved in acidification, pH control, heat treatment, or other critical factors of the operation **shall be under the operating supervision of a person who has attended a school** approved by the Commissioner for giving instruction in food-handling techniques, food protection principles, personal hygiene, plant sanitation practices, pH controls, and critical factors in acidification, and who has satisfactorily completed the prescribed course of instruction.

ACID FOOD

A food that has a natural pH of 4.6 or below.

ACIDIFIED FOOD

A low-acid food to which acid(s) or acid food(s) are added and which has a finished equilibrium pH of 4.6 or below and a water activity (aw) greater than 0.85.

FERMENTED FOOD

A food preserved by the growth of acid-producing microorganisms in the food which lowers the pH to 4.6 or less.

LOW-ACID FOOD

Any food (other than alcoholic beverages) with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85, excluding tomatoes and tomato products having a finished equilibrium pH less than 4.7.

Issued New July 18, 2005

Field Operations Manual

Procedure III-29
Revised

Home Kitchen Exemption

Overview

Effective July 1, 2013 the Virginia General Assembly passed legislation that amended Section 3.2-5130 of the Code of Virginia to expand the list of foods that can be processed in the private home without a state inspection. In 2008, Senate Bill 272 was enacted that allowed candies, jams/jellies not to be considered to be low-acid or acidified low-acid products, and baked goods that do not require time or temperature control for safety to be processed in the private home without state inspection.

The food products affected by the 2013 legislation can be broken down into 3 categories: Low Risk, Acidified Foods, and Honey.

Low Risk Foods

As mentioned above, in addition to the original exemption for candies, jams and jellies not to be considered acidified or low acid, and baked goods that do not require time or temperature control for safety, the legislation amended Section 3.2-5130 of the Code of Virginia to exempt the following additional products: dried fruits, dry herbs, dry seasonings, dry mixtures, coated and uncoated nuts, vinegars and flavored vinegars, popcorn, popcorn balls, cotton candy, dried pasta, dry baking mixes, roasted coffee, dried tea, cereals, trail mixes, and granola.

As with the original “home kitchen” exemption, the amended legislation places stipulations on selling the above products and special labeling requirements as detailed below:

a. They are to be sold to an individual for his/her own consumption and not for resale.
b. Not offered for sale to be used in or offered for consumption in retail food establishments.
c. The products are sold at the private home or at a farmers market.
d. Not offered for sale over the internet or in interstate commerce.
e. Affixed with a label displaying the name, physical address, and telephone number of the person preparing the food product and the date the food product was processed. The statement “NOT FOR RESALE – PROCESSED AND PREPARED WITHOUT STATE INSPECTION” must be placed on the principal display panel.

Acidified Foods

The legislation also allows for the sale of acidified foods. Private homes where the resident processes and prepares pickles and other acidified vegetables that have an equilibrium pH value of 4.6 or lower will be allowed if they meet the following:

a. They are to be sold to an individual for his/her own consumption and not for resale.
b. Not offered for sale to be used in or offered for consumption in retail food establishments.
c. The products are sold at the private home or at a farmers market.
d. Not offered for sale over the internet or in interstate commerce.
e. Affixed with a label displaying the name, physical address, and telephone number of the person preparing the food product and the date the food product was processed. The statement "NOT FOR RESALE – PROCESSED AND PREPARED WITHOUT STATE INSPECTION" must be placed on the principal display panel.

Additionally, producers of acidified foods must not exceed $3,000 in total annual gross sales for all acidified products produced.

Tomatoes – For purposes of this exemption, tomatoes will be considered a vegetable and not a fruit product.

Honey

Section 3.2-5130 has been further modified to eliminate the requirement for honey producers to provide an annual certification to VDACS. The criteria for the exemption include the following:

a. The resident sells less than 250 gallons of honey annually.
b. The resident does not process and sell other food products in addition to the honey, except as allowed above (ie: low risk foods and acidified foods).
c. The product is labeled "PROCESSED AND PREPARED WITHOUT STATE INSPECTION. WARNING: Do Not Feed Honey to Infants Under One Year Old."

The warning statement should be located on the principal display panel and be of such size as to be legible and prominently recognized.

In addition, the requirement for the home honey processor to prepare honey produced by his/her own hives does not require that the hives remain on the processor's property, all of the time. Instead, processors are permitted to move their hives around, from place to place, as part of the natural production of honey.

Furthermore, honey producers falling under the exemption do not have restrictions on where the honey can be sold.

NOTE: Infused honey would not fall under the exemption as it is considered to be value-added honey product, not pure honey. Creamed honey would be exempt.

Enforcement

Firms qualifying for the exemption are still obligated to comply with the Virginia Food Laws and will still be subject to complaint investigations. If complaint investigations reveal significant violations of the Virginia Food Laws, follow up inspections will be conducted until such time as voluntary compliance has been achieved or steps have been taken to force compliance.

In addition, this exemption does not preclude the need for standard labeling information on the product label (name of product, name and address of the manufacturer, distributor, or packer, net weight statement, an ingredient statement and possibly nutritional information).

Lastly, Inspectors should be aware that this exemption is very specific in nature and business operations that change significantly could lose their exemption. Exempt firms whose operations change and fall outside the exemption criteria should be scheduled for an inspection.

Note: Internet sales are not considered "sales at the home" and those businesses engaged in internet sales would not qualify for the exemption.

Revised July 2013

Virginia's New Home Kitchen Food Processing Exemptions

Food establishments, including private homes, that manufacture, process, pack or hold food for introduction into commerce (sale) are subject to the Virginia Food Laws as well as all applicable regulations. These laws and regulations are administered by the Virginia Department of Agriculture and Consumer Services (VDACS) and enforcement of these requirements includes regular periodic inspections of food establishments (including private homes). Additionally, establishments that are subject to periodic inspections are required to pay the agency an annual fee of $40.00.

On July 1, 2013 an amendment to § 3.2-5130 of the Code of Virginia went into effect that expanded the types of prepared foods individuals can make and sell from their homes or at farmers markets without VDACS inspection including certain low risk foods and acidified vegetables. This fact sheet addresses some frequently asked questions and requirements relating to the new legislation. Information regarding the production of honey in the home is also included. Please consult the Code of Virginia for specific requirements and if you have any questions contact the VDACS Food Safety and Security Program by phone at 804-786-3520 or via email at foodsafety@vdacs.virginia.gov.

I. Home-Canned Foods (§ 3.2-5130, item A.4)

What types of home-canned products are allowed under this exemption?

- Pickles and other acidified vegetables processed in a private home so that an equilibrium pH of 4.6 or lower is achieved.
- Acidified vegetable products include pickled products, salsa, chow-chow, relishes and similar vegetables that are processed in a private home to achieve an equilibrium pH of 4.6 or lower.

What types of home-canned products are not allowed under this exemption?

- Canned fermented foods
- Canned foods that require refrigeration for safety
- Canned Acid foods
- Canned fruits
- Low-acid canned vegetables that are processed with an equilibrium pH of greater than 4.6
- Any acidified food that is not a vegetable
- Any product not canned in a private home

How much home-canned pickled and acidified vegetable product can I sell?

- Producers of acidified foods must not exceed $3,000 in total annual gross sales for all acidified products produced. Producers should carefully document the amount of product sales incurred on an ongoing basis so that the information will be available for examination by VDACS.

What special precautions do I need to take in making home-canned pickles and acidified vegetables under this exemption?

- To reduce the likelihood of foodborne illness, home-canned acidified food must have an equilibrium pH value of 4.6 or lower to inhibit the growth and formation of toxins from the bacteria that cause botulism. In order to ensure that your product achieves the proper pH, an electronic pH meter should be purchased so that you can test the product to make certain that it is at a pH of 4.6 or lower.
- The home food processor is responsible for determining whether the product is an acidified food. We strongly advise that you have your manufacturing process reviewed and validated by a competent process authority. Home processors are strongly encouraged to complete a recognized Better Process Control School course. Information regarding times and locations for these courses can be obtained from Virginia Tech's Food Science Department(see helpful links below).

What are the labeling requirements for home-canned pickles and acidified vegetables?

- Product containers should have a a label displaying the name, physical address, and telephone number of the person preparing the food product and the date the food product was processed.
- The statement "NOT FOR RESALE – PROCESSED AND PREPARED WITHOUT STATE INSPECTION" must be placed on the principal display panel.
- In addition, this exemption does not preclude the need for standard labeling information on the product label (name of product, name and address of the manufacturer, distributor, or packer, net weight statement, an ingredient statement and nutritional information if applicable).

Where can I sell these products and who can I sell them to?

- Farmers markets
- From the private home where the product is manufactured
- To an individual for his/her own consumption

Where can't I sell these products?

- To other businesses (including retail establishments such as grocery stores or supermarkets)
- For resale
- On the internet
- Across state lines (interstate commerce)

Am I required to pay the annual $40.00 fee to the agency?

- No. Although you are still required to comply with all applicable laws and regulations, since you are exempt from the agency's periodic inspections, you will no longer be required to pay the annual fee. If you receive a bill from VDACS requesting that you pay the annual fee, please contact our agency at 804-786-3520 or foodsafety@vdacs.virginia.gov so that the matter can be resolved.

Additional Information Regarding pH

What is pH?

pH is a measurement of acidity or alkalinity using a numerical scale between 1 and 14. A pH value of 1 is most acidic, a pH value of 7 is neutral and values above 7 are referred to as basic or alkaline.

How is pH measured?

- Electronic pH meters are very accurate and pocket sized units are available for around $100.
- Paper strips are NOT accurate enough to measure acidity of home-canned and home-processed foods.

What is equilibrium pH?

- The pH of a food product after the food acid (e.g. vinegar) is distributed equally throughout the product.
- For example, the initial pH of the pickled cucumber that has been recently canned, will not be the same a few weeks later. It takes time for the vinegar (which is acid) to penetrate and distribute into the cucumbers. Therefore, testing the pH of only the brine (liquid) portion of a recently canned and processed product is not accurate.

How do you determine a product's equilibrium pH?

- For foods canned and processed less than 2 months: Food sample need to be finely ground in a blender prior to pH testing.
- For foods with a process date greater than 2 months: pH may be taken of the brine only since all contents of the canned product should be in equilibrium.

Who can test for pH?

- The person that processed the food as long as they are capable of performing an accurate pH test.
- When testing, follow the same recipe and procedures for each batch of food to be tested.
- A separate pH test is required for each different product offered for sale under this exemption
- Private laboratories
- Universities

Examples of pH for different foods

- Dill pickles (pH 2.6-3.8)
- Tomatoes (pH 3.7-4.9)
- Distilled water (pH 7)
- Garlic (pH 5.3-6.3)

II. Low Risk Foods (§ 3.2-5130, item A.3)

What types of home-processed low risk food products are allowed under this exemption?

- The original exemption included candies, jams and jellies not considered to be low-acid or acidified low-acid products and baked goods that do not require time or temperature control for safety and are produced in a private home.
- The expanded exemption includes the following additional products produced in a private home: dried fruits, dry herbs, dry seasonings, dry mixtures, coated and uncoated nuts, vinegars and flavored vinegars, popcorn, popcorn balls, cotton candy, dried pasta, dry baking mixes, roasted coffee, dried tea, cereals, trail mixes and granola.

What are the labeling requirements for food products in the low risk foods category?

- Product containers should have a label displaying the name, physical address, and telephone number of the person preparing the food product and the date the food product was processed.
- The statement "NOT FOR RESALE – PROCESSED AND PREPARED WITHOUT STATE INSPECTION" must be placed on the principal display panel.
- In addition, this exemption does not preclude the need for standard labeling information on the product label (name of product, name and address of the manufacturer, distributor, or packer, net weight statement, an ingredient statement and possibly nutritional information).

Where can I sell these products and who can I sell them to?

- Farmers markets
- From the private home where the product is manufactured
- To an individual for his/her own consumption

Where can't I sell these products?

- To other businesses (including retail establishments such as grocery stores)
- For resale
- On the internet
- Across state lines (interstate commerce)

Am I required to pay the annual $40.00 fee to the agency?

- No. Although you are still required to comply with all applicable laws and regulations, since you are exempt from the agency's periodic inspections, you will no longer be required to pay the annual fee. If you receive a bill from VDACS requesting that you pay the annual fee, please contact our agency at 804-786-3520 or foodsafety@vdacs.virginia.gov so that the matter can be resolved.

III. Honey Processing (§ 3.2-5130, item A.5)

What is the criteria for the exemption?

- Private homes where the resident processes and prepares pure honey produced by his own hives
- The resident sells less than 250 gallons of honey annually.
- The resident does not process and sell other food products in addition to the honey, except as allowed above (ie: low risk foods and acidified foods).

What types of home-processed honey products are NOT allowed?

- Infused honey products would not fall under the exemption as it is considered to be value-added honey product, not pure honey.

What are the labeling requirements for home-processed honey?

- The product is labeled "PROCESSED AND PREPARED WITHOUT STATE INSPECTION. WARNING:

Do Not Feed Honey to Infants Under One Year Old."

- In addition, this exemption does not preclude the need for standard labeling information on the product label (name of product, name and address of the manufacturer, distributor, or packer, net weight statement, an ingredient statement and possibly nutritional information).

Where can I sell these products and who can I sell them to?

- Currently there are not restrictions regarding where the products can be sold and who they may be sold to.

Is there still a requirement to provide an annual certification to the Department regarding compliance with the requirements of § 3.2-5130, item A.5?

- No. There is no longer a requirement to provide an annual certification.

Am I required to pay the annual $40.00 fee to the agency?

- No. Although you are still required to comply with all applicable laws and regulations, since you are exempt from the agency's periodic inspections, you will no longer be required to pay the annual fee. If you receive a bill from VDACS requesting that you pay the annual fee, please contact our agency at 804-786-3520 or foodsafety@vdacs.virginia.gov so that the matter can be resolved.

Helpful Links

Assistance with acidified vegetable processing from Virginia Tech:

- http://www.fcs.ext.vt.edu/fnh/food-innovations/sample/index.html

Virginia Tech link for information regarding Better Process School:

- http://www.fcs.ext.vt.edu/fnh/food-innovations/business/index.html

Home Canning information:

- http://extension.usu.edu/htm/publications/by=category/category=319
- USDA Complete Guide to Home Canning (PDF: 275 KB / 23 pages)

If you have questions or concerns please contact the VDACS Food Safety and Security Program at:
Phone: 804-786-3520
Email: FoodSafety@vdacs.virginia.gov

FIELD OPERATIONS MANUAL

PROCEDURE III-30
NEW

EMPLOYEE HEALTH POLICY

A new aspect to our recently adopted Retail Food Establishment Regulations is the issue of an Employee Health Policy (sections 2VAC5-585-80 through 2VAC5-585-120 in the Regulations). To address this issue, Food Safety Specialists should focus on 2 components during the inspection: Management awareness of the regulation and whether the firm has an actual health policy in place.

Management awareness:

The Person-in-Charge (PIC) is aware of the regulation that conditional or food employees are required to report certain symptoms or diagnosed illnesses. The PIC is responsible for excluding or restricting employees who show certain symptoms or are diagnosed with specific illnesses (review Part 1 Article 2 – Employee Health). In addition, the PIC is responsible for notifying the department when a food employee is diagnosed with an illness due to Salmonella typhi, Shigella spp., Shiga toxin-producing E-Coli, or Hepatitis A virus.

Employee Health Policy:

The PIC can convey knowledge of an employee health policy or have access to an employee health policy identifying what actions are necessary following a report that an employee has a certain symptom or diagnosed illness.

The policy must reflect the current provisions in the Retail Food Establishment Regulations. Verbal communication of the employee health policy must be specific to the types of illnesses and symptoms that require reporting. Nonspecific statements such as, “sick or ill employees are not allowed to work,” are not acceptable as meeting this requirement.

Employee Health Forms:

The Retail Food Establishment Regulations DO NOT require a written employee health policy. However, a written policy is recommended so that training and record keeping is easier to manage.

Attached below are forms that you may print out and hand to the PIC that will aid him/her in meeting this requirement. The PIC should review these forms with the conditional and/or food employee, have them sign the forms, and keep these forms on file. Again, it is not required that firms have these particular forms on file. They are intended to act as an aid/supplement to help the food establishment meet this requirement.

A firm will be in compliance when all of the above criteria are met. In the event that the PIC does not convey knowledge of the employee health requirement or have access to an employee health policy, you would document this as an objectionable condition on the inspection report.

Issued New September 2008

FORM 1-A

Conditional Employee and Food Employee Interview

Preventing Transmission of Diseases through Food by Infected Food Employees or Conditional Employees with Emphasis on illness due to Norovirus, ***Salmonella* Typhi, *Shigella*** spp., Enterohemorrhagic (EHEC) or Shiga toxin-producing ***Escherichia coli*** (STEC), or hepatitis A Virus

The purpose of this interview is to inform conditional employees and food employees to advise the person in charge of past and current conditions described so that the person in charge can take appropriate steps to preclude the transmission of foodborne illness.

Conditional employee name (print) _____
Food employee name (print) _____
Address _____
Telephone *Daytime:*_____ *Evening:* _____
Date _____

Are you suffering from any of the following symptoms? (Circle one)

		If YES, Date of Onset
Diarrhea?	**YES / NO**	_____
Vomiting?	**YES / NO**	_____
Jaundice?	**YES / NO**	_____
Sore throat with fever?	**YES / NO**	_____

Or

Infected cut or wound that is open and draining, or lesions containing pus on the hand, wrist, an exposed body part, or other body part and the cut, wound, or lesion not properly covered? **YES / NO**
(Examples: *boils and infected wounds, however small)*

In the Past:

Have you ever been diagnosed as being ill with typhoid fever (*Salmonella* Typhi) **YES / NO**
If you have, what was the date of the diagnosis? _____
If within the past 3 months, did you take antibiotics for *S. Typhi?* **YES / NO**
If so, how many days did you take the antibiotics? _____
If you took antibiotics, did you finish the prescription? _____ **YES / NO**

History of Exposure:

1. Have you been suspected of causing or have you been exposed to a confirmed foodborne disease outbreak recently? **YES / NO**
If YES, date of outbreak: _____

a. If YES, what was the cause of the illness and did it meet the following criteria?
Cause: _____

i. Norovirus (last exposure within the past 48 hours)	**Date of illness outbreak** _____
ii. *E. coli* O157:H7 infection (last exposure within the past 3 days)	**Date of illness outbreak** _____
iii. Hepatitis A virus (last exposure within the past 30 days)	**Date of illness outbreak** _____
iv. Typhoid fever (last exposure within the past 14 days)	**Date of illness outbreak** _____
v. Shigellosis (last exposure within the past 3 days)	**Date of illness outbreak** _____

FORM 1-A (continued)

b. If YES, did you:
- **i. Consume food implicated in the outbreak?** _____
- **ii. Work in a food establishment that was the source of the outbreak?** _____
- **iii. Consume food at an event that was prepared by person who is ill?** _____

2. Did you attend an event or work in a setting, recently where there was a confirmed disease outbreak? **YES / NO**

If so, what was the cause of the confirmed disease outbreak? _____

If the cause was one of the following five pathogens, did exposure to the pathogen meet the following criteria?

- **a. Norovirus (last exposure within the past 48 hours)** **YES / NO**
- **b. *E. coli* O157:H7 (or other** EHEC/STEC **(last exposure within the past 3 days)** **YES / NO**
- **c. *Shigella* spp. (last exposure within the past 3 days)** **YES / NO**
- **d. *S.* Typhi (last exposure within the past 14 days)** **YES / NO**
- **e. hepatitis A virus (last exposure within the past 30 days)** **YES / NO**

Do you live in the same household as a person diagnosed with Norovirus, Shigellosis, typhoid fever, hepatitis A, or illness due to *E. coli* O157:H7 or other EHEC/STEC**?**
YES / NO Date of onset of illness _____

3. Do you have a household member attending or working in a setting where there is a confirmed disease outbreak of Norovirus, typhoid fever, Shigellosis, EHEC/STEC **infection, or hepatitis A?**
YES / NO Date of onset of illness _____

Name, Address, and Telephone Number of your Health Practitioner or doctor:
Name _____
Address _____
Telephone – *Daytime:* _____ *Evening:* _____

Signature of Conditional Employee _____ **Date** _____

Signature of Food Employee _____ **Date** _____

Signature of Permit Holder or Representative _____ **Date** _____

FORM 1-B

Conditional Employee or Food Employee Reporting Agreement

Preventing Transmission of Diseases through Food by Infected Conditional Employees or Food Employees with Emphasis on illness due to Norovirus, ***Salmonella* Typhi, *Shigella*** spp., Enterohemorrhagic (EHEC) or Shiga toxin-producing ***Escherichia coli*** (STEC), or hepatitis A Virus

The purpose of this agreement is to inform conditional employees or food employees of their responsibility to notify the person in charge when they experience any of the conditions listed so that the person in charge can take appropriate steps to preclude the transmission of foodborne illness.

