PART I – GENERAL FRAMEWORK FOR REGULATIONS

Article 1.

Definitions

12 VAC 5-165-10. Definitions.

The following words and terms, when used in this regulation, shall have the following meaning unless the context clearly indicates otherwise:

- "Action level" means the limit established for a deleterious substance present in a product or the environment, above which level prescribed actions by the division may be required to protect public health.
- "Agency" means the Virginia Department of Health.
- "Certificate of Inspection" means a numbered certificate issued by the division to a shipper after an inspection confirms compliance with applicable regulations and standards.
- "Certification number" means a unique number assigned to each shipper upon issuance of a Certificate of Inspection.
- <u>"Certified Laboratory"</u> means a laboratory certified by the U. S. Food and Drug Administration for analysis of food products.
- "Critical Control Point (CCP)" means a point, step or procedure in a food
 process at which control can be applied, and a food safety hazard can as a result
 be prevented, eliminated or reduced to acceptable numbers.

"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

"Department" means the Virginia Department of Health.

"Division" means the Division of Shellfish Sanitation.

<u>"Establishment"</u> means any vehicle, vessel, property, or premises where crustacea, finfish or shellfish are transported, held, stored, processed, packed, repacked or pasteurized in preparation for marketing.

"HACCP Plan" means a written document that delineates the formal procedures
that a dealer follows to implement a Hazard Analysis Critical Control Point
methodology to assure food safety.

"Hazard Analysis" means a process used to determine whether there are food safety hazards that are reasonably likely to occur while repacking crab meat and to identify the preventive measures that the repacker can apply to control those hazards.

"Lot" means repacked crab meat that bears the same repack date and source code.

"Preventive measure" means actions taken to prevent or control a food safety hazard.

"Repacker" means a person who operates an establishment that transfers crab
meat from a container originally packed by another establishment to another
container.

"Repacking operation" means a process of transferring crab meat from the original shipper's packing container to a different packing container, including all steps beginning with the removal of the original containers of meat from the repacker's refrigeration and ending with the repacked crab meat in properly identified containers placed into refrigeration.

"Shipper" means a person who operates an establishment for the cooking, picking, repacking or pasteurizing of crab meat.

"Source Code" means a code designated by the repacker which represents the crab processing facility where crab meat was obtained.

Article 2.

General Information

12 VAC 5-165-20. Authority for Regulations.

Chapter 8 of Title 28.2 of the Code of Virginia (§28.2-800 et seq.) provides that the State Board of Health has the duty to protect the public health and to ensure that all shellfish, crustacea and finfish destined for public consumption be safe and wholesome. In order to discharge that duty, the board is empowered to supervise and regulate all establishments where shellfish, crustacea or finfish are found.

12 VAC 5-165-30. Purpose of Regulations.

The purpose of these regulations is to establish criteria by which crab processors can safely repack both domestic and imported crab meat.

12 VAC 5-165-40. Administration of regulations.

These regulations are administered by the following parties:

A. State Board of Health, which has responsibility for promulgating,

amending, and repealing regulations which ensure that crab meat or crab

meat products processed or packed in Virginia are safe and wholesome.

- B. State Health Commissioner, who is the executive officer of the State

 Board of Health, with the authority of the board when it is not in session

 and subject to such rules and regulations as may be prescribed by the

 board.
- C. Division of Shellfish Sanitation, which is designated as the primary
 reviewing agent of the board for the purpose of administering these
 regulations. The division examines and approves the technical aspects of
 all applications for establishments wishing to pick, pack or repack crab
 meat prior to the drafting of a Certificate of Inspection for final approval by
 the State Health Commissioner. The division also has primary
 responsibility for monitoring crab meat picking, packing and repacking
 operations to ensure that crab meat supplied to the public is safe and
 wholesome.
- D. Central and field offices, which are maintained by the division. The central office is located in Richmond, Virginia. The division maintains three field offices which are responsible for activities of the division within their service areas.

12 VAC 5-165-50. Compliance with the Administrative Process Act.

The provisions of the Virginia Administrative Process Act (§9-6.14:l et. seq. of the Code of Virginia) shall govern the promulgation and administration of these

regulations and shall be applicable to the appeal of any case decision based upon this chapter.

