

DEPARTMENT OF ENVIRONMENTAL CONSERVATION



18 AAC 34

Seafood Processing and Inspection

Public Review Draft

November 2018

Comment Period Ends:

5:00 pm, Friday, February 1, 2019

**Bill Walker
Governor**

**Larry Hartig
Commissioner**

18 AAC 34.005(b)(2) is amended to read:

(2) persons who store, clean, package **or** [AND] distribute whole seafood products to be sold as part of commerce and intended for human consumption;

18 AAC 34.005 is amended by adding a new subsection to read:

(h) An operator of a fishing vessel or a tender vessel who is not processing on board the vessel is exempt from the requirements of this chapter, except for 18 AAC 34.600 –

18 AAC 34.625. (Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register152; am 8/6/2006, Register 179; am ___/___/____, Register ____)

Authority:	AS 17.20.005	AS 17.20.072	AS 44.46.020
	AS 17.20.065	AS 17.20.180	

18 AAC 34.010(2) is amended to read:

(2) 21 U.S.C. 379e(a), as revised as of **January 12, 2018** [AUGUST 13, 1993];

18 AAC 34.010(3) is amended to read:

(3) 21 C.F.R. 101.1 - 101.108 (Food Labeling), as revised as of April 1, **2018**, [2006] **except 21 C.F.R. 101.69 and 21 C.F.R. 101.108 are not adopted by reference;**

18 AAC 34.010(4) is amended to read:

(4) 21 C.F.R. 102.5 - 102.57 (Common or Usual Name for Nonstandardized Foods), as revised as of April 1, **2018**, [2006] **except 21 C.F.R. 102.19 is not adopted by**

reference;

18 AAC 34.010 (5) is amended to read:

(5) 21 C.F.R. 108.35 (Thermal Processing of Low-acid Foods Packaged in Hermetically Sealed Containers), as revised as of April 1, **2018** [2006];

18 AAC 34.010(6) is repealed:

(6) repealed ____/____/____;

18 AAC 34.010(7) is amended to read:

(7) 21 C.F.R. 113.3 - 113.100 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers), as revised as of April 1, **2018** [2006]; **this regulation is adopted by reference as amended from time to time;**

18 AAC 34.010(8) is amended to read:

(8) 21 C.F.R. 114.3 - 114.100 (Acidified Foods), as revised as of April 1, **2018** [2006]; **this regulation is adopted by reference as amended from time to time;**

18 AAC 34.010(9) is amended to read:

(9) 21 C.F.R. 123.3 - 123.28 (Fish and Fishery Products), as revised as of April 1, **2018** [2006]; **this regulation is adopted by reference as amended from time to time;**

18 AAC 34.010(10) is amended to read:

(10) **21 C.F.R 172.5 – 172.898 (Food Additives Permitted for Direct Addition to Food for Human Consumption)** [21 C.F.R. 172.160, (POTASSIUM NITRATE)], as revised as of April 1, **2018** [2006];

18 AAC 34.010(11) is repealed:

(11) repealed ____/____/____;

18 AAC 34.010(12) is repealed:

(12) repealed ____/____/____;

18 AAC 34.010(13) is repealed:

(13) repealed ____/____/____;

18 AAC 34.010(14) is amended to read:

(14) 21 C.F.R. 179.21 - 179.45 (Irradiation in the Production, Processing, and Handling of Food), as revised as of April 1, **2018** [2006];

18 AAC 34.010(15) is repealed:

(15) repealed ____/____/____;

18 AAC 34.010(16) is repealed:

(16) repealed ____/____/____;

18 AAC 34.010(17) is repealed:

(17) repealed ____/____/____;

18 AAC 34.010(18) is repealed:

(18) repealed ____/____/____;

18 AAC 34.010 (21) is amended to read:

(21) 29 C.F.R. 1910.141(c)(1)(i) and Table J-1, as revised as of **July 1, 2018;**

[2000.]

18 AAC 34.010 is amended by adding new paragraphs to read:

(22) 21 U.S.C. 343(w) (Misbranded Food, Major Food Allergen Labeling Requirements), as revised as of January 12, 2018;

(23) 21 U.S.C. 381e(1) – (2), as revised as of January 12, 2018;

(24) 21 C.F.R. 73.1 – 73.615 (Listing of Colors Exempt from Certification; Foods), as revised as of April 1, 2018;

(25) 21 C.F.R. 74.101 – 74.706 (Listing of Color Additives Subject Only to Certification; Foods), as revised as of April 1, 2018;

(26) 21 C.F.R. 117.3 – 117.110 (Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; General Provisions, Current Good Manufacturing Practice), as revised as of April 1, 2018, except the definition of “facility” are not adopted by reference; this regulation is adopted by reference as amended from time to time;

- (27) 21 C.F.R. 161.30 – 161.190 (Fish and Shellfish), as revised as of April 1, 2018;
- (28) 21 C.F.R. 170.3 – 170.285 (Food Additives), as revised as of April 1, 2018, except 21 C.F.R. 170.6, 21 C.F.R. 170.15 , and 21 C.F.R. 170.17 are not adopted by reference;
- (29) 21 C.F.R. 173.5 – 173.405 (Secondary Direct Food Additives Permitted in Food for Human Consumption), as revised as of April 1, 2018;
- (30) 21 C.F.R. 175.105 – 175.390 (Indirect Food Additives: Adhesives and Components of Coatings), as revised as of April 1, 2018;
- (31) 21 C.F.R. 176.110 – 176.350 (Indirect Food Additives: Paper and Paperboard Components), as revised as of April 1, 2018;
- (32) 21 C.F.R. 177.1010 – 177.2910 (Indirect Food Additives: Polymers), as revised as of April 1, 2018;
- (33) 21 C.F.R. 178.1005 – 178.3950 (Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers), as revised as of April 1, 2018;
- (34) 21 C.F.R. 180.1 – 180.37 (Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending Additional Study), as revised as of April 1, 2018;
- (35) 21 C.F.R. 181.22 – 181.34 (Prior-Sanctioned Food Ingredients; Specific Prior-Sanctioned Food Ingredients), as revised as of April 1, 2018;
- (36) 21 C.F.R. 182.1 – 182.8997 (Substances Generally Recognized as Safe), as revised as of April 1, 2018;
- (37) 21 C.F.R. 184.1 – 184.1985 (Direct Food Substances Affirmed as Generally Recognized as Safe), as revised as of April 1, 2018;
- (38) 21 C.F.R. 186.1 – 186.1839 (Indirect Food Substances Affirmed as