I AGREE TO REPORT TO THE PERSON IN CHARGE:

Any Onset of the Following Symptoms, Either While at Work or Outside of Work, Including the Date of Onset:

1. Diarrhea
2. Vomiting
3. Jaundice
4. Sore throat with fever
5. Infected cuts or wounds, or lesions containing pus on the hand, wrist , an exposed body part, or other body part and the cuts, wounds, or lesions are not properly covered (*such as boils and infected wounds, however small)*

Future Medical Diagnosis:

Whenever diagnosed as being ill with Norovirus, typhoid fever (*Salmonella* Typhi), shigellosis (*Shigella* spp. infection), *Escherichia* coli O157:H7 or other EHEC/STEC infection, or hepatitis A (hepatitis A virus infection)

Future Exposure to Foodborne Pathogens:

1. Exposure to or suspicion of causing any confirmed disease outbreak of Norovirus, typhoid fever, shigellosis, *E.* coli O157:H7 or other EHEC/STEC **infection, or hepatitis A.**
2. A household member diagnosed with Norovirus, typhoid fever, shigellosis, illness due to EHEC/STEC, **or hepatitis A.**
3. A household member attending or working in a setting experiencing a confirmed disease outbreak of Norovirus, typhoid fever, shigellosis, *E.* coli O157:H7 or other EHEC/STEC **infection, or hepatitis A.**

I have read (or had explained to me) and understand the requirements concerning my responsibilities under the **Food Code** and this agreement to comply with:

1. Reporting requirements specified above involving symptoms, diagnoses, and exposure specified;
2. Work restrictions or exclusions that are imposed upon me; and
3. Good hygienic practices.

I understand that failure to comply with the terms of this agreement could lead to action by the food establishment or the food regulatory authority that may jeopardize my employment and may involve legal action against me.

Conditional Employee Name (please print) _____

Signature of Conditional Employee _____ **Date** _____

Food Employee Name (please print) _____

Signature of Food Employee _____ **Date** _____

Signature of Permit Holder or Representative _____ **Date** _____

Procedure III-31: Demonstration of Knowledge (Retail Establishment PIC)

The most current version of the retail regulations state that the operator of the establishment is the Person-In-Charge (PIC). Alternatively, the operator can choose to designate a PIC. The PIC is the individual present at a food establishment who is responsible for the operation at the time of inspection. A PIC is required to be present at the establishment during all hours of operation.

It is also a requirement that the PIC demonstrate knowledge of foodborne disease prevention, application of Hazard Analysis Critical Control Point principles, and an overall understanding of the Retail Food Establishment Regulations. The PIC must be knowledgeable about food safety as it relates to their operation. If, for example, the firm does not cook raw foods, they are not expected to be knowledgeable about cooking temperatures.

There are three (3) ways in which the PIC can demonstrate food safety knowledge. This can be accomplished by:

1. Having no violations of priority items during the current inspection;
2. Being a Certified Food Protection Manager (CFPM) who has shown proficiency of required information through passing a test that is part of an accredited program; or
3. Responding correctly to the questions asked by the inspector relating to the food operation.

In the event that the food establishment has violations of priority items during the inspection or a certified food protection manager is not on staff, then a set of questions can be administered to the PIC to determine compliance with the demonstration of knowledge requirement. Attached to this FOM is a list of approved questions that would be appropriate to ask in determining whether an individual can demonstrate this knowledge. All of these questions may not be appropriate for all food service operations. The FSS should ask questions that are appropriate for the level of food service at the establishment. Remember to make the inspection as interactive as possible. Ask questions of the PIC as you conduct your inspection, even if they are a CFPM.

In order to become a CFPM, the individual must pass a test that is part of an accredited program. Currently, only 4 programs have been accredited and they are below. Contact your local health department for more information.

1. 360training.com, Inc
2. National Registry of Food Safety Professionals
3. National Restaurant Association
4. Prometric Inc

At least one employee who has supervisory and management responsibility and the authority to direct and control food preparation and service shall be a certified food protection manager at the firm.

Exception to requirement of CFPM: firms that offer beverage service or serve, sell or distribute only prepackaged foods and beverages do not need a CFPM. However, they still must have PIC, and that PIC must demonstrate knowledge of their food operation. If the firm is conducting any level of food service, they will be required to have a CFPM. This can be something as simple as heating and hot holding hot dogs or precooked pork BBQ.

Classification

In the event the PIC is unable to demonstrate an appropriate level of knowledge, document this as an objectionable condition on the Inspection Report; the Inspection Report should be classified NAI, unless other conditions exist that would elevate the classification to VAI or OAI. An Informational Letter has been developed and is available on an as-needed basis.

Attachment 1: Demonstration of Knowledge Questions and Answers

Procedure III-31: Appendix DOK Questions and Answers

DEMONSTRATION OF KNOWLEDGE QUESTIONS

EMPLOYEE HEALTH & ASSIGNMENT OF RESPONSIBILITY

1. What are the symptoms associated with foodborne illness disease?
2. What diagnosed illnesses are food employees required to report to the person in charge?
3. Who is the person in charge and when must they be available at the food establishment?
4. Who must the person in charge notify if the food employee has been diagnosed with any of the following: Hepatitis A, Shiga toxin-producing Escherichia coli, Shigella spp., nontyphoidal *Salmonella* or Typhoid fever (caused by *Salmonella* Typhi)?

REASON FOR TEMPERATURE CONTROL & APPROVED SOURCE

1. What is a Time/Temperature Control for Safety Food (TCS)?
2. What is the Temperature Danger Zone?
3. Why do TCSs need to be kept out of the “danger zone”?
4. What foods are approved for use in a food establishment?
5. Shellfish tags must be kept for _____ days?

TCS TIME AND TEMPERATURE

1. To what temperature do you cook poultry?
2. To what temperature do you cook ground beef?
3. To what temperature do you cook fish?
4. To what temperature to you cook chopped or ground meats and fish?
5. To what temperature to you cook stuffed fish, meat, pork, pasta and poultry?

6. Hot, cooked TCS foods must be maintained above what temperature?
7. How do you know if TCSs are cooked to the proper temperature?
8. What is the minimum temperature that should be used to reheat foods?
9. What is the minimum holding temperature for cold TCS foods?
10. What are effective methods of cooling hot foods?
11. TCS food must be cooled from 140ºF to 70ºF within _____ hours, and to 41ºF or less within a total of 6 hours.
12. What foods are required to be date marked?
13. How are the foods to be marked?
14. What are the proper methods for thawing foods?
15. How should food be cooked in the microwave?
16. Ready-to-eat food is _____?
17. A Consumer Advisory is required when?

CROSS CONTAMINATION/HAND CONTACT/ HANDWASHING

1. What is cross contamination?
2. What are some examples of cross contamination?
3. What steps do you take to prevent cross contamination?
4. Bare hand contact is not allowed when handling _____?
5. When must food workers wash their hands?
6. What is the correct procedure for employees to wash their hands?
7. What is the most important personal hygiene step food handlers can take to help prevent a foodborne illness from occurring?
8. What should you do if your gloves become contaminated?

CLEANING & SANITIZING

1. What is the proper procedure for cleaning and sanitizing your equipment and utensils?
2. What is the required minimum temperature of water that is to be used for manual washing of equipment and utensils?
3. What is the correct strength for a chlorine solution used to sanitize food contact surfaces and how do you ensure that it is the proper strength?
4. What is the difference between cleaning and sanitizing?
5. What do you need to do if you transfer a chemical to a plastic spray bottle or a different container?
6. What is the best way to control cockroaches, mice, flies and other pests?
7. Where must you store chemicals such as cleaners and sanitizers?

DEMONSTRATION OF KNOWLEDGE ANSWER KEY

EMPLOYEE HEALTH

1. Vomiting, diarrhea, fever, jaundice, sore throat with fever
   2VAC5-585-80(A)(1)

2. Employees must report the following diagnosed illnesses to the PIC:
   a. Typhoid fever (caused by S*almonella* typhi);
   b. Shigella spp.;
   c. Shiga toxin-producing Escherichia coli;
   d. Hepatitis A virus and
   e. nontyphoidal S*almonella*

   2VAC5-585-80(A)(2)

3. The operator shall be the Person in Charge (PIC) or shall designate a PIC and shall ensure that a PIC is available at the food establishment during all hours of operation.
   2VAC5-585-50

4. The person in charge shall notify the regulatory agency.
   2VAC5-585-120

REASON FOR TEMPERATURE CONTROL & APPROVED SOURCE

1. A food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation:
   2VAC5-585-40

2. 41ºF to 135ºF
   2VAC5-585-820

3. Disease causing bacteria grow best in the temperature danger zone. The goal of time and temperature controls is to keep food entirely out of this danger zone or to pass foods through it as quickly as possible. When foods pass quickly through the danger zone, any bacteria present are not allowed an adequate time period in which to grow.

4. Any food that is from an approved source, properly labeled, and in proper condition.
   2VAC5-585-260 & 2VAC5-585-270

5. 90 days
   2VAC5-585-440(C)

TCS TIME AND TEMPERATURE

1. 165ºF for 15 seconds
   2VAC5-585-700(A)(3)

2. 155ºF for 15 seconds
   VAC 5-585-700(A)(2)

3. 145ºF for 15 seconds
   2VAC5-585-700

4. 155ºF for 15 seconds
   2VAC5-585-700(A)(2)

5. 165ºF for 15 seconds
   2VAC5-585-700(A)(3)

6. Above 135ºF at all times
   2VAC5-585-820(A)(1)

7. By using a properly calibrated probe thermometer to check the internal temperature of the food.
   2VAC5-585-1510

8. 165ºF for 15 seconds
   2VAC5-585-760

9. 41ºF or below at all times
   2VAC5-585-820(A)(2)

10. Placing food in shallow pans; separating the food into smaller portions; using rapid cooling equipment; stirring the food in a container placed in an ice bath; ice paddles or other effective methods.
    2VAC5-585-810

11. 2 hours
    2VAC5-585-800

12. Refrigerated, ready-to-eat, TCSs prepared and held in a food establishment for more than 24 hours and refrigerated ready-to-eat foods that are commercially prepared and packaged shall be marked when the package is opened and held for more than 24 hours. (Except exemptions)
    2VAC5-585-830

13. The foods must be clearly marked to indicate the date or day by which the food is to be sold, consumed on the premises, or discarded.
    2VAC5-585-830

14. Under refrigeration; running water that is 70ºF or below; in the microwave; or as part of the cooking process.
    2VAC5-585-790

15. Food should be rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat; covered to retain surface moisture; heated to a temperature of at least 165°F (74°C) in all parts of the food; and allowed to stand covered for two minutes after cooking to obtain temperature equilibrium. Check the food with a thermometer to ensure that it reached at least 165ºF.
    2VAC 5-585-710

16. Food that is edible without additional preparation to achieve food safety.
    2VAC 5-585-40

17. If an animal food is served or sold raw, or undercooked then the consumer must be made aware of the risk.
    2VAC 5-585-930

CROSS CONTAMINATION/HAND CONTACT/ HANDWASHING

1. When harmful substances or microorganisms are introduced into foods.

2. Contaminating cooked foods with drippings from raw foods; ready-to-eat food touching improperly cleaned and sanitized food contact surfaces; failure to wash hands before touching ready-to eat foods after handling raw foods or other contaminated items.

3. Proper hand washing after hands have been contaminated; proper washing and sanitizing of food contact surfaces when switching from raw to ready to eat foods, storing raw foods below and away from ready to eat foods.
    2VAC5-585-130 through 2VAC5-585- 255 and 2VAC5-585-470

4. Ready-to-eat foods.
    2VAC5-585-450(B)

5. After touching bare human body parts or hair other than clean hands and clean, exposed portions of arms; after using the toilet room; after caring for or handling support animals; after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking; after handling soiled equipment or utensils; during food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks; when switching between working with raw foods and working with ready-to-eat foods; before donning gloves for working with food; prior to donning single-use gloves if gloves are used; and after engaging in other activities that contaminate the hands.
    2VAC5-585-160

6. Food employees must wash hands thoroughly with hot water (100ºF) and soap, rub their hands vigorously together for 20 seconds, rinse their hands and dry their hands with a disposable paper towel or automatic hand dryer.
    2VAC5-585-140

7. Wash hands as often as necessary and do not touch ready-to-eat foods with bare hands.
    2VAC5-585-160 & 2VAC5-585-450

8. Remove the gloves, throw the gloves away, wash your hands and put on new gloves.
    2VAC5-585-580

CLEANING & SANITIZING

1. Pre-scrape, wash, rinse, sanitize and air-dry.
   2VAC5-585-1460, 2VAC5-585-1820 & 2VAC5-585-1960

2. 110ºF
   2VAC5-585-1650

3. The concentration must be between 50 and 100 parts per million, which can be measured with a chlorine test strip.
   2VAC5-585-1530, 2VAC 5-585-1700

4. Washing removes contamination and sanitizing reduces microorganisms by 99.999%.

5. You must properly label the container or spray bottle with what it contains.
   2VAC5-585-3330

6. The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by routinely inspecting incoming shipments of food and supplies; routinely inspecting the premises for evidence of pests; using methods, if pests are found, such as trapping devices or other means of pest control; and eliminating harborage conditions.
   2VAC5-585-3270

7. Away from any food or clean equipment or utensils.
   2VAC 5-585-3340

FIELD OPERATIONS MANUAL

PROCEDURE III-32
New

Equipment Sink Requirements in Retail Food Establishments

To help clarify the inspectional classification of various plumbing deficiencies within food establishments, the following guidelines have been developed in order to keep enforcement consistent across the state.

The Retail Food Establishment Regulations state that unless otherwise approved a sink with at least three compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.

The regulations do make allowances for the use of alternative manual warewashing equipment when there are special cleaning needs or constraints and its use is approved. Alternative equipment does include two-compartment sinks.

For firms utilizing a two compartment sink, the Food Safety Specialist will need to determine whether the existing set-up is adequate to meet the cleaning needs of the firm. In lieu of a formal approval process, we will base our actions on the documentation provided during the inspection.

Administrative approach

If the Inspector determines that the two compartment sink is adequate then the lack of a three compartment sink will not be documented on the Inspection Report, however, the Inspector will need to submit a separate memo to the office detailing the existing food preparation in the firm and that a two compartment sink was found adequate to meet the needs of the firm. No correspondence will be sent to the firm from the office acknowledging the adequacy of the two compartment sink.

NOTE: Any modifications to the foodservice/food processing operations would require the firm to upgrade their warewashing capabilities to include that of a three compartment sink.

In situations where the firm **only** has a two compartment sink and it is obvious that the sink does not meet the cleaning needs of the firm then it should be documented as an objectionable condition on the Inspection Report. The Inspection Report should be classified VAI and an Informational Letter should be requested. If the follow-up inspection finds the firm still non-compliant on this issue then the inspection should be classified OAI and a Letter of Warning should be requested. Further non-compliance will result in a Field Hearing, etc. The Inspector will need to submit a separate memo detailing the food preparation on-going in the firm.

On the other hand, if the firm has at least 1 three compartment sink available for warewashing within the firm, then the lack of a three compartment sink in a particular food preparation department (i.e. meat, seafood, deli, etc) should be documented and the Inspection Report classified NAI. This would be applicable whether the firm has an two compartment equipment sink available in the particular department or if there is no equipment sink available in that department. A memo

detailing the warewashing set-up should be submitted for the firm file.

NOTE: Inspectors should verbally discuss with management the cross contamination risks involved when utilizing a common (i.e. single) three compartment sink for warewashing equipment from multiple departments.

Situations where it is questionable as to the adequacy of the two compartment sink should also be documented on the Inspection Report. The Inspection Report should be left "unclassified" with the office making the classification decision. For proper evaluation, the Inspector will need to submit a detailed description of the existing food service/food preparation so that the office can fully evaluate the needs of the operation.

Classification guidance

As stated previously, the Food Safety Specialist should only write-up the lack of a three compartment sink if they consider it a food safety issue. Generally speaking, if the firm is conducting a limited foodservice/food processing business with a minimal number of kitchenware items to be cleaned and sanitized than the use of a two compartment sink will be adequate to meet the cleaning needs of the firm.

Example situations

- Beverage service only. *A two compartment sink is adequate.*
- Minimal food processing involving limited kitchenware such as knives, tongs, scoops, etc. *A two compartment sink is adequate.*
- Complex food processing such as frying, salads, raw/ready-to-eat products. *A two compartment sink is inadequate. A three basin sink is required.*
- New firm consultations. *New firms are to be advised of the need to provide a 3 compartment sink for warewashing purposes.*
- Multiple departments utilizing 1 three compartment sink in the firm. *The regulations only require 1 three basin sink in the firm. The situation should be documented and classified NAI.*
- No multiple compartment sink in the firm with a food processing operation (i.e. the firm is utilizing a single basin equipment sink for warewashing). *A three compartment sink is required unless you determine that a two compartment sink is adequate to meet the cleaning needs of the firm. The situation should be documented, the report left unclassified, and details provided in a separate memo to your Regional Manager.*
- No equipment sink at all in the firm with a food processing operation. *A three compartment sink is required unless you determine that a two compartment sink is adequate to meet the cleaning needs of the firm. The situation should be documented, the report left unclassified, and details provided in a separate memo to your Regional Manager.*

Finally, the above list of example situations is not meant to be all-inclusive. As new situations arise and a regulatory approach determined, they will be added to the list.

Issued New January 2009

Field Operations Manual

Procedure III-33
New

Smoking Restrictions in Retail Food Stores

The Virginia General Assembly passed legislation effective December 1, 2009 that bans smoking in restaurants with limited exceptions. This legislation impacts VDACS regulated establishments as the definition of "restaurant" means any place where food is prepared for service to the public on or off the premises, or any place where food is served. This will be applicable to our retail food stores with food service operations.

The law requires firms to:
a. Post signs stating "No Smoking" or containing the international "No Smoking" symbol in a clear and conspicuous manner in every business where smoking is prohibited.
b. Remove all ashtrays and other smoking paraphernalia from all areas of the business where smoking is prohibited.
c. Ensure that no person shall smoke in any area of the restaurant in which smoking is prohibited.

Exemptions:

Although the law makes allowances for exemptions they are limited and are primarily geared toward a traditional VDH establishment. The law does not make any exemption for firms based on seating. The law applies to all "restaurants" regardless of the seating capacity.

Probably the only exemption relevant to VDACS firms will be if a portion of the building is constructed in such a manner so that the portion where smoking is permitted is structurally separated from the non-smoking portions and to which ingress and egress is through a door. In addition, the smoking area must be separately vented to prevent the recirculation of air from the area of the restaurant where smoking is allowed into the non-smoking areas. At least one public entrance into the restaurant must be into a non-smoking area of the restaurant.

The local building official will review and approve the design for compliance with all applicable provisions of the building code.

How will the ban be enforced? What role will VDCAS have in enforcing the ban?

During your routine inspections, Food Safety Specialists will evaluate a firm's compliance with the ban. Food Safety Specialists will not document a firm's deficiency with meeting the requirements of the smoking ban on the Inspection Report.

Your initial review of a firm's compliance with the ban will be informational in nature. You will discuss the smoking ban with the firm management and advise them on any deficiencies they have in meeting the requirements of the ban.

If subsequent inspections find the firm to be non-compliant with the ban then the Inspector is to compose an email to their Regional Manager describing the situation. Virginia Department of Health will conduct any follow-up investigations related to the smoking ban. (NOTE: Firms that fail to meet the requirements of the smoking ban are subject to a civil penalty of not more than $25).

A firm's failure to meet the requirements of the smoking ban will not effect (change) the overall inspection classification.

Frequently Asked Questions:

Can a restaurant allow smoking throughout the facility if they advertise this fact to their patrons by posting signs alerting them that smoking is allowed anywhere in the restaurant? *No. The law requires either no smoking or smoking in very specifically designated areas.*

Do restrooms need to be smoke free*? Yes. The law prohibits smoking in all restrooms in a "restaurant".*

Does the law have any provisions for smoking after hours when children are not present? *No. The law is in effect at all times the "restaurant" is in operation.*

To what extent will smoking be allowed in outdoor areas? *Smoking can be permitted in outdoor areas of a "restaurant" provided the outdoor area is not enclosed by any screened wall, roll-up doors or other temporary enclosures.*

Can employees smoke in a "break room" or office? *The answer depends on the location of the break rooms and office spaces.*
a. If the break rooms/offices are located in close proximity to the food service and/or customer service areas where there is a strong likelihood of smoke drifting out to those areas then we will not permit employee smoking in a break room/office setting.
b. If the break rooms/offices are far removed from the food service and/or customer service areas of the store where the likelihood of smoke drifting out to those areas is minimal then we will permit employee smoking in a break room/office setting.
For example: A supermarket where the break room is located in the back stockroom and the deli is in the front of the store would be a situation where smoking would be acceptable in the break room.

