



Proposed Regulation Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-165
Regulation title	Regulations for the Repacking of Crab Meat for Human Consumption
Action title	
Date this document prepared	8/10/11

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The regulations under 12VAC5-165 et seq. pertain to the practice of transferring crab meat from one processor's container into the container of a different processor, primarily for marketing purposes. When these regulations were adopted in 2000, they were developed to address the sanitation, product traceability, and labeling concerns associated with the situation where one processor would purchase crab meat packed by another certified crab meat processor, whether of a domestic or foreign origin, and repack the meat into the new processor's container.

Currently, crab meat shipped into the United States from foreign companies originates from nearly thirty or more different processing facilities in the foreign country, even though it is shipped by one exporter to the US. Under this multi-source practice, the one-on-one relationship between the original processor and the Virginia crab meat processor can no longer exist. As such, several of the requirements that depended upon this relationship cannot be reliably met, and new processes for assuring the safety of this meat must be developed.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The legal authority to promulgate the regulations is §28.2-801 of the Code of Virginia. The promulgating entity is the State Board of Health.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

Some of the provisions of 12VAC5-165 either cannot be met by certified Virginia repacking establishments because of changes in the way that crab meat is being imported from foreign countries and shipped into the U.S or are unnecessary and have no relevance to public health. The amended regulations provide requirements that Virginia processors can reasonably meet and will address the existing risks of the importation of crab meat from unapproved sources and the repacking of foreign crab meat and labeling it as domestic crab meat.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The Department proposes repealing 12VAC5-165-70 which states that the Division of Shellfish Sanitation (Division) should be contacted when any condition that may compromise the safety of the product exists. This provision is unnecessary and burdensome to both industry and the Division. The repacker must be able to decide the appropriate disposition of product they are processing without the approval or disapproval of the Division.

The Department proposes modifying 12VAC5-165-90 which addresses the verification of shipping temperatures of imported crab meat. The modification is to include all crab meat and to clarify the verification.

The Department proposes modifying 12VAC5-165-100.A which addresses sampling requirements for imported crab meat to be repacked. The current U. S. Food and Drug Administration import requirements in the Code of Federal Regulations: 21 CFR 123.12 'Special requirements for imported products' have specific requirements for fish and fishery products which preclude the end product sampling requirement currently in place.

The Department proposes modifying 12VAC5-165-100.B, which addresses organoleptic sensing. There is a lack of local capacity to train persons in organoleptic sensing to the level of being certified in seafood decomposition, which has made this regulation impractical. In its place, repacking establishments may organoleptically sense, to the best of the individual’s capability, each container when opened and keep records attesting to this practice. Unsatisfactory containers would be discarded and a record kept of this process.

The Department proposes repealing 12 VAC5-200, which requires the repacker to pasteurize all imported crab meat that has not been pasteurized. Nationally, time has proven that unpasteurized foreign crab meat does not pose the elevated public health risk originally believed to exist.

The Department proposes modifying 12VAC5-165-220.B which requires that the lot number indicate the original source firm that picked the crab meat. Since a reliable indication of the establishment that picked the meat may be unrealistic, some other means of identifying lot numbers may be used by the repacker.

The Department proposes repealing 12VAC5-165-280 which requires that records must be kept separate from other production records. This requirement is unnecessary since the method and type of records being kept are dictated by the repacker’s Hazard Analysis Critical Control Point (HACCP) plan.

Other sections of this regulation may be addressed during this process.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

The proposed amendments will serve to protect the public’s health by clarifying requirements for repacking crab meat. The proposed amendments eliminate or modify certain regulatory requirements that are unnecessary, burdensome or no longer practical. For example, the proposed amendment to 12 VAC5-165-100 will eliminate burdensome and unnecessary sampling requirements. In addition, the repeal of 12 VAC5-165-280 will eliminate unnecessary recordkeeping requirements.

There are no disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

No applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

All localities will be affected equally.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Julie Henderson, 109 Governor Street, Suite 614, Richmond, Virginia 23219, (804)382-3223 (phone), (804)864-7481 (fax), julie.ray@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	None.
Projected cost of the regulation on localities	None.
Description of the individuals, businesses or other entities likely to be affected by the regulation	Crab meat processors.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than	The Division of Shellfish Sanitation currently has 19 certified crab meat dealers.

500 full-time employees or has gross annual sales of less than \$6 million.	
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	No additional costs to certified crab meat dealers.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

Regulations are mandated by Code of Virginia. No alternative exists.

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

- 1) All crab meat industries certified by the Division of Shellfish Sanitation are small business. As such, all compliance and reporting requirements are at the minimum that are needed to protect public health.
- 2) The schedules for reporting cannot be less stringent than required and adequately protect public health.
- 3) Reporting requirements have been consolidated and simplified as much as possible.
- 4) There is not any design or operational standards that replace performance standards.
- 5) Small businesses cannot be exempted from these regulations and still adequately protect public health.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

No comments received.