Generally Recognized as Safe), as revised as of April 1, 2018;

(39) 21 C.F.R. 189.1 – 189.300 (Substances Prohibited from Use in Human Food), as revised as of April 1, 2018. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am 6/28/2001, Register 158; am 8/6/2006, Register 179; am 11/24/2007, Register 184; am ___/___/____, Register ____)

Authority:	AS 17.20.005	AS 17.20.065	AS 17.20.180
	AS 17.20.044	AS 17.20.072	AS 44.46.020

The Editor’s Note for 18 AAC 34.010 is amended to read:

Editor's note: Effective 12/2/99, Register 152, the Department of Environmental Conservation readopted 18 AAC 34.010, to affirm the validity of that section following statutory amendments made in ch. 72, SLA 1998. The department also amended 18 AAC 34.010(16) and (19) and added 18 AAC 34.010(21). Chapter 72, SLA 1998 relocated department authority to adopt regulations in 18 AAC 34 from AS 03.05 to AS 17.20.

[THE DOCUMENTS ADOPTED BY REFERENCE IN 18 AAC 34.010 MAY BE REVIEWED AT THE DEPARTMENT’S ANCHORAGE, JUNEAU, AND KENAI OFFICES. THE SEAFOOD LIST IS AVAILABLE FROM THE SUPERINTENDENT OF DOCUMENTS, U.S. GOVERNMENT PRINTING OFFICE, MAIL STOP: SSOP, WASHINGTON, D.C. 20402-9328.] The *National Shellfish Sanitation Program: Guide for the Control of Molluscan Shellfish*, may be obtained from the United States Department of Health and Human Services, Food and Drug Administration, Office of Seafood, **5001 Campus Drive**, College Park, MD **20740** [20740-3835]; Internet address:

<http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.ht>

m [HTTP://WWW.CFSAN.FDA.GOV/~EAR/NSS2-TOC.HTML AND MAY BE VIEWED IN THE DEPARTMENT'S KETCHIKAN, KODIAK, AND VALDEZ OFFICES, AS WELL AS AT THE DEPARTMENT'S ANCHORAGE, JUNEAU, AND KENAI OFFICES]. The *American National Standard Sampling Procedures and Tables for Inspection by Attributes* is available from the American Society for Quality Control, Quality Press, 600 North Plankinton Avenue, Milwaukee, Wisconsin 53203; telephone: 800-248-1946; Internet address: www.asq.org.

18 AAC 34.035 is repealed and readopted to read:

18 AAC 34.035. Permit requirements. (a) A person may not conduct an activity described in 18 AAC 34.005(b) unless the person has been issued a permit or provisional permit in accordance with this section; a person required to have a permit under this chapter shall apply for a permit at least 60 days before conducting an activity described in 18 AAC 34.005(b).

(b) To apply for a permit, a person shall submit to the department a complete application which demonstrates compliance with this chapter and includes:

- (1) an application form provided by the department;
- (2) each applicable fee required by 18 AAC 34.900;
- (3) a site plan that accurately depicts the location of all processing and storage buildings, roads, alleys, docks, and other areas that are part of the facility and that will be used to support the processing, storage, or transportation of seafood products;
- (4) a facility floor plan that accurately depicts the location or placement of
 - (A) processing equipment; and

- (B) storage areas for seafood, food ingredients, and food packaging materials;
- (5) a plumbing schematic that shows
 - (A) piping used for potable water, nonpotable water, and wastewater;
 - (B) each plumbing fixture, including each floor drain and floor sink, located in a processing area; and
 - (C) toilets and handwash sinks;
- (6) a written description of the surface finish of walls, floors, and ceilings in processing, packaging, and storage areas;
- (7) a written description of how garbage and refuse will be stored, handled, and disposed of;
- (8) documentation showing that required approvals have been granted or permit applications have been submitted to the department for
 - (A) the facility's drinking water supply as required by 18 AAC 80;
 - (B) the facility's wastewater disposal system as required by 18 AAC 72;and
 - (C) the discharge of pollutants into waters of the United States as required by 18 AAC 83;
- (9) a list of ingredients to be used for seafood products that have two or more ingredients;
- (10) a written hazard analysis or hazard analysis critical control point (HACCP) plan, that meets the requirements of 18 AAC 34.045;
- (11) a recall plan that meets the requirements of 18 AAC 34.047;

(12) sanitation standard operating procedures that meet the requirements of 18 AAC 34.050;

(13) for any thermally processed product, a copy of

(A) the food canning establishment registration (FDA form 2541) and the food canning establishment process filing form (FDA form 2541a) submitted to the United States Food and Drug Administration (FDA); and

(B) the scheduled process as set out in 21 C.F.R. 113.83 (Establishing scheduled processes), adopted by reference in 18 AAC 34.010;

(14) for a person who wishes to conduct an activity described in 18 AAC 34.005(b) within a permitted processor's facility, a written statement of consent from the permitted processor authorizing the person to utilize the facility and the agreed upon times or locations that each person will conduct processing activities;

(15) an example label of the seafood products to be produced that meets the requirements of 18 AAC 34.110 and 21 C.F.R. 101.1 – 101.108, adopted by reference in 18 AAC 34.010; and

(16) any other information the department determines is necessary to find the application complete.

(c) To renew a permit, a permittee shall submit to the department a complete renewal application which demonstrates compliance with this chapter and includes

(1) the current year's application form;

(2) each applicable fee required by 18 AAC 34.900; and

(3) any plans and documents listed in (b)(3) – (16) of this section that have changed since the prior year.

(d) After receiving a complete application or complete renewal application, the department will review the application and will

(1) issue a permit;

(2) issue a provisional permit, that will state in writing the reasons for and the terms of the provisional approval; or

(3) issue a notice of denial.

(e) A permit or provisional permit issued under this section

(1) will be assigned a permit number;

(2) must be prominently posted in public view in the facility; a copy of the permit may be used to comply with this paragraph;

(3) is not transferrable; and

(4) expires on December 31 of the year in which the permit is issued, or per the terms of the provisional permit.

(f) A permittee who conducts one of the following activities must submit documentation described in (b) of this section related to the activity, including updated plans or procedures, at least 60 days before the beginning of the activity:

(1) extensively remodeling an existing seafood processing facility; or

(2) adding a new type of operation or process to an existing seafood processing facility.