Issued New December 2009

FIELD OPERATIONS MANAUAL

Procedure III-34
Revised

VARIANCE PROCEDURES

Overview

A "variance" means a written document issued by the department that authorizes a modification or waiver of one or more requirements of the 2010 Retail Food Establishment Regulations if, in the opinion of the department, a health hazard or nuisance will not result from the modification or waiver. The 2010 Retail Food Establishment Regulations (2VAC5-585-860) require that a food establishment obtain a variance from our department before:

1. Smoking food as a method of food preservation rather than as a method of flavor enhancement;
2. Curing food;
3. Using food additives or adding components such as vinegar:
    a. As a method of food preservation rather than as a method of flavor enhancement; or
    b. To render a food so that it is not potentially hazardous (time/temperature control for safety);
4. Packaging food using a reduced oxygen packaging method except as specified under 2VAC5-585-870 where a barrier to Clostridium botulinum in addition to refrigeration exists;
5. Operating a molluscan shellfish life-support system display tank used to store and display shellfish that are offered for human consumption;
6. Custom processing animals that are for personal use as food and not for sale or service in a food establishment;
7. Sprouting seeds or beans; or
8. Preparing food by another method that is determined by the regulatory authority to require a variance

During each retail food establishment inspection, the inspector should determine if the firm is engaged in any of the above processes and whether or not they have obtained a variance. If the firm carries out any of the above processes, they will need to be granted a variance if one has already not been granted.

For example, the majority of sushi operations under inspection by VDACS use food additives (vinegar) to render a food (rice) so that it is not potentially hazardous (time/temperature control for safety). These firms would require a variance. ***FYI: Sushi firms not wishing to apply for a variance have the option of using Time As a Public Health Control (See Procedure III-21 and 2VAC5-585-850).***

In addition the department may grant a variance by modifying or waiving the requirements of the Retail Food Establishment Regulations if in the opinion of the department a health hazard or nuisance will not result from the variance (2VAC5-585-3540).

Applying for Variance Procedure

In order to obtain a variance from VDACS, the firm must provide the following information **in writing** to the appropriate Regional Office:

1. A statement of the proposed variance of the regulation requirement citing relevant regulation section numbers;
2. An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant regulation sections will be alternatively addressed by the proposal; and
3. A HACCP plan, if required, that includes the information specified under 2VAC5-585-3630 as it is relevant to the variance requested. *NOTE: HACCP plans are required when the firm engages in any process listed in 2VAC5-585-860 (see above) and if a firm wishes to serve or offer for sale raw animal foods in ready-to-eat form (see 2VAC5-585-700 D 3).*

Office Procedure

The Regional Manager, Compliance Officer, or designee will review the information submitted and determine if the variance is approved or denied. Approval is based on inclusion of all necessary materials for processing a variance request indicated in 2VAC5-585-3541. Specifically, the variance request must include the following if applicable: appropriate CCPs depending on the product/process, presence of recipes, a flow chart, appropriate critical limits and corrective actions, and SSOPs for employees. In addition, published scientific work or a validated process prepared and signed by a recognized process authority may be required (See Procedure III-37 – Initial Validation of a HACCP Plan for additional information).

If the variance is approved a letter will be sent to the firm and the Food Safety Specialist will receive a copy of the letter as well as the information submitted when the variance was requested (See Items 1-3 above). A copy of the letter and the information will be retained in the firm's file.

Once the variance is approved and the FSS has received the letter, the FSS will need to visit the firm within 30 days of the date of the letter to assure the firm is complying with the procedures that were submitted and the HACCP plan (if one is required). If a HACCP plan is required, the inspector must request and review records pertaining to procedures for monitoring critical control points; monitoring of the critical control points, verification of the effectiveness of an operation or process; and necessary corrective actions if there is a failure at a critical control point (See 2VAC5-585-3542 - Conformance with approved procedures, 2VAC5-585-3630 - Contents of a HACCP plan, and Procedure III-38 – On-Site Verification of HACCP Plans)

If the reviewer determines that a variance should not be granted, a letter will be sent to the firm and the inspector will receive a copy of the letter. Again, once the FSS has received the denial

letter, the FSS will need to visit the firm within 30 days of the date of the letter to assure the firm is not engaging in the process in question.

Field Procedures

Classification of Inspection Reports

If an inspection reveals that a firm is engaging in processes that require a variance, the FSS should notify the firm of the need for a variance and explain the procedures for applying for a variance. The inspection should list the specific processes taking place and the products being manufactured, if applicable. The inspection will be classified VAI and given a 30 day follow up date. The inspector may also request that the appropriate letter of information be sent to the firm. Depending on the severity of the situation (for example if the firm is canning low acid foods or acidified foods without process approval) the FSS shall contact their Regional Manager who will determine if the firm would be required to discontinue the process immediately. If during the follow up inspection, a variance has been granted and the firm is following the conformed procedures, the firm will be in compliance and the inspection report will be classified NAI.

If the firm has not been granted a variance before the follow up inspection and is still engaged in the specialized process at issue, the firm will be ordered to immediately discontinue the process immediately. The inspection report will be classified OAI and given a 30 day follow up. A letter of warning will be sent to the firm to initiate the regulatory process.

Revised June 2014

Procedure III-35: On-Site Corrections in Retail Food Establishments

Achieving Compliance Using On-site Corrections - Taken from: Managing Food Safety: A Regulator's Manual For Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems (http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM078159.pdf)

On-site corrections are intended to achieve immediate corrective action of out-of-control risk factors posing an immediate, serious danger to the consumer during the inspection. These risk factors are:

1) Food obtained from unapproved sources,
2) Improper cooking of raw animal or plant foods,
3) Improper holding of time/temperature control for safety food,
4) Contaminated food contact equipment and surfaces, and
5) Poor personal hygiene of food employees.

Usually these violations are "operational" rather than structural and can be addressed by management at the time of the inspection. For example:

- Undercooking hamburger meat presents an immediate danger to the consumer that can be corrected on-site by additional cooking.
- Preparing lettuce on the same work surface previously used to cut raw chicken without having washed, rinsed, and sanitized the surface presents an immediate danger to the consumer that can be corrected on-site by discarding the contaminated lettuce.

Annex 6 of *Managing Food Safety: A Regulator's Manual For Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems* provides a full list of suggested on-site corrections for out-of-control procedures found during your inspections.

It is essential to consumer protection and to regulatory credibility for on-site correction to be obtained for any out-of-control risk factors. During your inspection, you must take on-site corrective action for any out-of-compliance risk factors. Obtaining on-site correction conveys the seriousness of the violation to management. Failure to require on-site correction when an out-of-control risk factor has been identified implies that the risk factor has little importance to food safety. If the operation is briefly stopped to address the out-of-control risk factor, the operator may be more responsive to addressing the practices resulting in the out-of-control risk factor in the future. A more favorable impact on future behavior may result that might not have been achieved through discussion alone.

When recommending on-site correction, effective communication regarding out-of-control risk factors is essential and can often be accomplished by -

- Discussing food safety concerns in words that can be easily understood by the person in charge and the food service workers
- Conveying the seriousness of the out-of-control risk factors in terms of increased risk of illness or injury

Although the person in charge is ultimately responsible for the conditions in the facility and should therefore be informed of all out-of-control risk factors, timely training of the food service workers can have a great impact on future behavior. A translator and/or special training material may be necessary when language or education barriers exist. Remember that while it is important for both the person in charge and food service workers to know why they are having to make a correction, the long-term effectiveness of making the correction may be lost if you are too technical or scientific in your rationale.

During the discussion of inspection findings with the person in charge, you should keep the discussion focused on correction of violations that present an immediate danger to the consumer. Discussion of lesser code violations should be deferred until out-of-control risk factors are discussed and on-site correction is obtained. It is important to point out to the operator that while most basic sanitation problems do not pose a significant threat to the public, foodborne illness caused by out-of-control risk factors often results in significant losses to consumers and the operator. Negligence for not having a strong food safety management system in place to control risk factors can result in financial ruin for even the largest of retail operations.

DETERMINING THE APPROPRIATE ON-SITE CORRECTION

To assist you in determining the appropriate on-site correction, you should reference existing regulatory policies and procedures. Your experience and professional judgment will also help you to offer the operator practical solutions for bringing the risk factors under control.

In most cases, selecting the most appropriate on-site correction when out-of-control risk factors are observed will be straightforward. For instance, if hamburgers are inadequately cooked, the on-site correction is to continue cooking until the appropriate cooking temperature is reached.

Determining the most appropriate on-site correction of out-of-control procedures such as inadequate hot and cold holding can be very complicated. Since determining on-site correction depends on a number of factors, you may need to conduct a hazard analysis of the food in order to determine the appropriate course of action to take. Annex 6 of the *Managing Food Safety: A Regulator's Manual For Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems* lists the out-of-control procedures that may require a hazard analysis in order to determine the appropriate on-site correction. Reference can also be made to FOM Procedure III-08 when deciding the appropriate corrective action for hot or cold foods found out of temperature control.

Limitations of Reheating as an On-site Correction

One on-site correction used in the field is reheating. A common misconception is that reheating is a "magic step" for eliminating hazards resulting from improper holding or cooling. If a ready-to-eat, potentially hazardous time/temperature control for safety food is improperly held or cooled, the potential for spore- or toxin-forming bacteria growth increases. Whether to recommend that the food be reheated or discarded depends on a number of factors including, but not limited to:

- the hazards of significance

- the nature of the food
- its intended use
- other important considerations discussed later in this section including the degree of time and temperature abuse

Although reheating can eliminate vegetative bacterial cells resulting from post-cook contamination (i.e. *Salmonella*) or from improper holding or cooling (i.e. *Clostridium perfringens*), it has limitations that must be considered.

Some bacteria form spores that survive cooking. These spores can germinate and grow if food is improperly held after cooking. Bacterial spores are likely to be present in most foods. When a food is expected to contain spores of toxigenic bacteria such as Clostridium botulinum or Bacillus cereus, reheating may be ineffective. The emetic toxin of B. cereus, which has been largely associated with outbreaks in starchy foods, is very stable to heat. While the toxin of C. botulinum may be destroyed with extended reheating, the critical limit for reheating in the Retail Food Establishment Regulations for Enforcement of the Virginia Food Laws (165 °F for 15 seconds) will not be effective in ensuring the food's safety.

Staphylococcus aureus does not produce spores, only a heat-stable toxin when present in large numbers. Time- or temperature-abused, RTE, TCS foods that are touched by bare hands, or otherwise contaminated with the organism, are at risk.

Neither cooking nor reheating destroys chemical hazards such as ciguatera toxin or scombrotoxin in fish; therefore, fish that are subject to these hazards and are received from unapproved sources or at improper temperatures should be rejected.

Viruses are somewhat resistant to heat and given their low infectious dose may not be reduced to safe levels using the reheating parameters in the Retail Food Establishment Regulations for Enforcement of the Virginia Food Laws. Therefore, if ready-to-eat food is touched with bare hands, you will need to address several questions in order to make the appropriate on-site correction recommendation, including:

- Does the facility have an employee health policy to identify, restrict, and exclude ill employees?
- Did the employees working with the food in question effectively wash their hands and are handwashing facilities adequate?
- Is there an approved, alternate procedure to no bare hand contact in place and was it followed prior to the bare hand contact?
- Has there been an opportunity for the employee's hands to become contaminated?
- Was the bare hand contact with ready-to-eat food limited or extensive?

Use these questions as the framework for making a recommendation for on-site correction that is based on current science and your extensive knowledge of the operation. Once you have answered these questions, you should have enough information to determine the likelihood of occurrence of hazards transmitted by bare hands. Remember that viruses may not be destroyed to safe levels by reheating, so if you determine in your

assessment that there is a high risk of viral contamination, then discarding the affected food may be the most appropriate recommendation for on-site correction.

When bare hand contact with ready-to-eat food is not observed or when bare hand contact is observed but the risk of viral contamination is low, additional analysis is needed before recommending reheating as an on-site correction for food found out of temperature. In order to properly evaluate the degree of time and temperature abuse and the proper disposition of the affected ready-to-eat food, the following questions should be considered:

- Are there any written procedures in place for using time alone as a public health control and, if so, are they being followed properly?
- What are the ingredients of the food and how was it made?
- Is it likely that the food contains *C. perfringens*, *C. botulinum*, or *B. cereus* as hazards?
- Has there been an opportunity for post-cook contamination with raw animal foods or contaminated equipment?
- If there has been an opportunity for post-cook contamination, can the hazards of concern be eliminated by reheating?
- Are the food workers practicing good personal hygiene including frequent and effective handwashing?
- Was the food reheated or cooked to the proper temperature before being placed out of temperature control?
- What is the current temperature of the food when taken with a probe thermometer?
- How long has the food been out of temperature control (ask both the manager and food employees)?
- Are the answers of the food employees and the manager consistent with one another when asked how long the food has been out of temperature control?
- Is it likely that food has cooled to its current temperature after being out of temperature control for the alleged time?
- Will the food be saved as leftovers?
- How long before the food will be served?
- Given what you know about the food, the food's temperature, the handling of the food, and the alleged time out of temperature, is it reasonably likely that the food already contains hazards that cannot be destroyed by reheating?

The answers to these questions, in combination with observations made during your inspection, should provide you with enough information to make the appropriate recommendation for on-site correction. If you are still unable to determine the most appropriate disposition of the food after you have conducted your assessment, you may want to consult your supervisor.

Follow-up Activities Pertaining to Risk Factor Violations

In a retail setting, it is required that the inspector take immediate corrective action on foodborne illness risk factor violations. For those risk factor violations that cannot be corrected on-site, they must be followed-up on during the next inspection, whether that is a follow-up compliance inspection or a routine inspection. For

instance, an employee health policy is not in place at the firm during the first inspection. This is a risk factor violation and the inspector should make a point to speak with management about the importance of employee health and reporting and leave the manager with information, such as FDA Form 1B Conditional Employee or Food Employee Reporting Agreement. During the next routine inspection, the inspector needs to ask management how they have implemented the policy, either by employee meetings, posting signage or having employees sign an agreement. Events that would trigger follow-up activities would include any violations marked under items number 1 through 23 on the retail inspection report as these items are considered foodborne illness risk factors.

Summary

As you can see, there is no "catch-all" rule for determining the appropriate on-site correction. Due to the economic hardship that may be involved, it is important for you to base your recommendations on sound science. It is crucial that you have a significant, working knowledge of food microbiology. Your final decision should be based on the best scientific analysis and professional judgment after considering all the information that you have at hand. In some cases, you may even need to consult with your Regional Manager to determine if a food is safe to eat or whether a correction is needed.

FIELD OPERATIONS MANUAL

PROCEDURE III – 36
New

Long Term Compliance in Retail Food Establishments

Achieving Long-Term Compliance - Taken from: Managing Food Safety: A Regulator's Manual For Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems
(http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM078159.pdf)

While on-site correction of out-of-control risk factors is essential to consumer protection, achieving long-term compliance is equally important. Overcoming several misconceptions about long term compliance will help you in achieving a desirable change of behavior. For example, we use a 55-item inspection report in which only observed violations are marked OUT. It is often taken for granted that if there are no violations marked, the risk factors are being controlled. This is not necessarily true since the observation of code violations is subject to many variables such as the time of day or duration of the inspection. Another misconception is that training alone will result in risk factors being controlled. While training may help, there is no guarantee that knowledge acquired will equate to knowledge applied in the workplace. Another assumption is that enforcement actions such as letters or administrative hearings or on-site corrections will automatically result in future management control. Unfortunately, there is no assurance that any of these actions will result in the long-term control of risk factors.

Long-term compliance may best be achieved through voluntary actions by the operator. If an operator supports the concept that a food safety management system is needed, there is a better chance that long-term compliance will be achieved. The following system components may be used alone or in combination by the operator to provide voluntary active managerial control of risk factors: equipment and layout; buyer specifications; recipe/process instructions; First-In, First-Out; Standard Operating Procedures; and Risk Control Plans.

Equipment and Layout - Critical limits are difficult to achieve when equipment does not work properly. Proper calibration of equipment is vital to achieving food safety. When calibration is unsuccessful or is not feasible, equipment should be replaced. In addition to equipment malfunctioning, poor equipment layout can present opportunities for cross contamination and must be considered. For example -

- Hamburgers with uniform thickness and weight are not all reaching a safe cooking temperature in a given time. Upon examination, it is determined that the grill is distributing heat unevenly. A new element is installed to correct the problem.
- Splash from a nearby handwashing sink is seen on a prep table. A splash guard is installed to prevent cross contamination from the handwashing sink to the prep table.

Buyer Specifications - Written specifications for the goods and services purchased by an establishment prevents many problems. For example -

- Fish posing a parasite hazard and intended for raw consumption has not been frozen for the specified time and temperature and no freezing equipment is on-site at the retail facility. Buyer specifications are established to place the responsibility for freezing the fish on the supplier.
- Lobster tails, hamburgers, or other products cooked with a set time parameter on a conveyor are not reaching the proper temperature in the specified time because they are larger than the size for which the conveyor is calibrated. Buyer specifications are established to restrict the size of products received from the supplier.

Recipe/Process Instructions - Simple control measures integrated into recipes and processes can improve management control over risk factors. For example -

- Process instructions that specify using color-coded cutting boards for separating raw animal foods from ready-to-eat products are developed to control the potential for cross contamination.
- Pasteurized eggs are substituted in recipes that call for raw or undercooked eggs to reduce the risk of foodborne illness.
- Commercially, precooked chicken is used in recipes calling for cooked chicken such as chicken salad to reduce the risk of contaminating food contact surfaces and ready-to-eat food with raw chicken.

First-In-First-Out (FIFO) - Product rotation is important for both quality and safety reasons. "First-In-First-Out" means that the first batch of product prepared and placed in storage should be the first one sold. Date marking foods as required by the *Retail Food Establishment Regulations for Enforcement of the Virginia Food Law* facilitates the use of a FIFO procedure. The FIFO concept limits the potential for pathogen growth, encourages product rotation, and documents compliance with time/temperature requirements.

Standard Operating Procedures (SOPs) - Following standardized, written procedures for performing various tasks ensures that quality, efficiency, and safety criteria are met each time the task is performed. Although every operation is unique, the following list contains some common management areas that can be controlled with SOPs:

- Personnel (disease control, cleanliness, training)
- Facility maintenance
- Sanitary conditions (general cleaning schedule, chemical storage, pest control, sanitization of food contact surfaces)
- Sanitary facilities (approved water supply and testing, if applicable, plumbing, sewage disposal, handwashing and toilet facilities, trash removal)
- Equipment and utensil maintenance

SOPs can also be developed to detail procedures for controlling risk factors:

- Procedures are implemented for measuring temperatures at a given frequency and for taking appropriate corrective actions to prevent hazards associated with inadequate cooking.
- Adequate handwashing is achieved by following written procedures that dictate frequency, proper technique, and monitoring.

Risk Control Plans (RCPs) - A RCP is a concisely written management plan developed by the retail or food service operator with input from the Food Safety Specialist that describes a management system for controlling specific out-of-control risk factors. A RCP is intended to be a voluntary strategy that you and the person in charge *jointly* develop to promote long-term compliance for *specific* out-of-control risk factors. It should be noted that you are not to develop this plan for the operator. Instead, you should provide resources and regulation code references for the operator to use. Once they have written the plan, review it and provide input. For example, if food is improperly cooled in the establishment, a system of monitoring and record keeping outlined in a RCP can ensure that new procedures are established to adequately cool the food in the future. By implementing basic control systems over a period of time (e.g., 60 - 90 days), it is likely that the new controls will become "habits" that continue.

A RCP should stress simple control measures that can be integrated into the daily routine. It should be brief, no more than one or two pages for a single risk factor, and address the following points in very specific terms:

- What is the risk factor to be controlled?
- How is the risk factor controlled?
- Who is responsible for the control?
- What monitoring and record keeping is required?
- Who is responsible for monitoring and completing records?
- What corrective actions should be taken when deviations are noted?
- How long is the plan to continue?
- How are the results of the RCP communicated to you?

By implementing a RCP, the retail or food service operator will have the opportunity to determine the appropriate corrective action for the identified problem and design an implementation strategy to best suit their facility and operation. Since the RCP is tailored to meet the needs of the establishment, the operator takes complete ownership of the plan and is ultimately responsible for its development and implementation. Your role as the food safety specialist is to consult with the operator by suggesting ways that the risk factor(s) might be controlled. By creating a RCP, the operator realizes that a problem exists in their food safety management system and commits to a specific correction plan rather than merely acknowledging a single violation. Follow up by telephone or in person indicates to the operator your interest in seeing their plan succeed. This also gives you an opportunity to answer any questions and offer feedback to make the RCP more useful. An example of a Risk Control Plan can be found in Annex B of the VDACS Procedures for Standardization of Food Safety Specialist Staff.