12 VAC 5-165-60. Powers and procedures of regulations not exclusive.

The commissioner may enforce this chapter through any means lawfully available.

Article 3

Procedures.

12 VAC 5-165-70. Certificate of Inspection Required.

No person, firm or corporation shall operate an establishment for the repacking or relabeling crab meat until the establishment first obtains the approval of the State Health Commissioner in the form of a Certificate of Inspection. Application for a Certificate of Inspection shall be submitted to the appropriate field office or central office.

12 VAC 5-165-80. Hazard Analysis and Critical Control Point (HACCP) Plan.

An establishment for the repacking or relabeling of crab meat shall have and maintain an approved Hazard Analysis Critical Control Point (HAACP) plan to include, at a minimum, the following:

- 1. A hazard analysis
- 2. The identification of preventive measures
- 3. The identification of critical control points
- 4. The establishment of critical limits for each critical control point
- 5. The monitoring records of each critical control point
- 6. The establishment of corrective action when a critical limit deviation occurs

- 7. The establishment and maintenance of a record-keeping system
- 8. The establishment of verification procedures.

12 VAC 5-165-90. Scope of Embargo.

In the event of a recall or embargo of repacked crab meat, the entire production bearing the lot number will normally be recalled or embargoed, unless a verifiable sublot coding system has been used.

12-VAC 5-165-100. Oversight for 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.

PART II – SOURCES OF CRAB MEAT FOR REPACKING

12 VAC 5-165-110. Source facility requirements

Crab meat for repacking shall be picked and packed by a crab processing establishment which is currently licensed, permitted or certified and inspected by either a state public health authority or by a foreign government public health authority; and shall operate under a HACCP plan approved by the state or foreign government public health authority, or the U. S. Food and Drug Administration.

12 VAC 5-165-120. Verification of HACCP for imported crab meat.

When imported crab meat is used as a source for repacking, the repacker shall obtain a letter from the foreign crab meat producer and foreign government public health authority or recognized seafood safety authority stating that the crab meat has been produced under a HAACP plan equivalent to the United States Food and Drug Administration Seafood HAACP Rule 21 CFR 123.

12 VAC 5-165-130. Verification of shipping temperatures for imported crab meat.

When imported crab meat is used as a source for repacking, the repacker shall provide a record of international transport temperature conditions for each shipment. Temperature recording may be by maximum temperature recording.

<u>Shellfish Sanitation.</u> The processor shall include the transport temperature conditions as a part of the receiving CCP in its HACCP plan.

12 VAC 5-165-140. Sampling and analysis requirements for imported crab meat.

- A. When imported crab meat is used as a source for repacking, the repacker shall take a minimum of five samples from every shipment prior to any processing or pasteurization to be analyzed by a certified laboratory for the following:
 - 1. Aerobic plate count; action level of >100,000/g.
 - 2. Fecal coliforms; action level of >93/100g.
 - 3. Escherichia coli; action level of >93/100g.
 - 4. Salmonella sp.; FDA guideline of zero per gram
 - 5. Listeria monocytogenes; action level of zero per gram.
 - 6. Staphylococcus aureus enterotoxin; FDA guideline of no detectable toxin. Product shall be rejected if any sample is found to contain S. aureus enterotoxin.
- B. When imported crab meat is used as a source for repacking, the repacker shall take a minimum of five samples from every shipment to be tested for decomposition by organoleptic sensing technique. These analyses shall be conducted only by a designated person trained in organoleptic sensing

technique either by Virginia Polytechnic Institute and State University

(Virginia Tech), the United States Food and Drug Administration (FDA), or

by other source approved by the division. The repacker shall submit to

the division a copy of the certificate of training or other documentation

denoting successful completion of the training from the trainer for each

individual conducting the analysis, and shall maintain a copy in their

records.

- C. If any sample is found to exceed an action level or guideline, or is found to show evidence of decomposition, the repacker shall stop processing the lot sampled and contact the division before proceeding with processing to determine the disposition of that lot.
- D. All records of sample analysis shall be kept on file at the repacker and shall be available for review by the division. These records shall be maintained for a period of one year from the date of processing for products packaged for fresh distribution, and two years for products packaged for frozen or pasteurized distribution.