Commenter	Comment	Agency response
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Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

- 1) The proposed modification of these regulations will neither strengthen nor erode the authority and rights of parents in the education, nurturing, and supervision of their children.
- 2) The proposed modification of these regulations will neither encourage nor discourage economic self-sufficiency, self-pride, nor the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents.
- 3) The proposed modification of these regulations will neither strengthen nor erode the marital commitment.
- 4) The proposed modification of these regulations will neither increase nor decrease disposable family income.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC 5-165-10	N/A	Importer not defined.	Importer means either the owner or consignee at the time of entry into the United States, or the agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation.
12VAC 5-165-10	N/A	Processor is defined as a person who operates an establishment that cooks,	Processor means any person engaged in commercial, custom, or institutional processing of crab meat, either in the United

		picks, packs, repacks or pasteurizes crab meat.	States or in a foreign country.
12VAC 5-165-70	N/A	Oversight of safety of product. Any condition that may compromise the safety of the final product shall be identified by the repacker and the Division shall be contacted for appropriate disposition of the product.	Repealed. The processor is responsible for the safety of the product and may decide the appropriate disposition independently from the Division in consult with VA Tech Seafood Extension or using the U. S. FDA Seafood Hazards Guide.
12VAC 5-165-80	N/A	Crab meat for repacking from a foreign government shall be picked and packed by a crab processing establishment which is currently licensed, permitted or certified and inspected by a foreign government public health authority and shall operate under a HACCP plan approved by a foreign government public health authority.	Added the FDA imports requirement that imported crab meat shall meet the requirements of the Code of Federal Regulations: 21 CFR 123.12 "Special requirements for imported products."
12VAC 5-165-90	N/A	Imported crab meat must be received with transport temperature conditions. The measuring device must be approved by the Division.	The regulation will be amended to include transport temperature receiving conditions for all crab meat whether domestic or foreign in line with the FDA requirements for pasteurized crab meat. The Division does not need to approve the temperature measuring device. The device used must meet the requirements of the FDA Seafood Hazards Guide for its intended use.
12VAC 5-165-100	N/A	Sampling and analysis of imported crab meat is currently required prior to repacking.	All imported crab meat must meet the FDA Code of Federal Regulations: 21 CFR 123.12 in order to be imported into the United States. The import requirements help to ensure that the crab meat is processed in a facility that is comparable to a U.S regulated facility, follows good manufacturing practices and Seafood Hazard Analysis and Critical Control Points (HACCP). The regulation is amended to allow for sampling prior to repacking and gives action levels for both aerobic plate counts and fecal coliform.
12VAC 5-165-120	N/A	Verification of container integrity for imported, pasteurized crab meat.	Amended regulation for all pasteurized crab meat to have a container integrity check and the records be kept on file for a minimum of one year.
12VAC 5-165-150	N/A	Containers of pasteurized crab meat destined for repacking shall be stored at a temperature of 36°F or less. Transportation is included.	Amended regulation to require all pasteurized crab meat to be stored at 36°F or less. Transportation requirement removed since it is the responsibility of the receiving company to ensure temperature requirements.

12VAC 5-165- 180	N/A	Cooling of crab meat after repacking.	Remove "or both", requirement is unnecessary.
12VAC 5-165- 200	N/A	Imported crab meat to be pasteurized is currently required to meet the National Blue Crab Industry Pasteurization and Alternative Thermal Processing Standards.	Amended regulation to remove requirement. The FDA Seafood Hazards Guide and in plant validation studies conducted by VA Tech Seafood Extension serves to control hazards in pasteurization.
12VAC 5-165- 220	N/A	Lot number requirements on containers referred to the source firm.	Amended regulation to change source firm to original processor for consistency.
12VAC 5-165- 230	N/A	Imported crab meat is required to be packed into containers which bear a declaration of the country of origin.	Stickers are often placed onto containers with the country of origin. These stickers are easily removed from the container so that consumer believes the crab meat is domestic, which demands a higher price. The regulation is amended to require a pre-printed container with country of origin on the principal display panel.
12VAC 5-165- 260	N/A	The individual crab meat shall be easily traceable.	The current regulation does not define the scope of what must be traceable. The regulation is amended to require lots of crab meat to be traceable.
12VAC 5-165- 270	N/A	The minimum records to be kept are listed.	The regulation is amended to better clarify and be consistent with the type of records and length of time they must be kept.
12VAC 5-165- 290	N/A	Decertification of certified facilities.	The regulation is repealed since the penalty for not labeling the repacked crab meat with the country of origin is a Class 1 misdemeanor.
12VAC 5-165- 310	N/A	Persons guilty of a Class 1 misdemeanor if found to be packing or repacking foreign crab meat into a container without the country of origin indicated on the principal display panel.	Persons are clarified. The owner of a facility and the supervisory employees of that facility may be guilty of a Class 1 misdemeanor. It is not the intent of the Division to charge the hourly employee who is found repacking foreign crab meat as domestic crab meat. The person making the decisions; the owner or supervisor would be charged by the Division.