Voluntary Food Safety Management Systems based on HACCP Principles: The *Retail Food Establishment Regulations for Enforcement of the Virginia Food Law* only requires HACCP plans for a few specific specialized processes; however, the development of voluntary HACCP plans is always encouraged. The FDA document *"Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishment"* is written for this purpose. A retail or food service operator, in consultation with their Food Safety Specialist or other food safety professional, can use this document to establish an effective food safety management system based on the principles of HACCP.

SUMMARY

The ultimate responsibility for food safety at the retail level lies with retail and food service operators and their ability to develop and maintain effective food safety management systems. Conducting an inspection provides you with an opportunity to work with an operator to evaluate and strengthen their active managerial control of foodborne illness risk factors. At a minimum, you should suggest some of these intervention strategies to retail food service operators as ways for them to make positive adjustments to their current operating procedures. Long-term compliance by the firm will reduce the recurrence of out-of-control risk factors and reduce the risk of foodborne illness in a facility. Having open conversations with the firm on ways they can improve is essential to long-term compliance. Instead of simply stating violations noted during the inspection, explain to management options for corrections and the public health reasons behind the violation. Help them learn, teach them what you know and assist them with incorporating these principles into their routine activities.

If a firm's inspectional history reveals a pattern of repeated risk factor violations then the Food Safety Specialist must discuss with firm management the options available (see Annex 6 of *Managing Food Safety: A Regulator's Manual For Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems*) to achieve long-term compliance of the out-of-control risk factors. The inspector should document the discussion and the planned remediation strategies in a separate memorandum or note that will be submitted with the inspection report.

A list of suggested intervention strategies to achieve on-site correction and long-term compliance for out-of-control procedures is found in Annex 6 of *Managing Food Safety: A Regulator's Manual For Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems.* The list illustrates the application of intervention strategies in an inspection program.

Issued New June 2014

Field Operations Manual

Procedure III-37
New

Initial Validation of a HACCP Plan Required by the Retail Food Establishment Regulations

Overview

This document describes/outlines the process utilized in validating a written HACCP Plan, when required by the regulations. Although the validation review will be conducted by the office staff such as Regional Managers, the Compliance Officer, or Technical Specialists, it is important that the field staff understand what goes into the review process in determining whether a HACCP plan is scientifically and technically sound.

Terms

To begin, we first define the term validation versus verification. **Validation** means those activities that determine if the HACCP plan has been appropriately designed with all required components and that the system is operating according to the plan. **Verification** is necessary to ensure that the validated HACCP plan reflects current establishment conditions and that it is functioning effectively. We will be using "initial" validation and "continued" validation. Initial validation will occur before the HACCP plan is put into action at the firm. Continued validation will occur during each routine inspection of the establishment thereafter, to ensure that the original HACCP plan is being followed.

The HACCP Plan Approval Process

Approving a HACCP plan requires both validation and on-going field verification by the regulatory authority. **An initial validation of the HACCP plan must be completed by the office staff (Regional Managers, the Compliance Officer, or Technical Specialists) before the HACCP plan is implemented and before the firm begins the process the HACCP plan was written for. Also, the HACCP plan will not be approved until a variance, if applicable, has been granted for the food process**. VDACS is only requiring that HACCP plans be reviewed when they are required by the *Retail Food Establishments Regulations for the Enforcement of the Virginia Food Laws.* This would include operations such as the following: acidification of rice, curing or smoking meats, and some reduced oxygen packaging applications of PHF/TCS foods. If a HACCP plan (without a variance) is approved a letter will be sent to the firm and the Food Safety Specialist will receive a copy of the letter as well as the information submitted when the HACCP plan was requested. A copy of the letter and the information will be retained in the firm's file. See Procedure III-34 for additional information regarding the approval process for variances.

The Validation Process

Validation is the process of making sure that a written HACCP plan is effective in controlling hazards that may result in illness or injury. The initial validation process primarily involves reviewing a plan to ensure that:

1) All of the necessary components of the written plan have been included, and that

2) The information and protocols are effective in preventing, eliminating or significantly reducing the hazards, if properly implemented.

Before validating the HACCP plan, the reviewer (i.e. Regional Manager, Compliance Officer, or Technical Specialist) should review the compliance history of the food establishment to ensure all HACCP prerequisites have been addressed (SOPs, GRPs) and no critical violations exist that were not corrected.

When validating a plan, the reviewer is using the principles of HACCP to verify that items, including but not limited to the following, have been properly identified:

- Product or process (flow chart)
- Hazards
- Selection of CCPs
- Critical limits, monitoring procedures, corrective actions and verification procedures for each CCP selected
- Verification (validation) procedures to ensure that the plan is updated and validated as needed by the PIC or HACCP plan administrator
- Recordkeeping procedures and forms
- Employee training

In some cases it may be necessary to request additional information such as product formulation, physical facility layout, standard operating procedures and scientific documentation or laboratory data for process used - for example a letter from a Process Authority.

Written HACCP Plan Review

The review of the written HACCP plan should be carried out to verify that the HACCP plan is complete. The Initial Validation of HACCP Plan Worksheet (Annex A) is to be completed and signed by the reviewer (Regional Manager, Compliance Office, or Technical Specialist) during the initial validation process before the firm begins the requested operation.

In order for a documented HACCP plan to be considered complete, it must be dated and signed by the designated person in charge or HACCP coordinator at the firm. It must also meet all regulatory requirements and include all required components of a HACCP plan as stated in 2VAC5-585-3630. Contents of a HACCP plan.

When any section of the written plan is found to be incomplete, the deficiencies should be described in the "Reviewer Comments" section of the Initial Validation of HACCP Plan Worksheet. Reasons for noted deficiencies (i.e. regulations, laboratory results, scientific data, etc.) should also be included. When all the items on the HACCP plan have been corrected, the

initial validation of the written plan is complete. A copy of the approved HACCP plan and a signed and dated Worksheet need to be put into the firm's file upon completion of the review. In addition, all of the required documents referenced herein shall be added to the LAN which is available to all Program staff under: H:\(F-o-o-d S-a-f-e-t-y and Security Program)\Variance Requests and HACCP Plans.

If the HACCP plan is found to require further information or modification, the components, which are not acceptable, should be returned to the establishment with an explanation of the deficiencies. The establishment is responsible for correcting all deficiencies and resubmitting the amended HACCP plan to the regulator for follow-up review. **Until all deficiencies have been corrected the HACCP plan will not be accepted by** VDACS.

When the reviewer is satisfied that the HACCP plan is in compliance, and the operator and Food Safety Specialist have been notified of this, the initial validation process is complete.

Elements of the HACCP Plan Validation Process

A. Hazard Analysis

Hazard analysis is one of the most important steps in developing a HACCP plan. An incorrect hazard analysis will significantly jeopardize the effectiveness of the HACCP plan. The establishment should evaluate hazards of significance and preventative measures needed for each food product and process. All hazards associated with incoming materials and ingredients should be specifically identified as biological, chemical, or physical in the HACCP plan. The hazards must at least include those that are commonly associated with a specific product.

B. Product Description

1. All incoming ingredients are identified by brand name and/or common name. All ingredients are obtained from approved sources.

2. Description of how the product is to be used, e.g., raw, ready to eat, ready to cook, etc.

3. Packaging material and packaging conditions used for the product(s) are identified.

4. Shelf life of the product(s) does not exceed accepted time/temperature requirement or manufacturer's date. If the shelf life is in excess of those stated in the regulation or the manufacturer's date, scientific documentation to support the safety of the chosen shelf life must be made available at the time of review.

5. Safe handling and usage information pertinent to the product is indicated, e.g., "keep refrigerated to maintain safety," or "thaw under refrigeration", etc.

6. If applicable, the HACCP plan includes a description of any special controls required during shipping and storage, i.e. temperature requirements at receipt of product, letters of guarantee, etc.

7. When applicable, labeling information for each product is available. See 2VAC5-585-870. Reduced oxygen packaging; criteria, specifies labeling requirements for reduced oxygen packaged foods.

8. Recipes are available upon request to determine if the formulation/method of preparation is consistent with those submitted with the HACCP plan.

9. When applicable, a brief description of the lot identification system.

C. Process Flow Chart and Facility Layout Diagram

The HACCP plan includes a complete step-by-step flow diagram of the process and layout of the facility, indicating all pertinent processing steps, including where ingredients, packaging materials, etc. enter the flow and any preparation and storage designs that will impact the food flow or processing parameters. Any hazards associated with possible cross-contamination are to be identified. A floor plan, showing the layout of the preparation and storage areas should be included; hand-drawn is acceptable.

D. Critical Control Point Identification

The proper identification of Critical Control Points (CCPs) is crucial to the ultimate effectiveness of a HACCP plan. The plan must specify where each identified hazard will be controlled. Hazards that cannot be controlled by the operator must be identified on the HACCP plan. The plan must indicate how these hazards will be addressed outside the establishment

Note: The evaluation for completeness of the written CCPs will ensure that all relevant information dealing with critical limits, monitoring, corrective actions, verification procedures and record keeping is specified for each identified hazard.

E. Critical Limits Established

- Critical limits have to be established for all critical components associated with each hazard that is controlled by a CCP.
- Critical Limits must meet or exceed regulatory requirements.
- Critical limits normally include measurements such as temperature, time, moisture level, pH, and water activity.
- For Critical Limits without regulatory or program requirements, the company must validate that the critical limits in its HACCP plan are appropriate. This could include product sampling and laboratory analysis and should be relevant to the hazard being addressed.

F. Monitoring Procedures

Monitoring procedures exist for each critical limit at each CCP to ensure that the CCP is under control. Monitoring procedures must be complete (What, How, Frequency, Who).

G. Corrective Action Procedures

- CA procedures exist for each CCP.
- CA procedures must state the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:
    - The cause of the deviation is identified and eliminated
    - No product that could put the public at risk as a result of the deviation reaches the consumer
- All corrective actions shall be documented in records that are subject to verification, under record keeping procedures, during the field verification inspection.

H. Verification Procedures

- Verification procedures exist for each CCP. Verification procedures must be complete (What, How, Frequency, Who). This may include review of operations & records, and analytical testing.
- Verification procedures ensure that the CCP is valid and effective (i.e. critical limits, monitoring procedures, and corrective action procedures are appropriate to ensure food safety).
- Examples of on-going verification activities include:
    - Calibration of monitoring equipment
    - Direct observations of monitoring activities and corrective actions
    - Record Review

I. Record Keeping

- The requirement to record monitoring procedures at CCPs on a regular basis ensures that preventive monitoring is occurring in a systematic way. Unusual occurrences must be corrected and recorded immediately with notation of the corrective action taken.
- The level of sophistication of the record keeping necessary for the food establishment is dependent on the complexity of the food preparation operation.

J. Employee Training

- **A brief description of the employee training program must be provided.** Records should include the training courses completed by each employee. The depth of training will depend on the particular employee's responsibilities within the establishment. Management or supervisory individuals will need a deeper understanding of the HACCP process because they are responsible for proper plan implementation and routine monitoring of CCPs such as product cooking temperatures and cooling times.

- **The training plan should be specific to the establishment's operation.** The use of recipes or Standard Operating Procedures (SOPs) which include the critical limits of cooking times and temperatures, with a final cooking time and temperature measurement step, should be included.

- **For all employees, the fundamental training goal should be to make them proficient in the specific tasks that the HACCP plan requires them to perform.** This includes the development of a level of competency in their decision-making about the implementation of proper corrective actions when monitoring reveals violation of the critical limit. The training should also include the proper completion and maintenance of any records specified in the establishment's plan.

K. Continued Validation of HACCP Plans

- When an establishment has made modifications to the HACCP plan, it will require a validation review. The modified HACCP plan must be submitted to VDACS in a timely manner for review.
- The firm operator is required to review the HACCP plan on a yearly basis to verify that it is effective over time. The review completed by the firm should be documented, preferably on the printed HACCP plan, and should include date and signature of person responsible for review. Whenever changes are made in any of the following areas, they must be incorporated into the HACCP plan and the HACCP plan must be revalidated by the regulatory agency.
    - Products added or changed
    - Formulations changed
    - Processes or packaging added or changed Suppliers, customers, equipment, or facilities changed
    - Regulatory requirements changed
    - Introduction of new technologies that may impact food safety
- Continued validation of the HACCP plan includes an on-site review and verification of all the components of the HACCP plan documented on the inspection report (items 26 and 29). This on-site review shall be made by the Food Safety Specialist and occur during each routine inspection of the firm (at a minimum of once every 12 months). The field inspector should be reviewing the HACCP plan against the one initially submitted to be sure that no changes have been made. If changes have been made, the Food Safety Specialist shall notify their manager and the plan should be validated by the VDACS reviewer.

New - June 2014

Initial Validation of HACCP Plan Worksheet
Annex A

Firm Name:	**Mailing Address:**
Physical Address:	**City/State/Zip Code:**
City/State/Zip Code:	**Phone Number:**
Food Product Evaluated:	
Date of Review:	**Owner/PIC:**

Verify that the following is included with the HACCP Plan

☐ Purpose of Submission (i.e. Variance or Code Requirement - Include Code Reference)

☐ Hazard Analysis

Product description

(check all that are applicable)

☐ List of ingredients

☐ Intended use

☐ Labeling

☐ Shelf life

☐ Recipe/process used

☐ Lot coding, if applicable

☐ Flow chart

☐ Floor plan

☐ Identification of each Critical Control Point (CCP)

For <u>Each</u> CCP

☐ Identification and description of the hazard(s)

☐ Critical limits have been established

☐ A description of monitoring procedure(s)

☐ A description of corrective action(s

☐ A description of verification procedure(s)

Record Keeping

☐ Forms used to document monitoring

☐ Forms used to document corrective actions

☐ Forms used to document verification procedures

Employee Training

☐ Employee training plan and sample form(s) that will be used to document successful completion	
If variance required for this operation, has it been granted? ☐Yes ☐No ☐NA *Note: the HACCP plan validation cannot be finalized until variance is granted.*	
Is the firm in good regulatory standing? ☐Yes ☐No *Note: reference the most current inspection report for critical violations.*	
Reviewer Comments:	
Name and Title of Reviewer:	Date Plan Validated:
Signature of Reviewer:	

FIELD OPERATIONS MANUAL

Procedure III-38
New

On-Site Verification of HACCP Plans Required by the Retail Food Establishment Regulations

Terms

To begin, we first define the term validation verses verification. **Validation** means those activities that determine if the HACCP plan has been appropriately designed with all required components and that the system is operating according to the plan. **Verification** is necessary to ensure that the validated HACCP plan reflects current establishment conditions and that it is functioning effectively.

On-Site Verification

On-site verification of a HACCP plan will be performed during each routine inspection conducted at a facility that has a HACCP plan required by the regulation. These inspections should be conducted at least every 12 months, as these firms are in the high risk category. Important: the written HACCP plan must be validated and accepted by the applicable VDACS Regional Office as complete before the on-site verification inspection takes place. In addition, the HACCP plan must be in implemented in the firm prior to the verification inspection.

On-site verification is used in conjunction with document and record review to determine whether the activities carried out in the facility are conducted according to the written HACCP plan. During the on-site verification, remember to look at whether activities you observe are consistent with what is noted in the records and supporting documents.

The Verification Process

Verification activities may include:

a. Review of the HACCP plan
b. Record review—monitoring, corrective action and verification
c. Sample collection and analysis to determine the product meets all safety standards
d. On-site observations of activities carried out by the responsible employees

Elements of the HACCP Plan Verification Procedures

1. Review of the HACCP Plan

Start by reviewing the firm's written HACCP plan. Make note of their identified CCPs and the critical limits they have set for each CCP. Also, make note of what records they should be keeping to monitor the CCPs. Remember, that before your on-site verification inspection is

conducted, the HACCP plan should have already undergone the initial validation. The purpose of your visit/inspection is to ensure that the firm is following the procedures they wrote. If the firm is in the process of measuring and recording their CCPs or CLs, observe that they are doing this correctly, e.g., measuring pH value of rice, or recording cooler temperature.

2. Record Review

The approved HACCP plan and associated records must be on file at the food establishment and available for review. It is the operator's responsibility to establish a system for maintaining records. Records must be kept to show that CCPs are properly controlled.

- Monitoring Records: documenting the monitoring of CCPs and their critical limits could include the recording of actual times, temperatures, pH values, as described in the establishment's HACCP plan
- Corrective Action Records: including all actions taken in response to a deviation that addresses the cause of the deviation AND ensuring that no affected product entered commerce
- Verification Records: the calibration of monitoring instruments, reviewing of records by responsible individuals

3. Corrective Actions

A deviation occurs when a predetermined critical limit is not met, resulting in a potential impact on the safety of the product. Corrective actions must include the course of action to be taken in order to deal with the deviations when they occur and they must match corrective action procedures listed in the validated HACCP plan. Employees should be able to demonstrate that they can identify deviations and understand the required corrective action to be taken as specified in the validated HACCP plan.

During the on-site observation, place special emphasis on determining whether corrective actions are taken when critical limits are not met. You should assume that corrective actions were anticipated in the operation of the system. The following questions can be asked of responsible personnel:

- Was the deviation handled in a manner prescribed in the plan?
- If not, how was the deviation handled?
- How was the process brought back under control so that the deviation would not reoccur?

4. Maintenance of HACCP Plan

The HACCP plan must be dated in order to identify the most current version. In addition, all modified pages of the HACCP plan must be signed by the responsible personnel to indicate approval. Only the most current version of a HACCP plan should be in use. All obsolete documents/pages should be removed.

5. Discussion with Firm Management and Employees

Be sure to ask the person in charge *and* the food employees open-ended questions to obtain information that you need about the operation. For example, ask, "How often do you check the temperature?" rather than, "Do you check the temperature every 2 hours?" The information you gather from the person in charge and the food employees, along with your own observations, should provide answers to the following questions:

- Are required activities being performed according to established procedures as outlined in the food safety management system?
- Are activities checked or monitored according to the established methods, with proper equipment, procedures, etc.?
- Do the individuals performing the activity understand their duties?
- Have the individuals performing the activity noted any problems that may be of concern?
- Are on-site observations consistent with the records kept and reviewed in the record review portion of your verification inspection?

6. Sample Collection

It may be necessary to collect a sample of a product that is produced under a HACCP plan. If you feel that the employees are not operating within the parameters of their HACCP plan, sample the product. Record review or on-site observations in the establishment may be indicators that the process is not being carried out safely. Products may be tested for pH and water activity, salt content, water phase salt, or bacterial contamination. However you are not limited to only choosing only these tests. If you require assistance in determining what to test a product for—call the Food Safety & Security Program staff member who initially approved the HACCP plan or your Regional Manager.

Non-compliant HACCP Systems

.

Verification of the validated HACCP plan will be made for each CCP. When any section of the validated HACCP plan does not comply with findings noted during the field inspection, the deficiencies shall be noted on the inspection report. Some of these deficiencies may include:

- The HACCP procedures used in the firm on a day-to-day basis does not match the validated HACCP plan
- Employees are not performing tasks specified in the validated HACCP plan
- The establishment fails to take corrective actions, as required by regulation, or as stated in the validated HACCP plan
- HACCP records are not being maintained as required by regulation or as stated in the validated HACCP plan
- Adulterated product is being produced or transported

Further compliance actions (informational letter or letter of warning) may need to be considered if significant violations with monitoring of critical control points and record keeping procedures

are noted. The inspection should be classified VAI or OAI depending on the severity of the violations and a follow-up inspection conducted within the required timeframes.

Verification Report

At the conclusion of the on-site verification, the HACCP Plan Verification Inspection Checklist (Appendix A) *may* be completed. This document is a tool that can be used during inspections and contains a list of items to be evaluated when conducting a verification inspection of a HACCP plan in use. Fill out one form per validated HACCP plan in place at the firm. This document is intended to be a guidance document and can be submitted in addition to the Retail Inspection Report that is required The inspector has the option of submitting this checklist with the inspection report, but it is **NOT** to be issued to the firm. Only leave the firm with the Retail Inspection Report, not the Verification Inspection Checklist. Use this checklist to simply assist you in verifying the firm is following the procedures outlined in their HACCP plan.