(g) If the department denies a permit, it will notify the applicant in writing of the reasons for denial. Not later than 30 days after issuance of the notice of denial, the applicant may request an adjudicatory hearing under AS 44.62 (Administrative Procedure Act) by submitting a request to the commissioner. Upon receipt of a timely request for an adjudicatory hearing, the

commissioner will either deny the request or refer the matter to the office of administrative hearings (AS 44.64.010) for a hearing and recommended decision under 2 AAC 64.100 - 2 AAC 64.990 to the commissioner or to the commissioner's designee if the designee is a person other than the person who issued the contested decision. (Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register 152; am 8/6/2006, Register 179; am 11/5/2017, Register 224; am ___/___/___, Register ___)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

18 AAC 34.045(d) is repealed:

(d) Repealed ___/___/____. (Eff. 12/18/97, Register 144; am 12/2/99, Register 152; am ___/___/___, Register ___)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

18 AAC 34 is amended by adding a new section to read:

18 AAC 34.047. Recall plan. (a) A processor shall develop, maintain, and make available for department review, written procedures sufficient to notify consumers of a product recall and remove affected product from commerce. These written procedures must describe the steps to be taken, and assign responsibilities for taking those steps, to perform the following actions as appropriate to the facility:

(1) notify each direct consignee of the recalled seafood, including how to return or dispose of the affected seafood;

- (2) notify the public about the hazard presented by the recalled seafood;
- (3) appropriately dispose of the recalled seafood by reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the seafood; and
- (4) verify, by means such as personal visits, telephone calls, written communications, or a combination thereof, that each consignee received notification of the recall and has taken the appropriate action.

(b) A processor shall notify the department immediately if the processor knows or has reason to believe that a product released into commerce might be adulterated or misbranded.

(c) A processor shall implement the procedures in (a) of this section either at the direction of the department or of their own accord if the processor knows or has reason to believe a product released into commerce might be adulterated or misbranded.

(d) A processor shall maintain records relating to implementation of recall procedures, including notifications to the department, consignees, and the public, and records of the product disposition. (Eff. ___/___/___, Register ___)

Authority:	AS 17.20.005	AS 17.20.072	AS 17.20.250	AS 17.20.270
	AS 17.20.180	AS 17.20.230	AS 17.20.260	AS 44.46.020

The section heading of 18 AAC 34.050 is amended to read:

18 AAC 34.050. Sanitation standard operating procedures [PLAN].

18 AAC 34.050(a) is amended to read:

- (a) [EXCEPT AS PROVIDED IN 18 AAC 34.525 FOR A DIRECT-MARKET FISHING VESSEL OPERATION AND 18 AAC 34.740 FOR A DIRECT-MARKET LAND-

BASED FACILITY, A] **A** processor **subject to this** chapter shall have and **implement** [COMPLY WITH A] **written** sanitation **standard operating procedures** [PLAN] that **meets the requirements of this chapter and 21 C.F.R. 123.3 – 21 C.F.R. 123.28, adopted by reference in 18 AAC 34.010** [DESCRIBES THE SANITATION PROCEDURES TO BE FOLLOWED AT THE FACILITY. THE PLAN MAY BE STRUCTURED TO APPLY TO EACH AREA WITHIN THE FACILITY OR TO EACH TYPE OF OPERATION WITHIN THE FACILITY]. The sanitation **standard operating procedures** [PLAN] must **also** describe how the processor will meet the [SANITATION REQUIREMENTS OF THIS CHAPTER, INCLUDING THE] monitoring **requirements in this chapter** [REQUIRED BY (b) OF THIS SECTION].

18 AAC 34.050(b) is repealed:

(b) Repealed ____/____/____.

18 AAC 34.050(c) is repealed:

(c) Repealed ____/____/____.

18 AAC 34.050(d) is repealed:

(d) Repealed ____/____/____. (Eff. 12/18/97, Register 144; am/readopt 12/2/99,

Register 152; am 8/6/2006, Register 179; am ___/___/___, Register ____)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

18 AAC 34.055 is repealed:

18 AAC 34.055. Facility plan approval. Repealed. (Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register 152; repealed ___/___/___, Register ___)

18 AAC 34.060 is repealed:

18 AAC 34.060. Facility requirements. Repealed. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am 8/6/2006, Register 179; repealed ___/___/___, Register ___)

18 AAC 34.065 is repealed:

18 AAC 34.065. Chemicals and compounds. Repealed. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am 8/6/2006, Register 179; repealed ___/___/___, Register ___)

18 AAC 34.070 is repealed:

18 AAC 34.070. Sanitizing. Repealed. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am 8/6/2006, Register 179; repealed ___/___/___, Register ___)

18 AAC 34.075 is repealed:

18 AAC 34.075. Plumbing. Repealed. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; repealed ___/___/___, Register ___)

18 AAC 34.080 is repealed:

18 AAC 34.080. Water supply and ice. Repealed. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am 8/6/2006, Register 179; am 11/24/2007, Register 184; repealed ___/___/____, Register ____)

18 AAC 34.085 is repealed:

18 AAC 34.085. Toilet and handwash sink requirements. Repealed. (Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register 152; am 8/6/2006, Register 179; repealed ___/___/____, Register ____)

18 AAC 34.090 is repealed:

18 AAC 34.090. Equipment and utensils. Repealed. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; repealed ___/___/____, Register ____)

18 AAC 34.095 is repealed:

18 AAC 34.095. Waste disposal. Repealed. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; repealed ___/___/____, Register ____)

18 AAC 34.100 is repealed:

18 AAC 34.100. Personnel. Repealed. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; repealed ___/___/____, Register ____)

18 AAC 34.105 is repealed:

18 AAC 34.105. Handling. Repealed. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; repealed ___/___/____, Register ____)

18 AAC 34.110 is repealed and readopted to read:

18 AAC 34.110. Labeling requirements. (a) Except as specified at 18 AAC 34.112, a seafood processor shall ensure that seafood products are not misbranded, and that each product label conforms to this section and the following requirements, adopted by reference in 18 AAC 34.010:

- (1) 21 U.S.C. 343(w);
- (2) 21 C.F.R. 101.1 - 101.108;
- (3) 21 C.F.R. 102.5 - 102.57;
- (4) 21 C.F.R. 161.30 – 161.190.