12 VAC 5-165-150. Verification of pasteurization for imported crab meat.

If the crab meat for repacking was pasteurized in a establishment outside the

United States, the repacker shall obtain a letter from the foreign crab meat

producer stating that the crab meat has received a pasteurization process

equivalent of F¹⁶₁₈₅=31 minutes and was processed utilizing HAACP controls.

12 VAC 5-165-160. Verification of container integrity for imported, pasteurized crab meat.

The repacker shall evaluate the container integrity of all imported pasteurized crab meat products. These evaluations shall also be conducted after any pasteurization by the repacker. This evaluation shall at a minimum include visual inspection of all containers for evidence of leaks.

PART III - OPERATIONAL REQUIREMENTS

Article 1.

Processing

12 VAC 5-165-170. Separation of operations.

All crab meat repacking operations shall be conducted separately in time or space from other packing operations.

12 VAC 5-165-180. Cleaning and sanitizing of tables.

The repacking tables shall be cleaned and sanitized prior to and after each crab meat repacking operation.

12 VAC 5-165-190. Pasteurized crab meat storage temperature.

Containers of pasteurized crab meat destined for repacking shall be stored and transported in a refrigerated room or vehicle at a temperature of 36°F or less.

12 VAC 5-165-200. Temperature of crab meat during repacking.

No portion of the crab meat shall exceed 50°F during the repacking process.

12 VAC 5-165-210. Cooling of crab meat after repacking.

Immediately after repacking, containers of repacked crab meat shall be either placed into crushed or flaked ice, placed into refrigeration not to exceed 36°F, or both.

12 VAC 5-165-220. Disposal of used containers.

Empty containers from which crab meat has been repacked shall not be kept on premises for any type of reuse. After removing the crab meat, the empty containers shall be placed immediately into waste disposal receptacles.

12 VAC 5-165-230. Imported crab meat to be pasteurized.

Prior to or after repacking, the repacker shall pasteurize all imported crab meat which has not been pasteurized in the country of origin. Pasteurization shall meet the current revision of the 1984 National Blue Crab Industry Pasteurization Standard; with records of pasteurization to be kept as required in Article 3. The heat penetration in the crab meat during the pasteurization process for all container sizes and types shall be confirmed in writing by Virginia Tech or other authority approved by the division, as meeting the aforementioned minimum requirements.

Article 2.

Labeling

12 VAC 5-165-240. Certification number to be on containers.

Crab meat shall be repacked only into containers bearing the repacker's Virginia certification number.

12 VAC 5-165-250. Lot numbers.

- A. Containers of repacked crab meat shall be stamped or embossed with the lot number.
- B. Lot numbers shall consist of a repack date and a code indicating the original source firm that picked the crab meat. All codes for lot numbers shall be logged in the processor records with an explanation of the code.

12 VAC 5-165-260. Country of origin for imported crab meat.

Imported crab meat shall be packed into containers which bear a declaration of the country of origin of the repacked crab meat on the principal display panel of the container. If the repacked crab meat is a blend from more than one source, the container shall declare the country of origin for all sources, regardless of the percentage of crab meat that the source represents.

Article 3.

Records and Record keeping

12 VAC 5-165-270. Accessibility of records.

All required records shall be kept in logical order, maintained by the repacker, and shall be readily accessible by Division of Shellfish Sanitation staff for inspection.

12 VAC 5-165-280. Crab meat sources and source coding.

The repacker shall maintain records clearly indicating the sources of crab meat used for repacking in relation to the source code identified on the containers of repacked crab meat.

12 VAC 5-165-290. Traceability of repacked crab meat.

The individual lots of crab meat shall be easily traceable from their source, through the repacking process to the buyer and from the buyer back through the repacker to the particular lot source.

12 VAC 5-165-300. Minimum records to be kept.

The repacker shall, at a minimum, maintain the following information on each lot of repacked crab meat: the source plant, quantity received from source, type of

meat, date of repacking, buyers, and quantities of repacked lots sold. Additional clarifying records may be required if individual lots of product cannot easily be traced.

12 VAC 5-165-310. Records to be kept separate.

Records for repacked imported crab meat shall be kept separate from other production records.

12 VAC 5-165-320. Traceability of blended crab meat.

The repacker shall maintain traceability via record keeping and coding for imported crab meat which is mixed with domestic product. These records shall include the exact amounts and sources of all crab meat used in the production lot.