Issued new June 2014

HACCP Plan Verification Inspection Checklist
Appendix A

Firm Name:	
Physical Address:	
City/State/Zip Code:	
Date Plan Validated:	**Food Product Evaluated:**
Date of Inspection:	**Owner/PIC:**

HACCP Plan Review

Identified CCPs and CLs

CCP	CL	Comments

1. Did you observe the firm measuring CCPs/CL during today's inspection?
   ☐Yes
   ☐No

Records--Monitoring, Corrective Action and Verification

Type of Record	Monitoring Frequency	Comments

Record Review and On-Site Inspection

2. Are monitoring actions performed according to the plan?
   ☐Full Compliance
   ☐Partial Compliance
   ☐No Compliance

3. When CLs established by the plan are not met, are immediate corrective actions taken and recorded?
   ☐Yes
   ☐No

4. Do the corrective actions taken reflect the same actions described in the establishment's plan?
   ☐Yes
   ☐No
   ☐Not Applicable

5. Are routine verification activities performed according to the plan?
   ☐Yes
   ☐No
   ☐Not Applicable

6. Are the records for the present day accurate for the observed situation in the facility?
   ☐Yes
   ☐No

Continued Considerations

7. Have there been any changes to the menu or recipes since the last verification visit?
   ☐Yes
   ☐No

8. Was the system modified because of these menu or recipe changes?
   ☐Yes
   ☐No
   ☐Not Applicable

9. If so, did the firm validate the plan with the changes?
   ☐Yes
   ☐No

10. Has the HACCP plan been validated yearly by the firm?
    ☐Yes
    ☐No

11. Is the firm using the most current version of the HACCP plan?
    ☐Yes
    ☐No

Training for Responsible Staff Members

12. Describe the training that has been provided to management and employees.

13. Is there documentation that the above training was accomplished? List and describe.

14. Do staff members demonstrate knowledge of the system? (Management and employees)
    ☐Yes
    ☐ No

Overall Verification Compliance

15. Is the firm adhering to the approved HACCP plan and procedures?
    - ☐ Yes
    - ☐ No; if no, indicate corrective actions

16. Was a sample collected during this inspection, related the HACCP program?
    - ☐ Yes
    - ☐ No

Additional Comments:

Name of Inspector:	**Signature of Inspector:**

FIELD OPERATIONS MANUAL

PROCEDURE III-39

CONSUMER COMPLAINT INVESTIGATIONS

The investigation of consumer complaints is a very important aspect of a Food Safety Specialist's duties. The Food Safety Program has a system for tracking and evaluating trends of consumer complaints. Therefore, all complaints must be thoroughly investigated, regardless of the nature. Often times it is the consumer that will identify a problem, perceived or otherwise, in an establishment or product.

Unless otherwise noted, routine consumer complaints will be investigated within 10 working days from the date the complaint was received.

Under unusual circumstances the RRT Coordinator or their designated representative will assign a complaint which will require immediate investigation. See Procedure II-01 Foodborne Illness Complaint Investigations and Procedure II-02 Suspected Tampering and Bioterrorism Investigations for additional information.

Agency Responsibilities:

Although another agency may have regulatory oversight for a particular food product, the VDACS Food Safety Program is required to determine which agency or department is responsible for resolving the complaint *and to document referral* according to the following guidelines:

Milk: If the complaint relates to conditions at a retail firm (spoiled, warm, improper rotation, etc.), the VDACS Food Safety Program will investigate. If the complaint relates to conditions outside the retail firm's control (chemical taste, foreign matter, etc.), the VDACS Food Safety Program will refer the complaint to the Health Department's Milk Sanitation Program.

Ice Cream: As above, if the complaint relates to conditions at the retail firm, the VDACS Food Safety Program will investigate. Otherwise, the complaint will be referred to the VDACS Dairy Services Program if manufactured in-state or to the applicable out-of-state Dairy Program if manufactured out-of-state.

Meat product: If the complaint concerns a store-packaged product or is related to store practices, the VDACS Food Safety Program will investigate. If the product is pre-packaged, and is from a USDA/OMPS inspected firm, we will refer it to the USDA Compliance Office or OMPS for follow-up. We may collect appropriate samples at the retail firm, and forward the results to USDA/OMPS to aid in the investigation.

Food products under the cognizance of the Food & Drug Administration (FDA): If the complaint concerns a product/ingredient manufactured or processed within the United States, the matter may be referred to the FDA for follow up and documentation purposes.

If complaints are referred to another agency, this shall be documented on the complaint form in the section reading "If referred, state to whom the complaint was referred to". In addition, please send an email to your Regional Manager indicating the need for referral so that it can be reviewed and forwarded to the appropriate authority in a timely manner.

Complaint Investigation:

ALL COMPLAINTS WILL BE INVESTIGATED. The scope of the investigation must be sufficient to determine the nature and extent of conditions leading to the complaint. A limited inspection of the implicated products, conditions, or personnel practices may be required to develop a reasonable hypothesis as to the root cause of the problem. This can be done as a physical on-premises inspection or in rare cases, as a "Virtual Inspection" as described in FOM Procedure I-00 Compliance and Enforcement.

In situations where an on-site inspection is conducted in response to the complaint or when samples are collected, the FSS will need to issue an inspection report to the firm in addition to completing the complaint form (Investigation Details section). A complaint investigation in which an inspection was not conducted and/or no samples were collected will only require the FSS to complete the complaint form and upload it to the LAN. The firm does not receive a copy of the complaint form. The complaint will be considered closed when a completed complaint form and/or inspection report have been submitted in VIPRS and/or uploaded to the LAN. The FSS shall mark the inspection purpose as "complaint" in the inspection screen in VIPRS for tracking and reporting purposes if an inspection report is left at the firm.

All complaints will receive due diligence from VDACS. To that end and for the purposes of timeliness, complaints falling into certain low-risk categories may be initially investigated and/or resolved by phone. However, nothing in this policy precludes an investigator from conducting an in-person investigation as warranted by the details of the case. The conversation between the FSS and the firm will be documented with particular emphasis on the resolution of the complaint. Complaints that by their nature pose the potential for a higher risk to the public, or that initial phone contact reveals a more serious issue than was initially conveyed, will be investigated in person.

During the in-person investigation the FSS will determine what, if any, objectionable conditions may have contributed to the complaint, e.g dirty equipment, poor personal hygiene, temperature abuse, etc. In addition, whether a complaint is investigated by phone or in-person, the FSS shall determine if the firm has received any similar complaints, and, if applicable, the firm's complaint records shall be reviewed if the firm grants permission. The firm is not legally obligated to share complaint records with the FSS. The FSS shall document when complaint records were reviewed by filling out the section on the complaint form that reads "Were complaint records at the firm reviewed?" The findings of the complaint investigation shall be documented clearly in a factual basis as they may be introduced as evidence in a subsequent enforcement action or civil

litigation. And, as relates to evidence, collect a sample as it pertains to the complaint when you determine that it will support your findings.

FOM III-21 Manufacturing Firm Inspections guides the inspection of manufacturing facilities. Complaint investigations at the manufacturing level require the same attention to detail and factual documentation. Always request that management provide complaint records for similar complaints within appropriate timeframes for the complaint being investigated.

Investigational approach

There are many factors and possible variations in trying to categorize complaints into 'low risk' where a phone call could suffice and 'high risk' where an on-site visit would be appropriate.

The following general framework should be utilized in determining your complaint response.

Complaints that may not require a visit:

a. Pets on premises if it appears to be an isolated event
b. Expired products for sale
c. Hair restraints not being worn
d. Dirty restrooms
e. Smoking on premises

Otherwise, the FSS should complete an on-site investigation. If a different situation arises that can be handled via phone, the FSS is to consult with their Regional Manager, Field Supervisor, or RRT Coordinator to determine if a phone call is sufficient. The bottom line in the decision making process should be what is the severity of the food safety hazard that was identified by the complainant and can it be adequately addressed by a phone consultation versus an on-site visit.

Revised 4-3-2015

Procedure III-40: FOOD SERVICE INSPECTIONS OF WINERIES, MEADERIES AND CIDERIES

INTRODUCTION

The Virginia Department of Health (VDH) and VDACS have signed a Memorandum of Understanding (MOU) to clarify and establish permitting and inspection responsibilities for wineries and meaderies offering food service to the public.
NOTE – Cideries will also fall under this MOU

Attached to this FOM is the MOU as well as a flow chart to assist in determining jurisdiction in these firms. Factors critical in making the determination of jurisdictional oversight include:

1. ABC licensing held by the food service operation and
2. The extent of foodservice offered in the tasting rooms.

General Agreement

Food Service operations in winery establishments with a "retail on-premise" or both a "retail on-premise and retail off premise" license for beer, wine or liquor from ABC will be inspected and permitted by VDH. The type of food service required for these type of ABC licenses would exceed the limitations of food service for a VDACS inspection, and would fall to VDH.

In all other instances, food service operations will fall to VDACS as long as the food service meets the limitations below. Establishments expanding food service beyond that which qualifies for inspection by VDACS are considered restaurants and will be inspected and permitted by VDH.

Food Service Limitations

To qualify for VDACS inspection, food service will be limited to serving the following food items:

a. Packaged food items from approved sources that comply with applicable law, such as sandwiches, crackers and similar items that are served 'as is' or require reheating only.
b. Ready-to-eat food items from approved sources that comply with applicable law that are unpackaged or have their packaging removed to allow for limited preparation and/or reheating for immediate service only. Food preparation shall be limited to cutting, slicing and sandwich assembly.
c. Examples of limited food service would be preparing a sandwich from packaged lunch meat, reheating a canned food product or frozen food item (ie: pizza), cutting up cheese, etc.

Operations that Exceed Limited Preparation

Operations that exceed limited preparation to the extent that they resemble a restaurant will be under the jurisdiction of VDH. For example: preparing a sandwich from 'scratch' such as making a chicken salad sandwich. In addition, any type of cooking/frying of food would fall outside of VDACS jurisdiction.

In addition if the firm wishes to hold any type of special event such as oyster roast, barbecue, pig roast, etc. involving the preparation of food, they must contact VDH to obtain a special event permit.

Inspection Report

Inspections of a winery/meadery/cidery with a production area and food service operation will require 2 inspection reports. The food service operation will be considered a 'Retail" inspection and the processing/manufacturing area will be considered a "GMP" inspection.

It is not necessary to leave a retail inspection report of the tasting room/food service operation if the operation is limited to the sampling of beverages only or the offering of pre-packaged food items.

Jurisdictional Questions

When a question arises regarding jurisdictional oversight, the Food Safety Specialist should contact their Regional Manager for guidance. In situations where jurisdiction remains questionable the following protocol is to be followed:

- The VDACS Food Safety Specialist or Regional Manager, in consultation with the facility owner, will confer with the local VDH Environmental Health Specialist (EHS) or EHS Manager to discuss whether a VDH Food Establishment permit is needed.

- If agreement cannot be reached, the matter will be referred to the VDH Division Director of Food and General Environmental Services in consultation with the VDACS Office of Dairy and Foods Program Supervisor for resolution.

Issued New 12-15-15

MEMORANDUM OF UNDERSTANDING

BETWEEN

THE VIRGINIA DEPARTMENT OF HEALTH

AND

THE VIRGINIA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

REGARDING FOOD SERVICE OPERATION INSPECTIONS OF WINERIES AND MEADERIES

PURPOSE

The purpose of this agreement between the Virginia Department of Health (VDH) and the Virginia Department of Agriculture and Consumer Services (VDACS) (collectively, "the Departments") is to clarify and establish permitting and inspection responsibilities for wineries and meaderies offering food service to the public. Historically, the Departments have mutually agreed to regulate specific facilities serving food for public consumption independently, even though both VDH and VDACS possess statutory authority to inspect food service operation facilities in the Commonwealth. Additionally, several types of food service operations are by statute (Code of Virginia § 35.1-25) exempt from VDH jurisdiction. This agreement allows the Departments to maintain the highest level of public health protection and ensure efficient use of state resources, while avoiding overly burdensome regulatory oversight of wineries and meaderies. This agreement abrogates neither agency's authority to inspect and/or permit any food service facility otherwise subject to regulation.

STATUTORY AUTHORITY

Code of Virginia § 3.2-5100 establishes VDACS's authority and responsibility for inspecting all establishments which manufacture, sell, expose, or offer food and drink products for sale. Code of Virginia §§ 35.1-1 and 35.1-5 give VDH responsibility for inspecting restaurants, including any place where food is served to the public, whether on or off premises, and any place where food is prepared. The inspection authority of VDACS and VDH overlap with respect to food service operations in wineries and meaderies.

GENERAL AGREEMENT

VDH and VDACS agree that inspection responsibilities for food service operations in wineries and meaderies shall be regulated as follows.

I. Wineries

Winery establishments with food service operations holding only a winery license or farm winery license, as defined by Code of Virginia § 4.1-207, will be inspected by VDACS, so long as the food service qualifies for inspection by VDACS under the criteria in the Procedural Agreement below.

Food service operations in winery establishments holding only retail on-premises or holding both retail on-premises and retail off-premises licenses for beer, wine or liquor, as defined by 3VAC5-50-110, will be inspected and permitted by VDH.

Food service operations in winery establishments holding only retail off-premises licenses for beer or wine, as defined by 3VAC5-50-100, will be inspected by VDACS, so long as the food service qualifies for inspection by VDACS under the criteria in the Procedural Agreement below.

Winery establishments expanding food service beyond that which qualifies for inspection by VDACS under the criteria in the Procedural Agreement below are classified as restaurants and will be inspected and permitted by VDH.

Wineries without food service will be inspected by VDACS.

II. Meaderies

Meaderies holding an ABC license pursuant to Code of Virginia §§ 4.1-206 and 4.1-208, or any other ABC license granted pursuant to Code of Virginia § 4.1-210, will be inspected by VDACS, so long as the food service qualifies for inspection by VDACS under the criteria in the Procedural Agreement below.

Meaderies expanding food service beyond that which qualifies for inspection by VDACS under the criteria in the Procedural Agreement below are classified as restaurants and will be inspected and permitted by VDH.

Meaderies without food service will be inspected by VDACS.

PROCEDURAL AGREEMENT

Qualifying wineries and meaderies under sections I and II above serving only the following food items in tasting rooms will fall under the jurisdiction and regular inspection protocol of VDACS:

- Packaged food items from approved sources[1] that comply with applicable law, such as sandwiches, crackers and similar items that are served "as is" or require reheating only.

- Ready to eat food items from approved sources that comply with applicable law that are unpackaged or have their packaging removed to allow for limited preparation and/or reheating for immediate service only. Food preparation shall be limited to cutting, slicing and sandwich assembly.

Operations that exceed limited preparation to the extent that they resemble a restaurant will be under the jurisdiction of VDH. When a question arises whether food service operations in wineries or meaderies exceed VDACS's jurisdiction pursuant to the Procedural Agreement, the VDACS Food Safety Specialist (FSS) or FSS Regional Manager, in consultation with the facility owner, will confer with the local VDH Environmental Health Specialist (EHS) or appropriate local EHS Manager to discuss whether a VDH food establishment permit is required. If agreement regarding whether a food establishment permit is needed cannot be reached, a final determination will be made by the VDH Division Director of Food and General Environmental Services in consultation with the VDACS Office of Dairy and Foods Program Supervisor, subsequent to an informal fact-finding conference held by VDH with due notice provided to the facility owner. Such final determination shall be a VDH case decision pursuant to Code of Virginia §§ 2.2-4001 and 2.2-4019. Any facility owner subject to an agency case decision may appeal the decision in accordance with Code of Virginia § 2.2-4000 *et seq*.

This Memorandum of Understanding shall be considered an addendum to the VDACS and VDH general Memorandum of Understanding dated March 1989.

AGREEMENT AND CONSENT

VDACS and VDH do hereby agree this agreement shall be effective upon signature by the State Commissioner of Agriculture and Consumer Services and the State Commissioner of Health, and shall delegate, to the extent legally possible, those responsibilities for carrying out the terms of this agreement.

Marissa J. Levine, MD, MPH, FAAFP
Commissioner
Virginia Department of Health

7/23/15
Date

Sandra J. Adams
Commissioner
Virginia Department of Agriculture and Consumer Services

June 25, 2015
Date

[1] An "approved source" means acceptable to the Departments based on a determination of conformity with principles, practices, and generally recognized standards that protect public health, or otherwise permitted as contemplated by applicable federal, state, and local laws, regulations, and ordinances.

Wineries, Meaderies, and Cideries Food Service Operations MOU Decision Tree

(Establishments with no Food Service are inspected by VDACS)

Does the firm have a retail on-premises (or on-premises AND off-premises) license from ABC?

YES

VDH Inspects Food Service

VDACS Inspects Manufacturing

NO

Food Service is within MOU Procedural Agreement

YES

VDACS Inspects Food Service and Manufacturing

NO

VDH Inspects Food Service

VDACS Inspects Manufacturing

Procedure III-41: FOOD SERVICE INSPECTIONS OF BREWERIES AND DISTILLERIES

INTRODUCTION

The Virginia Department of Health (VDH) and VDACS have signed a Memorandum of Understanding (MOU) to clarify and establish permitting and inspection responsibilities for breweries and distilleries offering food service to the public.

Attached to this FOM is the MOU as well as a flow chart to assist in determining jurisdiction in these firms. Factors critical in making the determination of jurisdictional oversight include:

1. Licensing held by the food service operation and
2. The extent of foodservice offered in the tasting rooms.

General Agreement

Food Service operations in brewery and distillery establishments with a "retail on-premise" or both a "retail on-premise and retail off premise" license from ABC for beer, wine or liquor will be inspected and permitted by VDH. The type of food service required for these type of ABC licenses would exceed the limitations of food service for a VDACS inspection, and would fall to VDH.

Breweries that operate in conjunction with a restaurant for on-site consumption only will fall under the jurisdiction of VDH. If the brewery engages in the wholesale distribution of beer then the processing/manufacturing operation will be inspected by VDACS.

In all other instances, food service operations will fall to VDACS as long as the food service meets the limitations below. Establishments expanding food service beyond that which qualifies for inspection by VDACS are considered restaurants and will be inspected and permitted by VDH.

Food Service Limitations

To qualify for VDACS inspection, food service will be limited to serving the following food items:

a. Beverage items that include beer or alcoholic beverages that are manufactured on premises and served for on-premises consumption and/or in closed containers for off-premises consumption. For example: serving draft beer by the glass through taps, bottles, etc. There may or may not be wholesale distribution.
b. Packaged food items from approved sources that comply with applicable law, such as sandwiches, crackers and similar items that are served 'as is' or require reheating only.
c. Ready-to-eat food items from approved sources that comply with applicable law that are unpackaged or have their packaging removed to allow for limited preparation and/or reheating for immediate service only. Food preparation shall be limited to cutting, slicing and sandwich assembly.
d. Examples of limited food service would be preparing a sandwich from packaged lunch meat, reheating a canned food product or frozen food item (ie: pizza), cutting up cheese, etc.

NOTE: Third- party food service operations do not affect the analysis of jurisdiction for the brewery or distillery under this MOU. Examples may include mobile food vendors or outside caterers. The third-party food service operations must be permitted/inspected by the appropriate regulatory agency.

Operations that Exceed Limited Preparation

Operations that exceed limited preparation to the extent that they resemble a restaurant will be under the jurisdiction of VDH. For example: preparing a sandwich from 'scratch' such as making a chicken salad sandwich. In addition, any type of cooking/frying of food would fall outside of VDACS jurisdiction.

In addition if the firm wishes to hold any type of special event such as oyster roast, barbecue, pig roast, etc. involving the preparation of food, they must contact VDH to obtain a special event permit.

Inspection Report

Inspections of a brewery/distillery with a production area and food service operation will require 2 inspection reports. The food service operation will be considered a 'Retail" inspection and the processing/manufacturing area will be considered "GMP" inspections.

It is not necessary to leave a retail inspection report of the tasting room/food service operation if the operation is limited to the sampling of beverages only or the offering of pre-packaged food items.

Jurisdictional Questions

When a question arises regarding jurisdictional oversight, the Food Safety Specialist should contact their Regional Manager for guidance. In situations where jurisdiction remains questionable the following protocol is to be followed:

- The VDACS Food Safety Specialist or Regional Manager, in consultation with the facility owner, will confer with the local VDH Environmental Health Specialist (EHS) or EHS Manager to discuss whether a VDH Food Establishment permit is needed.

- If agreement cannot be reached, the matter will be referred to the VDH Division Director of Food and General Environmental Services in consultation with the VDACS Office of Dairy and Foods Program Supervisor for resolution.