(b) Each master container and retail package of a seafood product must be labeled in letters at least one-eighth inch high and comparable in size and style to other label lettering as follows:

- (1) at the time of packaging, the date of packaging using a mark that is not removable, erasable, or able to be washed away;
- (2) before distribution, the permit number assigned to the processor under 18 AAC 34.035(c); if more than one processor is involved in manufacturing of a seafood product, the permit number must be that of the processor who last handled the product before sealing; or if participating in Salmon Control Plan, the Seafood Products Association number; and
- (3) if a seafood product is not shelf-stable, the holding statement “KEEP

REFRIGERATED” or “KEEP FROZEN”; if the product is a smoked seafood product that is also packaged in a reduced oxygen package or a modified atmosphere package, each container must include the holding statement

- (A) “KEEP REFRIGERATED BELOW 38° F” or “KEEP FROZEN” if the product
 - (i) contains at least 3.5 percent water phase salt;
 - (ii) contains, if allowed by 21 C.F.R. 172.175, adopted by reference in 18 AAC 34.010, both at least 3.0 percent water phase salt and not less than 100 ppm nitrite;
 - (iii) contains other suitable barriers to control *Clostridium botulinum*; or
 - (iv) is equipped with a time temperature indicator; or

(B) “KEEP FROZEN, THAW UNDER REFRIGERATION IMMEDIATELY BEFORE USE” if the product does not meet the requirements of (A) of this paragraph;

(4) the words “PREVIOUSLY FROZEN” if a container holds a seafood product that

- (A) has been previously frozen and thawed; and
- (B) will be sold without further processing;

(5) the words "NOT FOR SALE" if that container holds a seafood product that

(A) is described at 18 AAC 34.830(g) and is being held or processed at a facility subject to this chapter; or

(B) was not processed in compliance with this chapter;

(6) if a seafood product processed or sold in this state contains an ingredient that is

(A) farmed halibut, salmon, or sablefish product, the words “MADE WITH FARMED {HALIBUT, SALMON, OR SABLEFISH} FROM {STATE OR COUNTRY}”; or

(B) genetically modified fish or fish product, the words “MADE WITH GENETICALLY MODIFIED {MARKET NAME OF FISH OR FISH PRODUCT}”; and

(7) if a seafood product was sport-caught and was processed by a custom processor and the custom processor did not process the seafood product to address the hazard of parasites, the custom processor shall label the seafood product with the following statement:

“WARNING! This product has not been treated to kill naturally occurring parasites. Freezing to an internal temperature of 5° Fahrenheit for at least 12 days will kill these parasites.” (Eff.

12/18/97, Register 144; am 12/2/99, Register 152; am 8/6/2006, Register 179; am 11/24/2007, Register 184; am ___/___/____, Register _____)

Authority:	AS 17.20.005	AS 17.20.045	AS 17.20.180
	AS 17.20.010	AS 17.20.065	AS 17.20.290
	AS 17.20.040	AS 17.20.072	AS 44.46.020
	AS 17.20.044		

Editor's note: The Seafood Products Association may be contacted at 1600 S. Jackson Street, Seattle, WA 98144; telephone: (206) 323-3540; e-mail: inquiry@spa-food.org.

The introductory language for 18 AAC 34.112(b) is amended to read:

(b) A seafood product labeled “FOR EXPORT ONLY” may not be sold or offered for sale in domestic commerce and must be labeled on the outside of the container **in English, except as provided in 21 C.F.R. 101.15, adopted by reference in 18 AAC 34.010,** [IN ACCORDANCE WITH 18 AAC 34.110(b) AND] with

18 AAC 34.112(b)(2) is amended to read:

(2) the identity and name of the seafood product as described in **18 AAC 34.110(a)** [18 AAC 34.110(c)(4)];

18 AAC 34.112(b)(3) is amended to read:

(3) the temperature holding statement described in **18 AAC 34.110(b)(3)** [18 AAC 34.100(c)(8)] if applicable; and

(Eff. 12/2/99, Register 152; am 8/6/2006, Register 179; am ___/___/___, Register ___)

Authority:	AS 17.20.005	AS 17.20.045	AS 17.20.230
	AS 17.20.010	AS 17.20.065	AS 17.20.290
	AS 17.20.040	AS 17.20.072	AS 44.46.020
	AS 17.20.044	AS 17.20.180	

18 AAC 34.115 is amended to read:

18 AAC 34.115. Adulterated seafood products. The term "adulterated seafood product" has the meaning given "adulterated food" in AS 17.20.020 and AS 17.20.030. In addition, a seafood product is adulterated if

(1) it is contaminated with oil or another hazardous substance;

(2) it contains a food additive that is unsafe under 21 U.S.C. 348(a), adopted by reference in 18 AAC 34.010, or that is prohibited by the department;

(3) it contains a color additive that is unsafe under 21 U.S.C. 379e(a), adopted by reference in 18 AAC 34.010, or that is prohibited by the department; [OR]

(4) it was accidentally or intentionally subjected to radiation, unless the use of radiation was in conformity with 21 C.F.R. 179.21 - 179.45, adopted by reference in 18 AAC 34.010;

(5) for a food that is exported, it is not in compliance with 21 U.S.C. 381e(1) – (2), adopted by reference in 18 AAC 34.010; or

(6) does not meet the requirements of this chapter. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am ___/___/___, Register ___)

Authority:	AS 17.02.005	AS 17.20.065	AS 17.20.230
	AS 17.20.010	AS 17.20.072	AS 17.20.290
	AS 17.20.020	AS 17.20.180	AS 44.46.020
	AS 17.20.030		

18 AAC 34.120 is amended to read:

18 AAC 34.120. Misbranded seafood products. The term "misbranded seafood product" has the meaning given "misbranded food" in AS 17.20.040 and **AS** 17.20.045. In addition, a seafood product is misbranded if it is not labeled as required by 18 AAC 34.110 or 18 AAC 34.112. (Eff. 12/18 /97, Register 144; am 12/2/99, Register 152; am ___/___/___, Register ___)

Authority:	AS 17.02.005	AS 17.20.045	AS 17.20.180
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AS 17.20.010	AS 17.20.065	AS 17.20.230
AS 17.20.040	AS 17.20.066	AS 17.20.290
AS 17.20.044	AS 17.20.072	AS 44.46.020

18 AAC 34.122 is repealed and readopted to read:

18 AAC 34.122. Seafood product standards. (a) Seafood products that are processed for or placed into domestic commerce for human consumption may not be adulterated as described in 18 AAC 34.115 and must meet the following standards:

(1) for fresh or frozen seafood products other than shellfish:

(A) organoleptic: no contamination or decomposition detected; and

(B) histamine in scombroid fish: less than or equal to 50 ppm;

(2) for refrigerated or frozen ready-to-eat seafood product:

