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V

## Final Regulation Agency Background Document

<b>Agency name</b>	Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12VAC5-165
<b>Regulation title</b>	Regulations for the Repacking of Crab Meat for Human Consumption
<b>Action title</b>	Final amendments following periodic review
<b>Date this document prepared</b>	May 7, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.*

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 originates from nearly thirty or more different processing facilities in foreign countries, even though it may be shipped by a single exporter to the U.S. 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 crab meat have been developed.

### Statement of final agency action

*Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.*

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The final amendments to the Regulations for the Repacking of Crab Meat for Human Consumption (12VAC5-165) were approved by the State Board of Health on June 5, 2014.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.*

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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. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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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 no longer necessary and have no relevance to public health. The amended regulations are essential to protect public health in that they provide requirements that Virginia processors can reasonably meet and will address the existing risks of the importation of crab meat and the repacking of foreign crab meat and labeling it as domestic crab meat.

### Substance

*Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.*

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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. Pursuant to existing federal regulations, the repacker is responsible 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 12VAC5-200, which requires the repacker to pasteurize all imported crab meat that has not been pasteurized. A review of national illness data from the Centers for Disease Control indicates that unpasteurized foreign crab meat does not pose the elevated public health risk originally believed to exist; therefore this requirement is no longer necessary.

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 there are no disadvantages to the public or the Commonwealth, please 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 12VAC5-165-100 will eliminate burdensome and unnecessary sampling requirements. In addition, the repeal of 12VAC5-165-280 will eliminate unnecessary recordkeeping requirements.

There are no disadvantages to the public or the Commonwealth.

**Changes made since the proposed stage**

*Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-165-150 and 12VAC5-165-180	Containers of pasteurized crab meat destined for repacking shall be stored at a temperature of 36°F or less.	US FDA guidance for the cold holding temperature of pasteurized crab meat was changed from 36°F to 40°F	4 <sup>th</sup> Edition of FDA Seafood Hazards Guide allows for the cold holding temperature for pasteurized crab meat to be 40°F or less. Public comments addressed this issue.
12VAC5-165-230	Imported crabmeat is required to be packed into containers which bear a declaration of the country of origin. At the proposed stage the regulation was amended to require a pre-printed container with the country of origin on the principal display panel.	A permanent pre-printed label on the container will not be required.	Based on public comment the proposed regulation was changed. Permanent demarcation on containers will not be required. Labels will be allowed to be placed on containers identifying the country of origin. The requirement for pre printed containers will cause businesses to purchase containers that may not be used and therefore cause an upfront expense which may not be easily recouped based on the supplier at the time of repacking crab meat.

**Public comment**

*Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.*

Commenter	Comment	Agency response
Mike Jahncke, Director, Virginia Tech Seafood Extension	Suggested the refrigeration temperature for pasteurized crabmeat be changed from 36° F to 40° F or less.	Agree with temperature change. 40°F temperature will enable processors to meet HACCP guidelines.
Kelly Minor, Little River Seafood	Request refrigeration temperature for pasteurized crabmeat be changed from 36° F to 40°, and indicated that pg 252 of 4 <sup>th</sup> edition of FDA Hazards Guide; Fish and Fishery Products. If we do not change the temperature, she would not know how to report on HACCP documents when product was over 36°F but 40°F or less.	Agree with temperature change. 40°F temperature will enable processors to meet HACCP guidelines.
Kevin Wade	Production of preprinted cups poses an economic burden and prohibits business model	Proposed regulation has been changed to allow for the addition of a label after the container has been purchased as long as the requirement for labeling for country of origin is met.

**All changes made in this regulatory action**

*Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.*

<b>Current Section Number</b>	<b>Proposed new section number if applicable</b>	<b>Current requirement</b>	<b>Proposed change and rationale</b>
12VAC5-165-10	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.
12VAC5-165-10	N/A	Processor is defined as a person who operates as establishment that cooks, picks, packs, repacks, or pasteurizes crab meat.	Processor means any person engaged in commercial, custom, or institutional processing of crab meat, either in the United States or in a foreign country.
12VAC5-165-70	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.
12VAC5-165-80	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."
12VAC5-165-90	N/A	Imported crab meat must be received with transport temperature conditions. The measuring device must be approved by the	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

		Division.	need to approve the temperature measuring device. The device used must meet the requirements of the FDA Seafood Hazards Guide for its intended use.
12VAC5-165-100	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.
12VAC5-165-120	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.
12VAC5-165-150	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 40°F or less as a result of the public comment period. Transportation requirement removed since it is responsibility of the receiving company to ensure temperature requirements.
12VAC5-165-180	N/A	Cooling of crab meat after repacking.	Remove “or both”, requirement is unnecessary. Amend regulation to require refrigeration not to exceed to 40°F.
12VAC5-165-200	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.
12VAC5-220	N/A	Lot number requirements on containers referred to the source firm.	Amended regulation to change source firm to original processor for consistency.
12VAC5 - 165-230	N/A	Imported crab meat is required to be packed into containers which bear a declaration of the country of origin.	For the proposed stage it was noted that 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 was amended in the proposed stage to require a preprinted container with country of origin on the principal display panel. During the public comment period it was expressed that having to preorder containers printed with the country of origin may cause unnecessary expense to a firm due to the possibility of sources of crabmeat. A change in suppliers could render the firm with a large quantity of containers that could

			not be used due to the demarcation on the container.
12VAC5-165-260	<b>N/A</b>	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.
12VAC5-165-270	<b>N/A</b>	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.
12VAC5-165-290	<b>N/A</b>	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.
12VAC5-165-310	<b>N/A</b>	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 VDH to charge a subordinate employee who is found repacking foreign crab meat as domestic crab meat. The persons in charge such as the owner and/or supervisor are responsible to assure compliance with the regulations, and would be the named parties in an enforcement action.