Issued New 12-11-2015

MEMORANDUM OF UNDERSTANDING

BETWEEN

THE VIRGINIA DEPARTMENT OF HEALTH

AND

THE VIRGINIA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

REGARDING FOOD SERVICE OPERATION INSPECTIONS OF BREWERIES AND DISTILLERIES

PURPOSE

The purpose of this agreement between the Virginia Department of Health (VDH) and the Virginia Department of Agriculture and Consumer Services (VDACS) (collectively, "the Departments") is to clarify and establish permitting and inspection responsibilities for breweries and distilleries offering service to the public. Historically, the Departments have mutually agreed to regulate specific facilities serving food, including beverages[1], for public consumption independently, even though both VDH and VDACS possess statutory authority to inspect food service operation facilities in the Commonwealth. Additionally, several types of food service operations are by statute (Code of Virginia § 35.1-25) exempt from VDH jurisdiction. This agreement allows the Departments to maintain the highest level of public health protection and ensure efficient use of state resources, while avoiding overly burdensome regulatory oversight of breweries and distilleries. This agreement abrogates neither agency's authority to inspect and/or permit any food service facility otherwise subject to regulation.

STATUTORY AUTHORITY

Code of Virginia § 3.2-5100 establishes VDACS's authority and responsibility for inspecting all establishments which manufacture, sell, expose, or offer food and drink products for sale. Code of Virginia §§ 35.1-1 and 35.1-5 give VDH responsibility for inspecting restaurants, including any place where food is served to the public, whether on or off premises, and any place where food is prepared. The inspection authority of VDACS and VDH overlap with respect to food service operations in breweries and distilleries.

[1] 12VAC5-421-10 includes "beverage" within the definition of "food." Hereinafter, food and beverages are referred to as "food."

GENERAL AGREEMENT

VDH and VDACS agree that inspection responsibilities for food service operations in breweries and distilleries[2] shall be regulated as follows.

Distillery establishments with food service operations holding licenses under Code of Virginia § 4.1-206, will be inspected by VDACS so long as the food service qualifies for inspection by VDACS under the criteria in the Procedural Agreement below.

Brewery establishments with food service operations holding licenses under Code of Virginia § 4.1-208, will be inspected by VDACS so long as the food service qualifies for inspection by VDACS under the criteria in the Procedural Agreement below.

Food service operations in brewery and distillery establishments holding only retail on-premises or holding both retail on-premises and retail off-premises licenses for beer, wine or liquor under 3VAC5-50-110, will be inspected and permitted by VDH.

Food service operations in brewery and distillery establishments holding only retail off-premises licenses for beer or wine under 3VAC5-50-100, will be inspected by VDACS so long as the food service qualifies for inspection by VDACS under the criteria in the Procedural Agreement below.

Brewery and distillery establishments expanding food service beyond that which qualifies for inspection by VDACS under the criteria in the Procedural Agreement below will be inspected and permitted by VDH.

PROCEDURAL AGREEMENT

Qualifying breweries and distilleries as described above serving only the following food items direct to the consumer on-premises will fall under the jurisdiction and regular inspection protocol of VDACS:

- Beverage items that include beer or alcoholic beverages that are manufactured at premises and served for on-premises consumption and/or in closed containers for off-premises consumption.
- Packaged food items from approved sources[3] that comply with applicable law, such as sandwiches, crackers and similar items that are served "as is" or require reheating only.

[2] "[F]ood service operations in breweries and distilleries" does not include when a third-party entity shares the premises with the brewery or distillery and the third-party entity is preparing and serving food separate from the brewery or distillery establishment. The third-party's operations do not affect the analysis for the brewery or distillery under this MOU.

[3] An "approved source" means acceptable to the Departments based on a determination of conformity with principles, practices, and generally recognized standards that protect public health, or otherwise permitted as contemplated by applicable federal, state, and local laws, regulations, and ordinances.

- Ready to eat food items from approved sources[4] that comply with applicable law that are unpackaged or have their packaging removed to allow for limited preparation and/or reheating for immediate service only. Food preparation shall be limited to cutting, slicing and sandwich assembly.

Operations that exceed such limited preparation to the extent that they resemble a restaurant will be under the jurisdiction of VDH. When a question arises whether food service operations in breweries and distilleries exceed VDACS's jurisdiction pursuant to the Procedural Agreement, the VDACS Food Safety Specialist (FSS) or FSS Regional Manager, in consultation with the facility owner, will confer with the local VDH Environmental Health Specialist (EHS) or appropriate local EHS Manager to discuss whether a VDH food establishment permit is required. If agreement regarding whether a food establishment permit is needed cannot be reached, a final determination will be made by the VDH Division Director of Food and General Environmental Services in consultation with the VDACS Office of Dairy and Foods Program Supervisor, subsequent to an informal fact-finding conference held by VDH with due notice provided to the facility owner. Such final determination shall be a VDH case decision pursuant to Code of Virginia §§ 2.2-4001 and 2.2-4019. Any facility owner subject to an agency case decision may appeal the decision in accordance with Code of Virginia § 2.2-4000 *et seq*.

This Memorandum of Understanding shall be considered an addendum to the VDACS and VDH general Memorandum of Understanding dated March 1989. In any case where there is a conflict between this Memorandum of Understanding and the general Memorandum of Understanding dated March 1989, this Memorandum of Understanding shall control.

AGREEMENT AND CONSENT

VDACS and VDH do hereby agree this agreement shall be effective upon signature by both the State Commissioner of Agriculture and Consumer Services and the State Commissioner of Health, and shall delegate, to the extent legally possible, those responsibilities for carrying out the terms of this agreement.

Marissa J. Levine, MD, MPH, FAAFP
Commissioner
Virginia Department of Health

9/28/15
Date

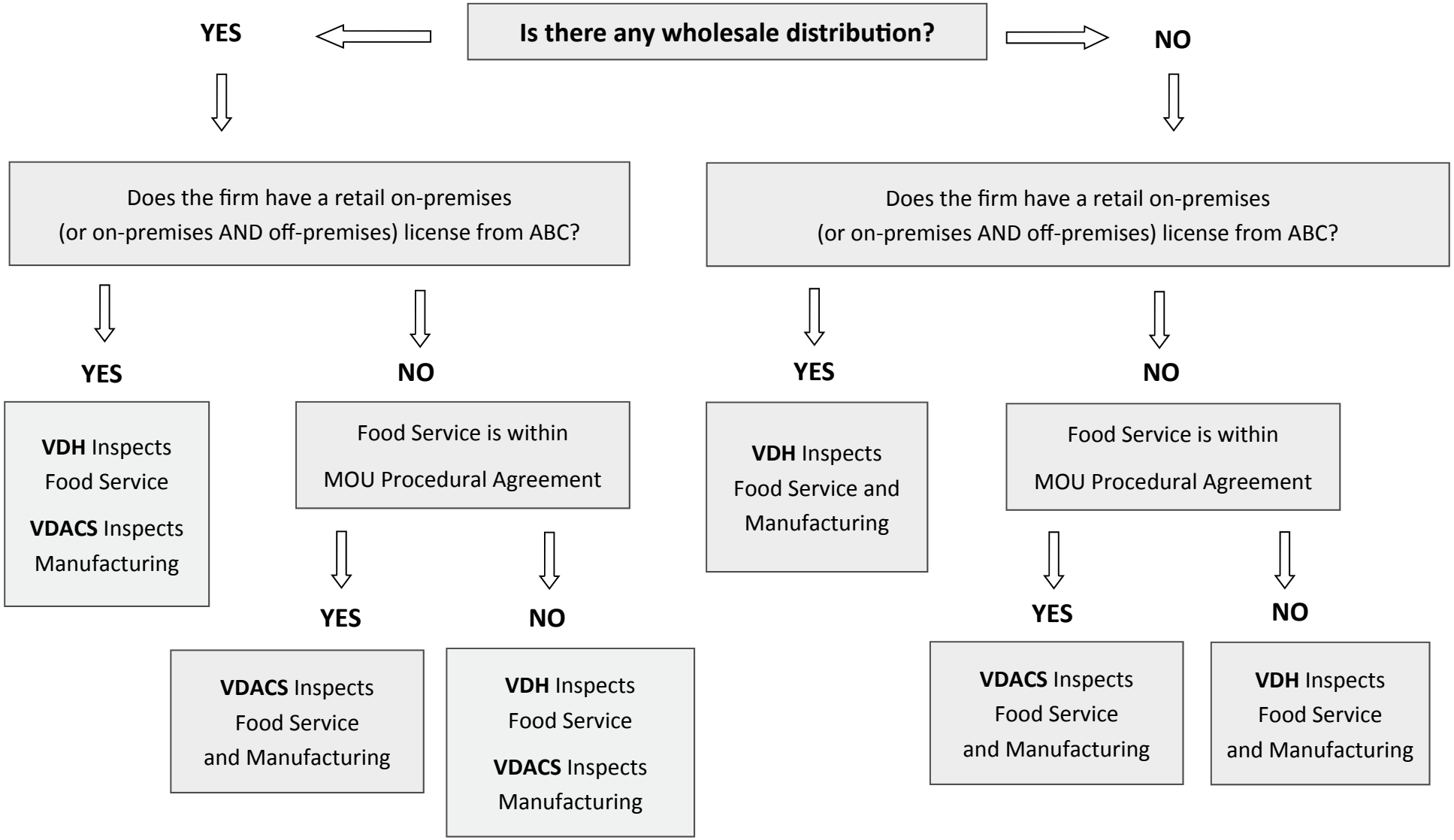
Sandra J. Adams
Commissioner
Virginia Department of Agriculture
and Consumer Services

10/06/15
Date

[4] See Footnote 3 for the definition of an "approved source."

Breweries and Distilleries Food Service Operations MOU Decision Tree

(Establishments with no Food Service are inspected by VDACS)



Procedure III-42: Inspection of Community Kitchens

A community kitchen is a facility owned by a municipality or private person(s) for use by individuals interested in preparing food—either for sale to the public or for personal use. In some cases, the kitchen space used is part of a restaurant. The space is fully equipped with all the necessary components like refrigeration, running water, restrooms, cooking equipment, work spaces, etc. If any of the food being prepared in the community kitchen will be offered for sale, the overall community kitchen must be under inspection. This is unless the kitchen, be it restaurant or community kitchen, has a valid permit from Virginia Department of Health (VDH) or is currently under inspection by VDACS.

Each separate operation preparing food for sale to the public must be under inspection. If the food prepared is for personal use only, the individual will not be placed under inspection. Non-profit organizations manufacturing foods in this setting and offering the products for sale to the public will not be exempt from inspection unless they are holding a one-day food sale. All processors that manufacture from community kitchens will be required to comply with applicable CFRs and Virginia Food Laws. They will not be inspected as retail establishments under the Retail Food Establishment Regulations. Individuals cannot use their home for storage of ingredients, finished product or equipment/utensils. All items related to the business must be stored in the community kitchen.

Administrative Process:

1. The overall community kitchen will be inspected. A firm ID will be assigned in VIPRS for the community kitchen. The only exception would be if the kitchen is permitted by VDH or under inspection by VDACS. In this instance, the overall kitchen will not be given a separate firm ID, only the operation using the space.

2. Each operator that wishes to produce in the commercial kitchen must complete and submit the "Application for a Commercial Kitchen Food Processing Operation ". With their application they must submit documentation from the community kitchen stating that they agree to allow this vendor to use their space.

3. The submitted paperwork will be reviewed by management just as any other packet and sent to the inspector once it has been completed. Included with the packet should be documentation from the restaurant or community kitchen giving the operator permission to use the space.

4. Schedule the inspection with the applicant at the earliest convenient time. In some cases, this may be difficult due to time slot availability at the community kitchen.

5. Upon inspection, a new firm will be created in VIPRS, using the physical address of the community kitchen, but including the mailing address of the individual for billing purposes or possible regulatory letters needing to be sent. Each operator that produces in the commercial kitchen will be assigned a separate firm ID in VIPRS.

These operations are similar to home operations in that you must work with the individual to schedule routine or follow-up inspections. Because the community kitchen offers time slots for the individuals to process, they may not be available during normal working hours, and you should schedule adjust to accommodate them. If this is a concern, consult with your Regional Manager.

Lastly, operations that wish to make products containing meat or poultry ingredients may be allowed to produce their products from a commercial kitchen if certain conditions are met. First, it must be determined if intended sales of the finished product are to wholesale customers (i.e. retail stores, restaurants, distributors, etc.) or strictly retail (i.e. sold directly to the end user).

Two scenarios are possible:

- If the product is found to exceed 3% raw or 2% cooked meat and the product is being sold wholesale, then Office of Meat and Poultry Services will be responsible for the operation.
- If the product is found to exceed 3% raw or 2% cooked meat and only being sold retail (i.e. directly to the end consumer or direct sales at the farmers market), then Food Safety will be responsible for inspection of the operation.

All meat products included in the recipe must be from an inspected source and bear the mark of inspection legend. The Regional Manager will be responsible for assuring these requirements are met when reviewing the application.

VDACS Sampling Procedures

Table of Contents

A. Introduction
B. Sampling Plans
    a. Rapid Response Team (RRT) sampling
    b. Manufactured Foods Regulatory Program Standards – International Organization for Standardization (MFRPS-ISO) sampling
    c. FDA Contract Samples
    d. Directed Sampling
C. Preparation of Sample Collection Report
D. Identification and Preparation of Samples
E. Aseptic Sampling
    a. Water Sampling
    b. Environmental Sampling
F. Sampling Procedures for Possible Rodent and Insect Defiled Foods
G. Following up on Adulterated Samples
H. Complaint Sampling
I. Service Samples
J. Chain of Custody (COC) Procedures
K. Tips on Sampling
L. DCLS Contact Information
Attachment A. DCLS Analytical Services
Attachment B. Environmental Supplies Check List
Attachment C. Environmental Sampling for Detection of *Listeria* monocytogenes
Attachment D. Environmental Sampling for Detection of *Salmonellae*

A. Introduction

The Virginia Department of Agriculture and Consumer Services' (VDACS) Food Safety Program is tasked with the responsibility to ensure that food products and dietary supplements in the Commonwealth of Virginia are safe, wholesome and properly labeled. One way in which this is accomplished is through our sampling program. Food Safety Specialists (FSS) must be prepared to obtain samples with each inspection, investigation and/or visit to a firm. Thus, each FSS is issued sampling supplies during orientation. The FSS is responsible for maintaining the sampling kit and notifying the Regional Office when additional supplies are needed. As the FSS performs inspections or investigations of firms, they must determine if samples are needed to support findings or determine if the procedures used during operations are effective in ensuring food safety. The following is a comprehensive guide to the VDACS' sampling program.

B. Sampling Plans

Currently, our sampling program consists of the following sampling plans:

a. Rapid Response Team (RRT) sampling
b. Manufactured Foods Regulatory Program Standards – International Organization for Standardization (MFRPS-ISO) sampling
c. FDA Contract Samples
d. Directed Sampling

a. RRT Sampling Plan
- This is a directed sampling program designed around a commodity-specific, statewide surveillance system where all Food Safety Specialists (FSS) will collect samples of the same type of product and submit them to DCLS for a predetermined set of analyses.
- Specific instructions regarding sample size, product to be collected, laboratory analysis, and timeline for collection will be sent to the field staff prior to the collection period via email.
- Pictures of the label of the food products collected must be taken, but do NOT need to be submitted with your sample report unless FSS are asked for them specifically. However, FSS shall keep the pictures in case they are needed in the future.
- The chain-of-custody (COC) form must accompany each sample to the lab.

b. MFRPS-ISO Sampling Plan
- This program was developed in partnership with DCLS. As with the RRT Program, it will be a directed sampling program targeting high risk manufactured foods known to be associated with specific adulterants.
- This program will require each FSS to collect one (1) sample per month either directly from the manufacturer, or from a retail firm.
- If the sample is collected from a retail firm, the product must be collected from intact, unopened containers that have not been repackaged or handled at the retail store. A corresponding statement, 'product is in an intact, unopened container that was not repackaged or handled at the retail establishment' will need to be added to the identification section of the sample collection report. In selecting the product to be sampled, preference is to be given to products manufactured in Virginia if available. Specific instructions regarding sample size, product to be collected, laboratory analysis, and timeline for collection will be sent to the field staff prior to the collection period via email.
- Pictures of the label of the food products collected must be taken, but do NOT need to be submitted with your sample report unless FSS are asked for them specifically. However, FSS shall keep the pictures in case they are needed in the future.
- COC forms must accompany each sample to the lab.

c. FDA Contract Samples
- Only collect the commodity directed by the FDA contract coordinator. If you feel a different commodity or test is appropriate, get prior approval. If a sample cannot be collected, contact your Regional Manager.
- If you feel that a sample should be taken when one is not directed, contact your Regional Manager for approval.
- These samples should not be shipped under Chain of Custody unless otherwise directed.

d. Directed Sampling
- The Directed Sampling program is intended to focus our resources on surveillance of products that have been previously associated with adulterants, or products that could be at risk of adulteration. A sampling assignment will be sent monthly with details on the commodity to collect and the number of samples and/or sub-samples that are to be collected, as well as the specific test service to request.
- These sample should not be shipped under Chain of Custody unless otherwise directed

C. Preparation of Sample Collection Reports

Prepare the collection report in VIPRS sample module in the following manner:

VDACS Sample Number: Barcode labels will be provided to you by your Regional Office. This serves as your sample number. The inspector shall use their barcode scanner to enter the sample number to ensure accuracy.

Commodity: The name of the product collected, nothing more.

Portion left with Vendor: Marked Yes if the sample was collected in two parts and marked No if the sample was collected in one part. This will automatically default to No in the sample screen in VIPRS.

Cost of Sample: Marked Yes if the sample was paid for, marked No if there was no charge for the sample. If marked as Yes, the cost of the sample will also be entered into the sample screen of VIPRS. The Virginia Food Law, section 3.1-417, requires that we offer to pay for samples.

Region ID: This is prepopulated depending on which region the firm is located.

Collected By: This is prepopulated with the name of the inspector who is conducting or leading the inspection.

Collected From a Lot of: Total amount of product from which the sample was collected.
Example: Collected from a lot of 24/100 lb. bags of rice offered for sale on the retail shelf.

Collected Date and Collected Time: This is prepopulated with the date the sample was added and the time. The date and time can both be changed, if necessary, but must be entered in military format.

Sample Type: This is a dropdown menu containing the types of samples collected by this Program. Select the appropriate type.

Priority ID: This is pre-selected to 7- normal priority routine. If MFRPS-ISO or RRT are selected from the dropdown above, 2-chain of custody must be selected. VIPRS will automatically require this. Prior approval must be obtained from your Regional Manager when using priority codes other than 7. Talk to your Regional Manager if the sample analysis must be expedited, like in cases where the firm is holding a large amount of product pending the sample results.

Related Samples: VDACS sample numbers of any samples which are directly related, such as food products from the same lot or products prepared from the same lot of raw materials. Also, the original sample number for follow-up samples. These will show as available so you must click to add the listed sample number if desired.

Outbreak Number: This is not a required field and will only be filled out if this number is provided to you by your Regional Manager or the Rapid Response Team Coordinator.

FDA Product Code: This is only a required field when MFRPS-ISO, RRT or FDA Contract Sample is selected. Use the FDA's Product Code Builder (link here) to make a product code for the product you specified in the commodity section. VIPRS will automatically require this.

Human Illness: pre-selected to No. Only mark otherwise if instructed by management.

Customer Notes: Any information that would be of assistance to the analyst or the office in the evaluation of the sample. For example:

1. If a sample is taken in response to a consumer complaint, provide a brief description of the problem the complainant encountered and any other pertinent information as per FOM IV-07.
2. If the sample was stored overnight in your locked state vehicle, provide that note.
3. If it is a compliance follow-up sample, indicate the results of the previous sample.
4. Information such as "Routine FDA contract sample".

Identification: All pertinent information from the label should be recorded such as: name of the product, name and address of the manufacturer, ingredients, and net weight. For products with up to 5 ingredients, the list of ingredients is to be typed. Products with more than 5 ingredients, the first few ingredients can be listed and subsequent ingredients can be listed with ".....". It is also a good rule of thumb to take a picture of the product label of any sample you are collecting. If the product is not a labeled product, then it should be identified by its exact name and a note should be made that the product was unlabeled.
Example: Ingredients: (Corn Syrup Solids, Hydrogenated Vegetable Oil (Coconut and/or Palm Kernel and or Soybean, Sodium Caseinate (a milk derivative),…….)

Lot/Production Code: If the product has a unique code, include the full code (all numbers or dates and letters) in this section. In the absence of a number that is identified as a "Lot Number", if there is any other UNIQUE identifier on the package, enter that information. A Universal Product Code (UPC) barcode number is not a unique identifier and is not to be listed as a lot number. If no unique code is available, write "N/A" or "not available".

Is the Product Imported: According to the label information, check Yes or No. If yes, you will be required to select the country from the dropdown menu.

Reason for Sample Collection: This is a dropdown menu containing the reasons for sample collection, select the appropriate reason.