(A) *Listeria monocytogenes*: none detected;

(B) *Salmonella* spp.: none detected;

(C) *Escherichia coli*: less than or equal to 1,000 MPN per gram, or the equivalent;

(D) *Staphylococcus aureus*: less than or equal to 10,000 MPN per gram, or the equivalent; and

(E) organoleptic: no contamination or decomposition detected;

(3) for smoked salmon or sablefish:

(A) sodium nitrite: less than or equal to 200 ppm; and

(B) sodium nitrate: less than or equal to 500 ppm;

(4) for smoked tuna, sodium nitrite: less than or equal to 10 ppm;

(5) for cod roe, potassium nitrate: less than or equal to 200 ppm;

(6) for shelf-stable seafood product,

(A) the product must meet the standards in paragraph (a)(2) of this section;

(B) the product must be capable of being stored at room temperature for extended periods without production of pathogenic or toxigenic microorganisms or product deterioration; and

(C) the product must meet one of the following standards:

(i) the product has been thermally processed;

(ii) the product has a water activity below 0.85 or a water phase salt of 20 percent or greater;

(iii) the product is acidified below a pH of 4.6; or

(iv) the product complies with 21 C.F.R. 172.385, adopted by reference in 18 AAC 34.010, for whole fish protein concentrate;

(7) for shellfish,

(A) either in the shell or shucked, but not eviscerated:

(i) a fecal coliform density less than or equal to 230 MPN per 100 grams; and

(ii) an aerobic or standard plate count of less than or equal to 500,000 bacteria per gram; or

(B) shucked and eviscerated, fresh or frozen:

(i) a fecal coliform density of less than or equal to 100 MPN per 100 grams; and

(ii) an aerobic or standard plate count of less than or equal to 100,000 colony-forming units (CFU) per gram;

(8) for live, fresh, or frozen snails and shellfish, including uneviscerated shellstock:

(A) PSP: less than 80 μg per 100 grams tissue; and

(B) domoic acid: less than 20 ppm;

(9) for live, fresh, cooked, or frozen whole crab product:

(A) PSP: less than 80 μg per 100 grams tissue; and

(B) domoic acid: less than 30 ppm.

(b) A substance, color additive, indirect food additive, or direct food additive may be added to food if the substance, color additive, indirect food additive, or direct food additive is not prohibited, has been approved for use in human food, is used for its intended use, is used at appropriate use rates, and is considered by FDA to be generally recognized as safe under the following requirements, adopted by reference in 18 AAC 34.010:

(1) 21 C.F.R. 73.1 – 73.615;

(2) 21 C.F.R. 74.101 – 74.706;

(3) 21 C.F.R. 170.3 – 170.285;

(4) 21 C.F.R. 172.5 – 172.898;

(5) 21 C.F.R. 173.5 – 173.405;

(6) 21 C.F.R. 175.105 – 175.390;

(7) 21 C.F.R. 176.110 – 176.350;

(8) 21 C.F.R. 177.1010 – 177.2910;

(9) 21 C.F.R. 178.1005 – 178.3950;

- (10) 21 C.F.R. 180.1 – 180.37;
- (11) 21 C.F.R. 181.22 – 181.34;
- (12) 21 C.F.R. 182.1 – 182.8997;
- (13) 21 C.F.R. 184.1 – 184.1985;
- (14) 21 C.F.R. 186.1 – 186.1839; and
- (15) 21 C.F.R. 189.1 – 189.300. (Eff. 12/18/97, Register 144; am/readopt

12/2/99, Register 152; am 8/6/2006, Register 179; am ___/___/____, Register ____)

Authority:	AS 17.02.005	AS 17.20.030	AS 17.20.180
	AS 17.20.010	AS 17.20.065	AS 17.20.290
	AS 17.20.020	AS 17.20.072	AS 44.46.020

18 AAC 34.125(d) is repealed and readopted to read:

(d) A processor producing a refrigerated or frozen ready-to-eat product shall submit to a qualified laboratory twelve random product samples from the first lot produced each calendar year. In addition

(1) the processor shall hold the lot and may release the lot only when results show the product samples meet the standards of 18 AAC 34.122(a)(2)(A) and (B); and

(2) the processor shall immediately notify the department of a result that does not meet the standards of 18 AAC 34. 122(a)(2)(A) and (B).

18 AAC 34.125(e) is repealed:

(e) Repealed ___/___/____.

The introductory language of 18 AAC 34.125(f) is amended to read:

(f) A processor who uses sodium nitrite, sodium nitrate, or potassium nitrate in a seafood product intended for the domestic market shall submit to a qualified laboratory [OR OTHER COMMERCIAL LABORATORY] a sample for testing from the first lot produced in each calendar year. A seafood product containing sodium nitrite, sodium nitrate, or potassium nitrate must meet the applicable standards in 18 AAC 34.122 and the applicable requirements of 21 C.F.R. 172.160, 21 C.F.R. 172.170, or 21 C.F.R. 172.175, adopted by reference in 18 AAC 34.010. [IN ADDITION, IF THE PRODUCT IS A SMOKED OR SMOKE-FLAVORED PRODUCT, IT MUST MEET THE REQUIREMENTS OF 18 AAC 34.310(d). IF A SAMPLE IS SUBMITTED TO A COMMERCIAL LABORATORY THAT IS NOT A QUALIFIED LABORATORY, THE DEPARTMENT WILL NOT ACCEPT THE SAMPLE UNLESS THE COMMERCIAL LABORATORY TESTS THE SAMPLE]

18 AAC 34.125(f)(1) is repealed:

(1) repealed ____/____/____;

18 AAC 34.125(f)(2) is repealed:

(2) repealed ____/____/____.

18 AAC 34.125(g) is amended to read:

(g) Products that are thermally processed by a processor covered under the Salmon Control Plan are exempt from the requirements of (a) [AND (e)] of this section. The processor

shall, upon request from the department, provide copies of the results of laboratory tests conducted under the Salmon Control Plan to show compliance with **18 AAC 34.122(a)(6)** [18 AAC 34.122(6)].

(Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register 152; am 8/6/2006, Register 179; am ___/___/____, Register _____)

Authority:	AS 17.20.005	AS 17.20.072	AS 17.20.200
	AS 17.20.065	AS 17.20.180	AS 44.46.020
	AS 17.20.070		

Editor's note: Effective 12/2/99, Register 152, the Department of Environmental Conservation readopted 18 AAC 34.125, to affirm the validity of that section following statutory amendments made in ch. 72, SLA 1998. The department also amended 18 AAC 34.125(c), (d), and (f), and repealed and readopted 18 AAC 34.125(g). Chapter 72, SLA 1998 relocated department authority to adopt regulations in 18 AAC 34 from AS 03.05 to AS 17.20.

[INFORMATION ABOUT HOW TO REVIEW OR OBTAIN A COPY OF A REQUIREMENT REFERRED TO IN 18 AAC 34.125 AND ADOPTED BY REFERENCE IN 18 AAC 34.010 IS SET OUT IN THE EDITOR'S NOTE TO 18 AAC 34.010.

THE AOAC OFFICIAL METHODS REFERRED TO IN 18 AAC 34.125 MAY BE FOUND IN THE OFFICIAL METHODS OF ANALYSIS OF AOAC INTERNATIONAL, AVAILABLE FROM AOAC INTERNATIONAL, SUITE 500, 481 NORTH FREDERICK AVE., GAITHERSBURG, MARYLAND 20877-2417.]

18 AAC 34.200(a) is amended to read:

(a) A person who harvests, handles, prepares, processes, shucks, packs, repacks, or transports fresh or frozen shellfish for sale as part of commerce intended for human consumption shall meet the requirements of 18 AAC 34.200 - 18 AAC 34.210. In addition, except for a person who is a shellfish harvester, a person described in this section must also meet the requirements of 18 AAC 34.030 - 18 AAC 34.125, **18 AAC 34.803 - 18 AAC 34.855**, and 18 AAC 34.900 - 18 AAC 34.990.

18 AAC 34.200(b) is amended to read:

(b) A person described in (a) of this section, including a person who is a shellfish harvester, shall comply with the standards for fresh or frozen shellfish relating to sanitation, harvesting, handling, shucking, and transporting contained in the *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish*, [AND 21C.F.R. 1240.60, BOTH OF WHICH ARE] adopted by reference in 18 AAC 34.010.

(Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register 152; am ___/___/___, Register ___)

Authority:	AS 17.20.005	AS 17.20.072	AS 44.46.020
	AS 17.20.065	AS 17.20.180	

18 AAC 34.205(b) is amended to read:

(b) Except for a shellfish harvester, a shellfish permit applicant shall meet the requirements of 18 AAC 34.035, **18 AAC 34.045, 18 AAC 34.047, and 18 AAC 34.810** [- 18 AAC 34.060] and pay the permit fee required by 18 AAC 34.900.

(Eff. 12/18/97, Register 144; am 12/2/99, Register 152; am ___/___/___, Register ___)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

18 AAC 34.300 is repealed:

18 AAC 34.300. Applicability of smoked or smoke-flavored seafood product processing requirements. Repealed. (Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register 152; repealed ___/___/____, Register ____)

18 AAC 34.310 is repealed:

18 AAC 34.310. Processing requirements for smoked or smoke-flavored seafood products. Repealed. (Eff. 12/18/97, Register 144; am 12/2/99, Register 152; repealed ___/___/____, Register ____)

18 AAC 34.315 is repealed:

18 AAC 34.315. Native-style smoked or smoke flavored dried salmon. Repealed. (Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register 152; am 8/6/2006, register 179; am 11/24/2007, Register 184; repealed ___/___/____, Register ____)

18 AAC 34.320 is repealed:

18 AAC 34.320. Finished product handling. Repealed. (Eff. 12/18/97, Register 144; am/readopt 12/2/99, repealed ___/___/____, Register ____)

The table of contents of Article 4 is amended to read:

Article 4. Thermal and Acidified Food Processing.

The section heading of 18 AAC 34.400 is amended to read:

18 AAC 34.400. Thermal and acidified food processing.

18 AAC 34.400(a) is amended to read:

(a) A person who [THERMALLY] processes seafood products intended for human consumption,

(1) if the seafood product is thermally processed, must meet the requirements of [THIS SECTION AND THE REQUIREMENTS OF] 21 C.F.R. 108.35 and 21 C.F.R. 113.3 - 113.100, adopted by reference in 18 AAC 34.010, in addition to the requirements of 18 AAC 34.030 - 18 AAC 34.125, [18 AAC 34.200 - 18 AAC 34.215,] 18 AAC 34.300 - 18 AAC 34.320, **18 AAC 34.803 - 18 AAC 34.855,** and 18 AAC 34.900 - 18 AAC 34.990;

(2) if the seafood product is acidified, must meet the requirements of 21 C.F.R. 108.25, 21 C.F.R. 113.3 - 113.100, and 21 C.F.R. 114.3 – 100, adopted by reference in 18 AAC 34.010, in addition to the requirements of 18 AAC 34.030 - 18 AAC 34.125, 18 AAC 34.300 - 18 AAC 34.320, 18 AAC 34.803 - 18 AAC 34.855 and 18 AAC 34.900 - 18 AAC 34.990.

18 AAC 34.400(b) is repealed:

(b) Repealed ____/____/____.

18 AAC 34.400(c) is repealed:

(c) Repealed ____/____/____. (Eff. 12/18/97, Register 144; readopt 12/2/99,

Register 152; am ____/____/____, Register ____)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

18 AAC 34.500(a) is amended to read:

(a) A person who operates a direct-market fishing vessel to process seafood products for sale as part of commerce intended for human consumption shall meet the requirements of 18 AAC 34.500 - 18 AAC 34.525. In addition, an operator of a direct-market fishing vessel must meet the requirements of 18 AAC 34.030 [, 18 AAC 34.035(a)(1), (3), (5), and (6), 18 AAC 34.035(c) - (g), 18 AAC 34.045, 18 AAC 34.055, 18 AAC 34.060(1)(A), (B), (D), and (E), 18 AAC 34.060(2) - (3), 18 AAC 34.060(4)(A), (B), and (D), 18 AAC 34.060(5), 18 AAC 34.065 - 18 AAC 34.075, 18 AAC 34.090] - 18 AAC 34.122, 18 AAC 34.125(a), (c), and (h), **18 AAC 34.803 - 18 AAC 34.810, 18 AAC 34.820(a) - (c), (g), (h), (i), and (l), 18 AAC 34.825 - 18 AAC 34.855,** and 18 AAC 34.900 - 18 AAC 34.990.

(Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register 152; am ____/____/____, Register ____)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

Editor's note: Effective 12/2/99, Register 152, the Department of Environmental Conservation readopted 18 AAC 34.500, to affirm the validity of that section following statutory amendments made in ch. 72, SLA 1998. The department also amended 18 AAC 34.500(a) and

added new subsection (d). Chapter 72, SLA 1998 relocated department authority to adopt regulations in 18 AAC 34 from AS 03.05 to AS 17.20.

The International Pacific Halibut Commission may have other restrictions on processing halibut. Information on those restrictions may be obtained by contacting the International Pacific Halibut Commission, **2320 West Commodore Way** [P.O. BOX 95009], Seattle, Washington **98199-1287** [98145-2009]; **telephone: (206) 634-1838; Internet address: www.iphc.int.**

18 AAC 34.520(e) is amended to read:

(e) Ice used on a direct-market fishing vessel must comply with **18 AAC 34.830(b)** [18 AAC 34.080(g)].

18 AAC 34.520(f)(1) is amended to read:

(1) each food-contact surface is cleaned and sanitized as specified in **18 AAC 34.815** [18 AAC 34.070]; and
(Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am 8/6/2006, register 179; am ___/___/___, Register ___)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

18 AAC 34.525 is repealed:

18 AAC 34.525. Cleaning and sanitizing. Repealed. (Eff. 12/18/97, Register 144; am 12/2/99, Register 152; repealed ___/___/___, Register ___)

18 AAC 34.600 is amended to read:

18 AAC 34.600. Applicability. (a) The requirements of 18 AAC 34.600 – 625 are in addition to all other applicable requirements of this chapter. [, AND APPLY,]

(b) The requirements of 18 AAC 34.602 apply

(1) where there is a visible oily sheen on the water; and

(2) to

(A) fishing vessels;

(B) tender vessels;

(C) buying stations; and

(D) processing facilities.

(c) The requirements of 18 AAC 34.605 – 625 apply

(1) if the department finds that an oil spill threatens to contaminate a body of water where seafood that is intended to be sold as part of commerce and intended for human consumption is caught; and

(2) to

(A) fishing vessels or tender vessels involved in the response to and cleanup of the oil spill;

(B) fishing vessels, tender vessels, buying stations, processing facilities, and processors who handle, transport, prepare, store, or process seafood caught in the water affected by the threatened oil spill contamination; and

(C) any other fishing vessel or tender vessel operating in a body of water that the department has found to be threatened. (Eff. 12/18/97, Register 144;

readopt 12/2/99, Register 152; am 8/6/2006, Register 179; am ___/___/___, Register ___)

Authority:	AS 17.20.005	AS 17.20.065	AS 17.20.180
	AS 17.20.020	AS 17.20.072	AS 44.46.020

18 AAC 34 is amended by adding a new section to read:

18 AAC 34.602. Prohibition on taking on water with visible oily sheen. In an area where there is a visible oily sheen on the water, an operator of a fishing vessel or a tender vessel, or a processor, may not take on sea water for

- (1) fluming, pumping, unloading, or chilling seafood;
- (2) holding live seafood products; or
- (3) cleanup purposes. (Eff. ___/___/____, Register ____)

Authority:	AS 17.20.005	AS 17.20.072	AS 44.46.020
	AS 17.20.065	AS 17.20.180	

18 AAC 34.605(b)(1) is amended to read:

(1) oil contamination is removed from any surface that might contact seafood, using only chemicals described in **18 AAC 34.815** [18 AAC 34.065]; and (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am 8/6/2006, Register 179; am ___/___/____, Register ____)

Authority:	AS 17.20.005	AS 17.20.070	AS 17.20.200
	AS 17.20.020	AS 17.20.072	AS 44.46.020
	AS 17.20.065	AS 17.20.180	

18 AAC 34.700(a)(1) is amended to read:

(1) shall meet the requirements of 18 AAC 34.700 - **18 AAC 34.730**

[18 AAC 34.740].

18 AAC 34.700(a)(2) is amended to read:

(2) except as specified in 18 AAC 34.700 - **18 AAC 34.730** [18 AAC 34.740], shall meet the requirements of 18 AAC 34.005, 18 AAC 34.010, 18 AAC 34.030 - [, 18 AAC 34.035(a)(1), (3)(A) and (B), and (6) - (8), 18 AAC 34.035(c) - (g), 18 AAC 34.045, 18 AAC 34.050, 18 AAC 34.055, 18 AAC 34.060(1)(A) - (E), 18 AAC 34.060(2) - (3), 18 AAC 34.060(4)(A)-(D), 18 AAC 34.060(5) - (7), 18 AAC 34.065 - 18 AAC 34.075, 18 AAC 34.080, 18 AAC 34.085, 18 AAC 34.090] 18 AAC 34.122, 18 AAC 34.125(a), (c), and (h), **18 AAC 34.803 - 18 AAC 34.805, 18 AAC 34.820(a) - (c), (e) - (g), (i), and (l), 18 AAC 34.825 - 18 AAC 34.835,** and 18 AAC 34.900 - 18 AAC 34.990.

18 AAC 34.700(c) is repealed:

(c) Repealed ____/____/____. (Eff. 8/6/2006, Register 179; am ____/____/____,

Register ____)

Authority:	AS 17.20.005	AS 17.20.072	AS 44.46.020
	AS 17.20.065	AS 17.20.180	

18 AAC 34.720(d)(1) is amended to read:

(1) each food-contact surface is cleaned and sanitized as specified in **18 AAC 34.815** [18 AAC 34.070]; and

18 AAC 34.720(f) is amended to read:

(f) Ice used in a direct-market land-based facility must comply with **18 AAC 34.830(b)**

[18 AAC 34.080(g)]. (Eff. 8/6/2006, Register 179; am ___/___/____, Register ____)

Authority:	AS 17.20.005	AS 17.20.072	AS 44.46.020
	AS 17.20.065	AS 17.20.180	

18 AAC 34.730 is amended to read:

18 AAC 34.730. Toilet and handwash sink requirements. If a direct-market land-based facility operator installs a portable toilet or privy in accordance with **18 AAC 34.820(g)** [18 AAC 34.085(d)], the operator shall monitor the use of the handwash sink located at the entrance to the processing area to ensure that employees are washing hands after exiting the toilet facility. (Eff. 8/6/2006, Register 179; am ___/___/____, Register ____)

Authority:	AS 17.20.005	AS 17.20.072	AS 44.46.020
	AS 17.20.065	AS 17.20.180	

18 AAC 34.740 is repealed:

18 AAC 34.740. Cleaning and sanitizing. Repealed. (Eff. 8/6/2006, Register 179; repealed ___/___/____, Register ____)

18 AAC 34 is amended by adding new sections to read:

Article 8. Good Manufacturing Practice.