Sample Location: enter the location in the establishment where the sample was collected.
Examples:

1. Retail display
2. Processing line 2B
3. Deli display refrigerator

Sample Consisted of: Close approximation of the amount collected. Exact amount is preferred. Your statement will provide information as to whether the sample was collected in 1, or 2 or 3 parts, as explained in this

procedure. For samples collected in 2 or 3 parts you need to indicate the disposition of the sample parts not sent for analysis. FSS shall use the words "taken at random" in this section if the sample is indeed taken at random.

Examples:

1. 4/8 oz. containers of barbecue taken at random from the meat display case in one part
2. 6/8 oz. containers of barbecue taken at random from the meat display case in two parts. One part (3/8 oz. containers) was left with vendor.

Method of collection: select either aseptic or non-sterile for the method of obtaining the sample. If the sample is in packaged form, select non-sterile. If the product is unpackaged and being collected for potential bacterial contamination or filth, the product must be collected aseptically.

Packaged Product: Select Yes or No based on the product.

Prepared in the Following Manner: This field is populated with the following statement and does not need to be modified: "Placed in a poly VDACS sampling bag and officially sealed and identified". If the sample is shipped on blue ice the statement can be modified to include that additional information.

Delivered To: Exact location from which the Food Safety Specialist mailed/shipped the sample to the laboratory. *Examples*: UPS Lynchburg or DCLS or VDH Courier Service

Delivery Date: prepopulated to the date of collection but can be changed if the product is delivered the following day.

Type of Establishment: Select the type of establishment where the sample was collected.

Distributor or Manufacturer: Name and address of the manufacturer, packer, or distributor of the product.

Shipper/Dealer: Name and address of the product shipper.

Date of Shipment: the exact or approximate date of shipping.

Request Sample Services: click "Add" in order to select from a dropdown the service to be run on the product.

Service Name: using the dropdown, find the desired service.

Number of Units: the number of parts or pieces being submitted for analysis; use only numerical values.

D. Identification and Preparation of Samples

All samples should be submitted to the lab in poly bags. The office carries two sizes of poly sample bags to accommodate most all sample sizes. The sample should be placed in a poly bag, identified with only the barcode label provided by the Regional Office and sealed. The sample number, date and inspector initials **do not** need to be written on the sample bag; this information is received by the lab via the barcode through VIPRS. The sample bag must be sealed with the VDACS seal that has been identified with your initials and the date of collection.

Ensure that the sample is sealed and that the barcode is placed on the poly bag in the presence of a witness. The witness will be the same person that signs for the inspection report and initials for the sample.

When samples of refrigerated or frozen products are being collected to be analyzed for the presence of microbial organisms such as bacteria, yeasts, and molds, a Temperature Control (TC) must also be taken at the same time and in the same manner to accompany samples in transport to the lab. The TC will consist of one additional unit of the same product (and same size) collected for testing. The TC will be placed in a separate poly bag, identified with a "Temperature Control" label provided by the Regional Office, and shipped together with the test sample. Examples of test requests that would require a TC include: Salmonella, Listeria, E. coli O157:H7, and any other test for contamination with microorganisms.
Once the sample has been collected from the firm, all the identifying information should be completed in VIPRS, the sample submitted (and synchronized if using the Offline VIPRS Client) and the sample manifest printed. You must ship the sample the same day the sample report is submitted (and synchronized if using the Offline VIPRS Client) in VIPRS. The manifest is the only paperwork that needs to accompany the sample to the lab. The only exception is if a chain of custody form is also required. If you are unable to ship the sample the same day it is entered into VIPRS, you must wait to submit the sample in VIPRS until it is shipped. Once the sample is submitted (and synchronized if using the Offline VIPRS Client) in VIPRS, the information will be sent to the lab and they will be expecting to receive the sample. Samples shall not be shipped to the lab until the sample is submitted and synchronized in VIPRS.

Samples can be collected in 1, 2 or 3 "parts"

- Samples collected in 1 part—These are routine samples where the vendor does not desire a portion of the sample. All packages that comprise the sample are submitted to DCLS by the FSS for analysis.

- Samples collected in 2 parts—These are routine samples where the vendor desires a portion of the sample. The FSS leaves a portion of the total number of packages collected with the firm. The number of packages left with the vendor does not have to be equal to the number of packages sent to the lab. Remember to check the appropriate box on the sample screen in VIPRS as to whether the vendor desired a portion of the sample. Make every effort to also ensure that, if a lot code is present, it matches what is left with the firm and what is sent to the lab. The vendor's portion must be placed in a poly bag and marked with the same sample number used on the sample going to the lab. The inspector will record the sample number with permanent marker on the sample bag since a duplicate barcode will not be available. The bag should be sealed with a VDACS seal that is marked with your initials and the date.

- Samples collected in 3 parts (Commissioner's Reserve)— In this situation, in addition to the lab and vendor receiving a portion of the sample, a third portion is collected and sent to the lab, designated as a Commissioner's Reserve. A Commissioner's Reserve sample will only be taken at the direction of your Regional Manager. Commissioner's Reserve samples must be collected in 3 equal parts. In other words, if you collect 3 cans for lab analysis, you need to collect 3 cans for the vendor's portion and 3 cans for the Commissioner's Reserve. Make every effort to also ensure that, if a lot code is present, it matches what is left with the firm, what is taken for the Commissioner's Reserve, and what is sent to the lab. As above, the Commissioner's Reserve must be placed in a poly bag and marked with the same sample number used on the sample being sent to the lab. The inspector can write with permanent marker the sample number since a duplicate barcode will not be available. The bag should be sealed with a VDACS seal that is marked with your initials and the date. The inspector will hold the Commissioner's Reserve

sample until further instructions from their Regional Manager. Indicate in the "Customer Notes" section of the Sample Collection Report that the sample contains a Commissioner's Reserve portion.

We must, by law, offer to pay for the sample collected. If the firm desires tender for the sample, mark Paid for Sample as YES and record the dollar amount on the sample screen in VIPRS. In order to get a reimbursement for the cost of the sample, secure an itemized receipt and submit an expense voucher. If the firm does not desire payment, Paid for Sample will be marked as NO on the sample screen in VIPRS.

E. Aseptic Sampling

Aseptic sampling is a technique used to collect a sample in a way that prevents contamination of the product being sampled. Aseptic sampling involves the use of sterile sampling techniques and implements. In this sampling technique, the product being sampled is contacted only by the sterile sampling implements and/or the container. Aseptic sampling is often used in the collection of environmental samples, water samples, and samples of unpackaged product. **If you are collecting an unpackaged sample for filth or microbial contamination, you must collect the sample using aseptic method and aseptic tools/containers.**

Basic principles of aseptic sampling technique are as follows:

- When opening sterile sampling containers, work rapidly so that contaminants from the environment do not compromise the sample or equipment. Open sterile sampling containers only to admit the sample and close the container immediately. Do not touch the inside or opening of the sterile container.

- Use only sterile equipment and containers. These are supplied to each inspector upon hire and should be obtained from the Regional Offices when your supply runs low.

- If it is necessary to open product containers in order to collect a sample, open the container in a way that does not contaminate the product, then wash hands and don sterile gloves in order to collect the sample aseptically.

- Take steps to minimize exposure of product and sampling equipment to the environment. Dust in the air surrounding the container can carry pathogenic bacteria.

- Use a fresh glove for each sample submitted under a new number

- For TCS samples, store sampling containers under refrigeration until they are ready to use. Once collected, return samples to a cooler with ice packs to maintain them below 41°F during collection time and transport to DCLS.

a. Water Sampling

According to 2VAC5-585-2100, water from a nonpublic water system shall be sampled and tested at least annually and as required by state water quality regulations. Therefore, a retail food establishment on a nonpublic water system shall sample their water at least annually and the sample results shall be retained on file at the establishment. In addition, the Code of Federal Regulations states that water shall be safe and of adequate sanitary quality. Therefore, it is not the responsibility of the FSS to conduct routine water sampling and if the firm does not have the annual water sample results on file it shall be listed as an objectionable

condition. Water sampling should only be done by a FSS for regulatory compliance, due to a consumer complaint, or for reasons discussed with your Regional Manager.

Sampling Procedures

The following procedure will be used in the collection of water samples from private water supplies. The initial water sample taken should be tested with 226-116 Colisure for Presence/Absence for Ag Waters.

Collecting a water sample that is representative of the water source is critical to obtaining accurate results. Samples must be taken using an appropriate container supplied by DCLS, and using proper technique to avoid bacterial contamination. Samples must be delivered to DCLS within 24 hours of collection.

1. Do not open the collection bottle until it is time to collect the sample.
2. The sample should be taken from a frequently used faucet inside the establishment. The 3 compartment equipment sink and handwashing sinks are appropriate for water sampling.
3. Do not remove the aerator or sanitize the faucet prior to collecting the sample.
4. Open the tap fully and allow water to run for 3-5 minutes. The water should run for a length of time such that the sample collected is not of water that has been sitting in the lines between the well and the faucet.
5. Reduce the water flow to permit filling of the sample container with accuracy.
6. Wash your hands in a convenient hand washing sink.
7. Open the sample container by removing the tamper proof seal and unscrewing the cap. Do not touch the inside of the container or the lid. Avoid laying the cap down while collecting the sample. The water can be filled into the bottle while holding the cap with your other hand.
8. Do not rinse the container. There is a fine white powder in the sample container necessary for accurate test results.
9. Fill the sample container to the 100 ml mark. Any sample containing less than 100 ml will not be accepted by the laboratory for testing. Filling the bottle very slightly over the 100 ml mark is acceptable, but be sure to leave air space between the top of the sample and the lid for proper mixing of the sample prior to testing.
10. Identify the sample with the barcode label and VDACS seal. The barcode should be placed on the water sample bottle and the VDACS seal placed across the top of the container.
11. Keep the marked and sealed sample cool and deliver to the laboratory within 24 hours of sample collection along with a sample manifest.

Regulatory Procedures

If the analysis of a water sample is positive (+) for coliform and negative (-) for fecal the following procedure will be used:

1. A letter (Water Coliform Letter 1) will be sent to the firm from the office and the firm will be rescheduled in four months for a follow-up water collection. The test on the water sample should be 226-122 Total Coliform and E. coli in Drinking Water by QT.
2. If the 4 month follow-up water sample is NAI then there is no further action.
3. If the 4 month follow-up water sample is violative then a letter will be sent to the firm asking for the firm to reply in 10 days with the steps they have taken to rectify the problem (Water Coliform Letter 2). The firm will be scheduled in four months for a follow-up water collection. The sample should be tested with 226-122 Total Coliform and E. coli in Drinking Water by QT.

4. If the third water sample is NAI then there is no further action. It will then be the firm's responsibility to have a water test performed annually.
5. If the third water sample is violative a letter (Water Coliform Letter 3) will be sent to the firm stating that they must discontinue the food processing until their water has been treated and lab results prove it is a potable source. The inspector will visit the firm within 30 days of the date of the letter to assure that food service has been discontinued if lab results have not been submitted to show the water is potable.

If the analysis of a water sample is positive (+) for coliform and positive (+) for fecal use the following procedure:

1. A letter will be sent to the firm from the office (Water Fecal Coliform 1). Return to the firm within 30 working days to take a follow-up sample. The sample should be tested with 22226-122 Total Coliform and E. coli in Drinking Water by QT.
2. If the follow-up sample analysis shows (+) coliform and (+) fecal then a letter will be sent to the firm asking for the firm to reply in 10 days with the steps they have taken to rectify the problem (Water Fecal Coliform Letter 2). The firm will be rescheduled for a follow-up water sample in 30 days.

If the third sample is adulterated then a letter will be sent to the firm stating that they must discontinue food processing until their water has been treated and lab results prove it is a potable water source. The inspector will visit the firm within 30 days of the date of the letter to assure that food service has been discontinued if lab results have not been submitted to show the water is potable

b. Environmental Sampling

This is a sampling method that does not include taking samples of food products. Instead, surfaces inside the firm, non-food contact, and food contact, are swabbed for the presence of pathogenic organisms. Samples are taken using aseptic technique and supplies. The target organisms for environmental sampling are *Salmonellae* and *Listeria* monocytogenes. Not included is *Escherichia coli* O157:H7 because environmental swabs have historically not tested positive for this organism. It is thought that this organism does not readily colonize processing environments, but is most likely in a contaminated ingredient or product. **This sampling technique will only be used at the direction of the management team in our Program.** Generally, these samples are collected under Chain of Custody, unless otherwise directed by your Regional Manager.

In preparation for the sampling assignment, gather a team. Ideally, environmental sampling will involve a team that includes one person devoted to swabbing, an aide to the swabber, a photographer taking pictures of each sampling location, a scribe taking notes of sampling location, a lead inspector in charge of communicating with firm management, a data entry person inputting the sample information into VIPRS and an individual who will deliver the samples to DCLS. This type of sampling will always be done by a team, but members may be required to multitask. A meeting with all the members should be conducted, prior to the sampling date, to go over the plan of action, gather all supplies (Attachment B. Environmental Supplies Checklist), review past violations of establishment, and discuss each person's role. Sterile containers can be labeled with barcodes and sample seals filled out in advance to save time on the day of sampling. The number of samples to be taken should also be discussed during this meeting; this will be a recommendation by the Regional Manager. This meeting will be led by one individual with prior experience conducting this type of sampling.

On the day of sampling, the lead inspector should meet with firm management to inform them of the purpose of the visit. The following should be obtained from management prior to leaving the establishment: lot number for day's production, volume of product in each lot, package sizes and types in lot and intended distribution of

products. Members of the team should do an initial walk-through to decide where to collect samples. The environmental sampling zone concept should be utilized in determining where to conduct environmental sampling. It is recommended that sampling start in Zone 1 for Listeria and in Zone 2 for *Salmonellae*. Environmental samples will be taken by the swabber using the procedures described below, at the same time, a photograph will be taken (with a placard), while the scribe records details of each location. The scribe should include comments on the possible link between the sample taken and the risk of food contamination with the target organisms. Samples are to be packed on ice packs immediately after collection of each. The lab should be notified on how many samples they are to expect and when. Whenever possible, drive the samples to the lab in order to ensure testing begins within 24 hours of collection.

Sampling Zones

A large majority of the environmental samples collected should be taken from Zones 1 and 2, and to a lesser degree, Zone 3 areas. Very few, if any, environmental samples should be taken from Zone 4 areas.

- Zone 1: Refers to all direct food contact surfaces such as slicers, mixers, conveyors, utensils, racks, work tables, etc. For inspections focusing on the presence of *Salmonellae*, such as firms producing peanut products and other dry product environments, food contact surfaces are normally not sampled. In contrast, for inspections focusing on detection of *Listeria* monocytogenes, such as firms producing seafood or cheese products in a wet environment, sampling of food contact surfaces is essential.
- Zone 2: Encompasses the areas directly adjacent to Zone 1. For investigations focusing on *Salmonellae*, this is the area where environmental contamination is most likely to directly affect safety of the product. In a small production room, Zone 2 encompasses all non-food contact surfaces in the processing area, such as the exterior of equipment, framework, food carts, equipment housing, gears, ventilation and air handling equipment, and floors. In a much larger room Zone 2 is the area around the exposed product in which you could envision a pathway to product contamination either through the actions of man or machine.
- Zone 3: The area immediately surrounding Zone 2. Zone 3 is an area which, if contaminated with a pathogen, could lead to contamination of Zone 2 via actions of humans or movement of machinery. Examples of Zone 3 areas include corridors and doorways leading into food production areas or areas in a large production room that are further away from food handling equipment than typical zone 2 areas. Walls, phones, forklifts and “mules”, even if physically located in Zone 2, should be considered Zone 3 due to a decreased likelihood of cross-contamination.
- Zone 4: The area immediately surrounding Zone 3, generally considered a remote area. Zone 4 is an area which, if contaminated with a pathogen, could lead to contamination of Zone 3 via the actions of humans or machinery. Examples of Zone 4 areas include an employee locker room if not immediately adjacent to food production rooms, dry goods storage warehouse, finished product warehouse, cafeterias, hallways, and loading dock area.

Target Pathogens

- Listeria: This pathogen is more common in areas that are consistently wet like seafood operations. When targeting *Listeria*, swabs will be collected primarily from Zones 1 and 2. Every effort should be made to conduct sampling when the facility has been in production for at least 4 hours, and before any

wet cleaning is performed. See Attachment C. Environmental Sampling for Detection of *Listeria* monocytogenes, for more guidance.

- Salmonella: Environmental sampling of *Salmonellae* should be considered at manufacturing plants that are typically dry environments where water occasionally wets the area, either intentionally as part of a periodic wet cleaning or inadvertently as the result of leaking pipes or valves or a leaking roof. Look for *Salmonellae* in areas that occasionally get wet, but that are dry for long periods. In most cases, samples for *Salmonellae* will be collected from Zones 2 and 3. Zone 1 areas are unproductive for *Salmonellae* because these are not areas where the organism grows and finds harborage. Zone 1 surfaces are usually cleaned too often to become a harborage for *Salmonellae*. See Attachment D. Environmental Sampling for Detection of *Salmonellae,* for more guidance.

Sampling should be performed by two people: one who maintains sterility, and one who assists by holding sampling equipment (non-sterile). Use of sponge for sampling is preferred over swabs because they can cover a larger area. Sponges and swabs that are pre-moistened with a buffer broth should be used. Below are procedures for both sampling tools.

<u>Sponge sampling:</u>

1. Wash and sanitize hands up to mid-forearm. Dry with disposable paper towels and don sterile gloves. After gloves are put on, do not contact any non-sterile surface, even the outside of the sample bag.
2. Grab the bag by bottom and shake in a downward motion to get the sponge (and/or handle) to the top of the bag.
3. Push sponge (or handle) from the outside of the bag until it is near the top of the bag. Tear open the bag.
4. Remove the sponge/handle from the bag with the gloved sampling hand. Be careful not to touch the outside of the bag.
5. While removing the sponge squeeze the bag to make a wide opening.
6. Sample an area of 1’ x 1’ for cleaned and sanitized areas, and 3’ x 3’ for uncleaned areas. Press evenly and firmly as if to scrub the area. Make your first pass with the sponge in an up and down direction. Repeat using a side to side motion over the same area.
7. Place the sponge back inside the sample bag. Be careful to not touch the sponge to the outside or lip of the sample bag.
8. Squeeze as much air out of the bag as possible. Roll the top of the bag over several times until it is folded all the way down to the sponge. Fold in the tabs to lock the fold in place. Place the sponge bag inside another empty Whirl-Pak or equivalent bag and seal as before. Both bags must be tight enough to provide both a leak proof seal and minimal airspace during shipment of the moistened sponge. The barcode should be placed on the outside of the second bag and the initialed and dated VDACS seal will be placed to hold the bag closed.
9. Place in a cooler with ice packs.
10. Remove your glove by grasping the cuff and pulling up. Discard used glove.
11. If at any point in this process, the sample or aseptic equipment is compromised, discard and start with new equipment.
12. Gloves should be discarded and changed between each sample taken.

Swab sampling:

1. Wash and sanitize hands up to mid-forearm. Dry with disposable paper towels and don sterile gloves. After gloves are put on, do not contact any non-sterile surface, even the outside of the swab tube.
2. Press the pre-labeled swab against the edge of the tube to squeeze out excess medium.
3. Remove the sterile, pre-moistened swab from the tube being careful not to touch the outside of the container or lip of the tube.
4. Carefully swab the surface by scrubbing from left to right. Insert the swab back in the tube so that it comes in contact with the medium and is remoistened. Press the swab against the edge of the tube to squeeze out excess solution. Re-swab the same surface by changing direction 90 degrees. Repeat, switching to a diagonal direction covering the equivalent of a 4” x 4” area. If visible soil or residue is present, sample the surface by vigorously rubbing the swab over the designated area until the soil or residue is removed
5. Place the swab back in its sterile container, avoiding contact with the lip or outside of the tube.
6. Secure the lid and place the barcode and the initialed and dated VDACS seal on the tube.
7. Place in a cooler with ice packs.
8. Remove your gloves by grasping the cuff and pulling up. Discard the glove.
9. If at any point in this process, the sample or aseptic equipment is compromised, discard and start with new equipment.
10. Gloves should be discarded and changed between each sample taken.

F. Sampling Procedures for Possible Rodent and Insect Defiled Foods

Hantavirus is a virus that is shed by rodents and can be transmitted to humans. Therefore, take precaution when collecting possibly contaminated samples of either rodent or insect infestation. Wear gloves and wash hands thoroughly after collecting samples. Double bag the contaminated sample and seal the outer bag with the initialed and dated VDACS seal and adhere a barcode. On the sample report, clearly state that the product has been rodent or insect defiled. You can use catalog number 226-101 to confirm adulteration.

G. Following up on Adulterated Samples

If a sample is found to be adulterated, the Regional Manager will grade the sample as such in VIPRS and make the inspector aware. In most cases, the firm will be sent a letter of warning, and in some cases the inspector may be asked to collect additional samples or to conduct follow up activities during the next routine or follow up inspection. Follow up activities shall be completed by the date listed in the Actions and Other Information section in the Sample Screen in VIPRS.

H. Complaint Sampling

Whenever you are collecting an official sample as a result of a consumer complaint at a firm, be sure to include a brief description of the nature of the complaint for benefit of the lab in the "Customer Notes" section of the collection report. Also mark the Sample Type as Complaint on the collection report.

Complainants who want to be notified of investigation details need to submit a FOIA request to the appropriate regional office. Inspectors should not volunteer sample results but direct them to write a brief letter requesting the results of their complaint investigation and any samples that were collected.

I. Service Samples

A service sample occurs only when a consumer requests that we sample product in their possession. If a service sample is taken, it is not linked to a firm, even if the firm where the product was purchased is known. You are collecting the sample from the consumer, not from the firm. For these cases, you will fill out the service sample form (paper copy only) and hard copy sample report. The information is not entered into VIPRS because it cannot be linked to a firm. This means that a sample manifest will not accompany the sample to the lab, only the hard copy sample report. You will adhere the barcode to the poly bag and seal the bag with the VDACS seal. The complainant will initial and sign the service sample form.

A service sample will only be collected when it is directed by your Regional Manager.

J. Chain of Custody (COC) Procedures

Anytime you are collecting samples that may result in an administrative hearing or a court case; are part of the MFRPS-ISO or RRT sampling directives; or is an environmental sample, complete the Chain of Custody form. Samples taken under COC will always accompany a sample that is shipped with a Priority 2. Do not use Priority 2 or COC for other situations unless directed by your Regional Manager. One form has been created and will be used for both the following delivery methods:

<u>For In-Person Transfer of Samples under Chain of Custody</u>

1. Enter the Sample Commodity as it appears on the sample report
2. Enter the Sample Number into the space provided, using your barcode scanner to ensure accuracy
3. Choose In Person for Delivered Via
4. Mark Yes if the sample was sealed
5. Type your name
6. Under the received by column, mark In Person
7. Print the form and have it and the Sample Manifest ready for sample custody transfer to the next person.
8. Phone the Sample Support Services (SSS) Group from the Guard's desk at 804-648-4480 extension 138 to alert staff that a sample needs to be relinquished.
9. A DCLS scientist will come to collect the sample, and at that time you will sign your name, and write the date and time it was relinquished to the lab, and the DCLS scientist will sign as the sample recipient. Date and time of sample being relinquished and sample being received need to match for an in-person delivery to prevent a broken Chain of Custody.
10. All samples must be delivered by 5 pm. If the sample cannot be delivered by 5 pm, please call your Regional Manager for further instructions.

<u>For UPS or Courier Service Shipping of Samples under Chain of Custody</u>

1. Enter the Sample Commodity as it appears on the sample collection report
2. Enter the Sample Number into the space provided, using your barcode scanner to ensure accuracy
3. Choose one option for Delivered Via, either UPS or Courier

4. Mark Yes if the sample was sealed
5. Type your name
6. Print the form, sign your name, and write the date and time you dropped the sample at the delivery service.
7. Under the Received By column, mark ONE of the applicable methods and enter the tracking number provided to you. When using the VDH Courier, the tracking number may be provided to you verbally or in the form of a sticker that can be placed directly on the COC form. The tracking number for shipments via UPS will appear on your receipt; write this number on the COC form.
8. Put this printed form, with the Sample Manifest, in a plastic sheet protector, and put it inside the outer box.
9. Send via preferred method

K. Tips on Sampling

- State of samples—samples must arrive at the lab in the same state they were collected from the firm. If a sample is stored at the firm frozen, it must be delivered to the lab in a frozen state. If a sample is stored at the firm refrigerated, it must be delivered to the lab on ice or surrounded by ice packs, not frozen but below 41°F.
- Sampling bags—keep in mind that the inside of the poly sample bag is not sterile so you should not place un-packaged samples into a sample bag. Sterile sampling supplies were provided to you, and should be used when necessary. An exception to this is products being tested for pesticide residue like fish or produce.
- Sampling without a poly bag—it is appropriate to adhere the barcode and sample seal on hermetically sealed, tamper-proof packages if they do not fit into the poly bags supplied. For example, the barcode and sample seal can be placed directly on a large product like a 5 gallon water bottle. Place the sample seal around the opening of the container, adhere the barcode and place in a box large enough for shipping via UPS or deliver to DCLS.
- When to sample—Collect samples during routine or follow-up inspections. You are discouraged from visiting a firm for the sole purpose of collecting a routine sample. In some instances, it is appropriate, i.e., a directed sample is uncommon and you may need to visit more than one store to find it.
- Lot codes—if the product being collected has a lot code and you require more than one package per sample number, collect the same lot code.
- Delivery days—when collecting refrigerated samples, the lab prefers to receive these early in the week so plan accordingly. Do not ship refrigerated samples on Friday via UPS or FedEx. If you must ship a refrigerated sample on a Friday, use a courier service, otherwise, avoid collecting TCS samples on Fridays.
- Overnight storage of samples—make every effort to ship samples the same day they are collected. In some cases though, samples cannot be shipped the same day they are collected. You are discouraged from holding TCS samples overnight but this cannot always be avoided. For TCS samples, store them in your home refrigerator or freezer but only for ONE (1) night. For non-TCS samples, storing them in your locked state car is sufficient. Non-TCS samples should be shipped within two working days from date of collection. If the sample is not shipped the same day it is collected, you must wait to submit the sample in VIPRS until the day of shipping. The sample shall remain in the sealed sample bag and a note about the overnight storage should be made in the Customer Notes section of the sample collection report. Questions about special circumstances can be directed to your Regional Manager.

- Collecting samples—take complete portions of samples in order to meet the minimum sampling required for analysis of the lab. If taking a sample from a home operation, collect the sample in the packaging as it is sold to the consumer. For example, if the firm sells whole cakes in a box then the entire cake in the firm's packaging should be collected instead of taking one slice.
- Submitting your sample—the sample information in VIPRS is sent electronically to the lab twice each day, at noon and at midnight. If you are collecting a sample close to noon, double check that the information on the report is accurate before it is submitted. Once the sample information is sent to the lab, it is more difficult to correct. Additionally, if you are collecting more than one sample at a firm, and it is close to noon, wait until after noon to submit them both so that the manifest prints correctly.
- Please take care in adequately packing your samples in the cooler to ensure that they will not be damaged by the ice packs shifting around in transport. Newspaper or other packaging material may be used.
- If you are collecting a food product but want it to be analyzed for different tests, then separate samples must be collected. For example, if you want to test ground beef for filth, fat, and bacteria, then you must collect 3 separate packages under 3 different sample numbers. The laboratory will not share a unit/package for separate analysis with different labs within DCLS.
- Minimum sample sizes—this is the amount that the lab needs to analyze the sample (see Attachment A), but sometimes the minimum amount is not available. For routine samples the minimum sample size must be collected but if the sample is for regulatory purposes and the minimum is not available, collect what is available to you. There may be instances where your Regional Manager directs you to take a larger sample size than what is required.
- Expiration dates—when collected a food that has a specified expiration date by the manufacturer, or a date mark by the retail firm, be sure that the sample arrives to the lab prior to that date.

L. DCLS Contact Information

Address: 600 N. 5th Street, Richmond, VA 23219

Contact Name or Lab	Extension(s)	Email
Main number	(804) 648-4480	
Lauren Turner, PhD, Lead Scientist	122	Lauren.Turner@dgs.virginia.gov
Norma Roadcap- Manager Food, Feed, and Fertilizer Chemistry and Metals	350	
Stephanie DelaCruz- Manager Food and Water Microbiology	280	Stephanie.DelaCruz@dgs.virginia.gov
Bob Glowacky- Manager Trace Organics	360	Robert.Glowacky@dgs.virginia.gov
Microscopy Lab Contact: Victoria Ashcraft	316	Victoria.Ashcraft@dgs.virginia.gov
Water Micro Lab	265, 266, 267	
Food Micro Lab	288, 314	
Sample Support Services Lab	138	
Michelle Mouer, Senior Scientist --Metals Testing	351	Michelle.Mouer@dgs.virginia.gov

Attachment A. DCLS Analytical Services

Service Number	Short Name	Long Name	Product Examples	Additional Notes	Minimum sample size
226-001	PR-FRVEG	Pesticide Residues in Fruits and Vegetables	Fresh herbs Fruit: fresh or canned: (apple, grapes, peach, nectarine, strawberry, tomato) Vegetables (potato, celery, cucumber, snap peas, greens, squash, peppers, beets)		500 g
226-002	PR-FISH	Pesticide Residues in Fish	Fresh/raw, smoked, canned, salted		100 g
226-008	PB-FOOD	LEAD IN FOOD PRODUCTS	Candy manufactured in China		20 g
226-009	CD-FOOD	CADMIUM IN FOOD PRODUCTS			20 g
226-010	CU-FOOD	COPPER IN FOOD PRODUCTS	Apple butter		20 g
226-011	ZN-FOOD	ZINC IN FOOD PRODUCTS			20 g
226-012	HG-FOOD	MERCURY IN FOOD PRODUCTS			20 g
226-013	AS-FOOD	ARSENIC IN FOOD PRODUCTS			20 g
226-015	FYAFLA GR	Aflatoxin in Foods	Dried figs, tree nuts, peanuts, nut butters, spices, chili paste, corn* product	*does not include sweet corn Look for products from warm climate countries	200 g
226-017	FC HIST	Histamine in Foods	Scombroid specie finfish (tuna, bluefish, shad, etc)		100 g
226-019	FC SALT	Salt in Meat and Other Foods			3 g
226-020	FC SPECIES	Species Determination of Meat			0.5 lb
226-022	SULFITE	Sulfites in Food	Fresh shrimp, dried fruits and dried mushroom when sulfites are not		100 g

			declared on the label		
226-023	FC PH AW	pH and Water Activity in Foods	fermented foods: sausages, kimchi, sauerkraut, pepper sauce	Exploratory test for determination of TCS food. Use for foods stored ambient but you are unsure of product safety.	50 g
226-024	FC F HEAVY	Heavy Filth in Foods*			200 g
226-025	FC F BAKGD	Filth in Baked Goods*			225 g
226-026	FC F FLOUR	Filth in Flour*			50 g
226-027	FC F GDMET	Filth in Ground Meats*			225 g
226-028	FC F PASTA	Filth in Pasta*			225 g
226-029	FC F BEVSOL	Filth in Beverages and Soluble Ingredients*			1 bottle
226-030	FC F CERCH	Filth in Breakfast Cereals and Corn Chips*			50 g
226-031	FC F WHETG	Filth in Wheat Germ*			50 g
226-032	FC F POTCH	Filth in Potato Chips*			100 g
226-033	FC F CNVEG	Filth in Canned Mixed Vegetables*			100 g
226-034	FC F DRESS	Filth in Food Dressings and Yogurt*			200 g
226-035	FC F FISH	Filth in Fish*			100 g
226-036	FC F INFFD	Filth in Infant Food*			250 g
226-037	FC F COFFE	Filth in Coffee, Coffee Substitutes, and Ground Chicory*			100 g
226-038	FC F NUTS	Filth in Nuts, Except Pecans*			100 g
226-040	FC F PBTR	Filth in Peanut Butter*			100 g
226-041	FC F PEPSA	Filth in Pepper Sauce*			50 g
226-042	FC F PBEAN	Filth in Peas and Beans (Not Dried)*			1 can
226-043	FC F CANDY	Filth in Candy*			225 g
226-044	FC F COCOA	Filth in Cocoa, Instant Cocoa*			50 g
226-045	FC F ICE	Filth in Ice*		Determining compliance with retailer	1 bag

				bagging own ice	
226-046	FC F SYRUP	Filth in Syrup, Honey, Sorghum*			200 g
226-047	FC F JUICE	Filth in Juice and/or Pulp*			250 ml
226-048	FC F WHMET	Filth in Unground Meats, Pickles, etc*			whole pickle or slice of meat
226-049	FC F PICKL	Filth in Chopped Pickles and Relish*			100 g
226-050	FC F SAUER	Filth in Sauerkraut*			900 g
226-051	FC ORGANO	Organoleptic Examination of Foods*		Used for complaints	no minimum
226-052	FC AU HON	Authenticity on Honey			80 g
226-053	FC AU MS	Authenticity of Maple Syrup			80 g
226-054	FC AU SOR	Authenticity of Sorghum			80 g
226-055	FAT-MEAT	FAT CONTENT OF MEAT			10 g
226-056	XM REG FD	Regulatory Foods for Bacterial Contamination			150 g
226-057	XM SOFT DR	Soft Drinks for Bacterial Contamination			100 g
226-058	XM YOG	Yogurt for Bacterial Contamination			100 g
226-059	XM CAN FD	Canned Food for Bacterial Contamination			1 can
226-060	XM LISFNEG	Listeria in Foods, with confirmation of Positive (culture)	Any RTE foods		100 g
226-064	MOIST-MEAT	MOISTURE IN MEAT			200 g
226-067	FC S TOM	Standards on Tomatoes	Do not use this test unless directed by Manager		1 can
226-073	FC F MILK	Filth in Milk*			225 g
226-074	XM ECOLIH7	E Coli O157:H7 in Foods (culture)	bagged salad greens, fermented sausage, raw ground beef, raw nuts, custard/cream filled pastry, dried spices, fresh herbs, tomatoes, cut produce, sprouts		100 g

226-075	FC F UNPOP	Filth in Unpopped Popcorn, Dried Grains, Peas, and Beans*			225 g
226-076	FC F DAIRY	Filth in Dairy Products*			225 g
226-077	FC F JAMJE	Filth in Jams and Jellies*			100 g
226-078	SALMONE	Salmonella (culture)	Soft cheese, tomatoes, cut produce, sprouts, raw nuts, custard/cream filled pastry, dried spices, fermented sausage, fresh herbs, bagged salad		100 g
226-079	FC F OATML	Filth in Oatmeal and Dried Infant Cereal*			50 g
226-080	FC F TOMPR	Filth in Tomato Products*			200 g
226-081	FC F RAISN	Filth in Raisins*			225 g
226-083	FC SALT WP	Water Phase Salt	brined or dry cured fish or meat	Determining the shelf-stability of salted products	150 g
226-084	FC F RICEF	Filth in Rice Flour*			100 g
226-085	FC F LEVEG	Filth in Canned Leafy Vegetables*			100 g
226-088	FC F TEA	Filth in Tea*			10 g
226-089	FC F POPED	Filth in Popped Popcorn*			50 g
226-090	FC F SPICE	Filth in Spices (General)*	imported spice		10 g
226-091	FC F PECAN	Filth in Pecans*			100 g
226-092	FC F DRIFR	Filth in Dried Fruit*			50 g
226-093	FC F CNMLG	Filth in Corn Meal and Grits*			50 g
226-094	FC F MUSTD	Filth in Mustard*			100 g
226-096	FC F PKLWH	Filth in Whole Pickles*			whole pickle
226-097	FC F CINN	Filth in Cinnamon*			50 g
226-098	FC F PH	pH in Foods			50 g
226-099	FC URINE	Confirmation of Urine on Food Packaging			1 cm of food package
226-100	FC EXCRETA	Confirmation of Excreta in Foods			1 excreta
226-101	FC CONF	Confirmation of adulteration, contamination, or tampering		Used as initial sample analysis when gnawed,	no minimum

				urine, feces observed.	
226-102	CA-FOOD	CALCIUM IN FOOD			20 g
226-103	FC SUGAR	Sugars in Foods and Beverages			50 g
226-108	XM H2O	Bacteriological Testing on Bottled Water			1 bottle
226-111	SHIGELLA	Shigella			100 g
226-113	XM CAMPLYO	Campylobacter			100 g/ml
226-114	XM STAPH	Staphylococcus Aureus			100 g
226-115	FY AFLAGIA	Aflatoxin Screen in Grains, Foods, Feeds	Dried figs, tree nuts, peanuts, nut butters, spices, chili paste, corn* product	*does not include sweet corm Look for products from warm climate countries	200 g
226-116	MW ACOLIPA	Colisure for Presence/Absence for Ag Waters	Well water	Initial well water test	100 mL
226-122	MPN QT A	Total Coliform and E. coli in Drinking Water by QT		Only used in follow-up situations	100 mL
226-124	DON-FOOD	Vomitoxins in Food			200 g
226-126	LIST-SCRN	Listeria Screen			100 g
226-127	SALM-SCRN	Salmonella Screen			100 g
226-128	O157-SCRN	E.coli O157 Screen			100 g
226-129	FDABOT	Metals Testing of Bottled Water			250 ml/ 1 bottle
226-130	FDAVOC	VOC Testing of Bottled Water			1 bottle
	*You are discouraged from taking routine filth samples unless you have good reason to believe the sample is adulterated or if you are collecting from a home-op, especially one with pets.				

Attachment B. Environmental Supplies Check List

Trash Bag Camera Placard for photos Clipboard Paper for scribe Writing utensils (pencil and pen) Sharpie Post-it notes Insulated coolers Cooling media (ice packs) Measuring tape/ruler VDACS sample seals VDACS barcodes Tape Papertowels Scissors Flashlight Batteries Facility map/layout Compass	Whirl pack bag (varying in size) Sterile cups Sterile spatulas Sterile tongs Sterile gloves Swabs and sponges Neutralizing broth Aseptic Wipes	Clean lab coat Tyvek suits Hair net Hand sanitizer Shoe covers Ear plugs Safety goggles Steel toe boots

Attachment C. Environmental Sampling for Detection of *Listeria* monocytogenes

DO Collect Samples From:	**DON'T Collect Samples From**:
Moist/wet areas with standing water	Dry, clean areas
Direct food contact surfaces	Employees – work shoes, hands etc
Floors and related areas – Under floor mounted equipment, scales (floor and table mounted)	Hand wash or eyewash stations
Sanitizing foot mats – if disinfectant is not maintained this can be a good harboring source and point of transfer to other areas of the facility	Packaging materials – jars, lids, etc
Cleaning Equipment – automated floor cleaning equipment, brooms, mops, waste containers especially underside, etc	Raw agricultural products – raw peanuts etc or any food contact surface used exclusively for raw foods.
Air conveying equipment – pressurized air lines, air hoses, condensate from pressurized air lines, HVAC evaporators and evaporator condensate pans	Outside the plant – roof, parking lot, walkways, etc.
Product conveyors – cables, belts, joints, where product residue accumulates, exposed bearings and rollers, sponge or felt rollers used to remove moisture from product	Zone 4
Motor and Electrical Housings – that are not cleaned and/ or sanitized.	
Cracked equipment – boots (shock absorbing equipment), metal joints, etc.	
Under sinks / safety stations – Under hand wash or eyewash stations if appearance of leaks, cracks, etc.	
Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks and crannies.	
Doorways - floor area leading directly into production areas	
Drains – Not during production	
Ice Makers – inside, scoops, underside of top of ice chamber	
Ceilings and Walls – in production areas coolers and freezers	
Door gaskets to coolers and freezers; damp insulation around pipes	

Attachment D. Environmental Sampling for Detection of *Salmonellae*

DO Collect Samples From:	**DON'T Collect Samples From:**
Floors and related areas – Under floor mounted equipment, scales (floor and table mounted)	Employees – work shoes, hands etc.
Sanitizing foot mats – if dry	Hand wash or eyewash stations
Cleaning Equipment – central vacuum systems, automated floor cleaning equipment (e.g., Tenent type walk-behind or riding sweepers, brooms, mops, etc.) Pay particular attention to the collection of floor sweepings or the dry contents of vacuum cleaner bags or tanks.	Packaging materials – jars, lids, etc.
Air conveying equipment – air filters; air ducts and intake and exhaust vents; food residue on equipment and floors if old and dry	Direct food contact surfaces –cleaned often, would be unlikely to have residual organism growth.
Product conveyors – cables, belts, joints, where product residue accumulates, if the residue is old and dry	Raw ingredients– raw peanuts refined sugar, etc.
Unsealed control and drive chambers; electrical/ mechanical service boxes that are not cleaned and/ or sanitized. Look for dry dust and residue in these boxes.	Outside the plant – roof, parking lot, etc
Cracked equipment – boots (shock absorbing equipment), metal joints, etc.	Areas with running water and very wet areas
Under sinks / safety stations – Under hand wash or eyewash stations if appearance of leaks, cracks etc.	Zone 4
Equipment – areas that are difficult to reach and clean, non-food contact surfaces, nooks and crannies if dry.	
Doorways - floor area in doorways leading into or out of the production facility or onto the roof	
Pallets – Floor under wooden or plastic pallets and pallets themselves	
Floor drains - use a sponge to scrub dry residue from floor drain grids and walls	