18 AAC 34.803. Qualifications and training. A processor shall ensure each individual who processes seafood is qualified to perform their duties as required in 21 C.F.R. 117.4, adopted by reference in 18 AAC 34.010. Records that document training must be retained and made available as required in in 21 C.F.R. 117.301, adopted by reference in 18 AAC 34.010, and 18 AAC 34.920. (Eff. ___/___/____, Register ____)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

Editor's note: The subject matter addressed in 18 AAC 34.803 was formerly addressed in 18 AAC 34.100. The history for 18 AAC 34.803 does not include the history of the earlier section.

18 AAC 34.805. Personnel; disease control and hygienic practices. A processor shall ensure adequate disease control and hygienic practices to protect against allergen cross-contact and contamination of food through instruction, training, and supervision of employees as required in 21 C.F.R. 117.10, adopted by reference in 18 AAC 34.010. (Eff. ___/___/____, Register ____)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

Editor's note: The subject matter addressed in 18 AAC 34.805 was formerly addressed in 18 AAC 34.100. The history for 18 AAC 34.805 does not include the history of the earlier section.

18 AAC 34.810. Plant and grounds. (a) A processor shall ensure that each facility and the grounds about the facility under the control of the processor are designed and constructed in a manner that facilitates sanitary operations and protects food from contamination as required at 21 C.F.R. 117.20, adopted by reference in 18 AAC 34.010, and other requirements of this section.

(b) The outside walls and the roof

(1) if made of a flexible material such as rubberized nylon, polypropylene, polyester-based vinyl, or nylon-based vinyl, must be at least 20 mils thick, with the seams heat-welded; and

(2) must protect the facility from weather and the entry of insects, rodents, and other animals.

(c) The facility must have lighting of at least

(1) 50 footcandles, measured at the work surface, in areas where

(A) seafood products, food ingredients, or additives are inspected, sorted, graded, or processed; and

(B) processing equipment control panels and food packaging materials, including tin stock, jars, and retort pouches, are tested or examined; and

(2) 20 footcandles, evenly distributed to all other areas not described in (1) of this paragraph, including product holding, food packaging, food storage, and container cooling areas.

(d) The inside walls in

(1) any area that will likely be splashed with water or other processing wastes during processing and cleaning must be made of a solid material that is nonabsorbent, durable, smooth, easily cleanable, and sealed to the floor; if the material is less than the full height of the

wall, the top of the material must be sealed to the wall;

(2) food processing areas, built-in refrigerators, and freezers used in the processing of seafood products must be made of tile, sealed or noncorrosive metal, fiberglass, glass panels, or another nonabsorbent, durable, smooth, and easily cleanable material designed for its intended use;

(3) storage freezers and ingredient storage areas must be easily cleanable and may be made of wood if the wood is sealed with a visible sealant; and

(4) dry storage areas must be easily cleanable and may be made of unsealed wood if the walls are cleaned without using water or another cleaning liquid.

(e) Floors in

(1) processing areas where large amounts of water are used must be durable, smooth, and easily cleanable, must be made of concrete, sealed or noncorrosive metal, fiberglass, or another suitable material approved by the department and must be adequately sloped to floor drains;

(2) refrigerator and freezer areas that are subject to dripping from condensation must be durable, smooth, and easily cleanable, and must be made of concrete, sealed or noncorrosive metal, fiberglass, or another suitable material approved by the department; and

(3) warehouse and storage rooms used for dry storage must be made of a material that is easily cleanable; floors may be made of unsealed wood if cleaning methods do not require the use of water or another liquid.

(f) Floor drains are required in areas where

(1) refrigeration or freezer pipes produce condensate that accumulates;

(2) normal operations release or discharge water or other liquid waste onto the

floor; and

(3) wastewater could contaminate a processing area. (Eff. ___/___/___,

Register _____)

Authority:	AS 17.20.005	AS 17.20.072	AS 44.46.020
	AS 17.20.065	AS 17.20.180	

Editor's note: The subject matter addressed in 18 AAC 34.810 was formerly addressed in 18 AAC 34.060. The history for 18 AAC 34.810 does not include the history of the earlier section.

18 AAC 34.815. Sanitary operations. (a) A processor shall ensure that each facility meets the requirements of 21 C.F.R. 117.35, adopted by reference in 18 AAC 34.010, and other requirements of this section.

(b) Pesticides must be used according to 18 AAC 90.

(c) When a chemical or compound is used for sanitizing, the processor shall verify the concentration is correct with a test kit, test strip, or other device. (Eff. ___/___/___, Register _____)

Authority:	AS 17.20.005	AS 17.20.072	AS 44.46.020
	AS 17.20.065	AS 17.20.180	

Editor's note: The subject matter addressed in 18 AAC 34.815 was formerly addressed in 18 AAC 34.065 and 18 AAC 34.070. The history for 18 AAC 34.810 does not include the history of the earlier sections.

18 AAC 34.820. Sanitary facilities and controls; plumbing, water supply, toilets and handwash sink requirements, and waste disposal. (a) A processor must ensure that each facility is equipped with sanitary facilities and accommodations as required in 21 C.F.R 117.37, adopted by reference in 18 AAC 34.010, and other requirements of this section.

(b) Notwithstanding the applicability limitations of the state plumbing code, plumbing must be installed and operated in accordance with the state plumbing code under AS 18.60.705. Except for the toilet and sink requirements in (i) of this section, the state plumbing code applies statewide to all facilities subject to this chapter, including mobile processing vessels.

(c) Water provided by a processing facility for drinking or ice making for human consumption must comply with 18 AAC 80.

(d) A processing water supply must be approved by the department, on the basis of whether public health and consumers are adequately protected; in addition to complying with (c) of this section, for a processing water supply that is not directly plumbed to a community public water system or a non-transient non-community public water system, a processor

(1) must disinfect to maintain a measureable residual of free chlorine or another disinfectant approved by the department;

(2) must sample for coliform bacteria contamination before beginning operations and once every 30 days during the operational season, and must resample

(A) as required in 18 AAC 80.415, or as required by the department to serve the interests of public health and consumer protection, after notification of a sample result that exceeds the maximum contaminant level for total coliform bacteria set out in 18 AAC 80.300(b)(5); however, resampling requires no more than two water samples; or

(B) if a sample is invalidated as set out in 18 AAC 80.425; however,

resampling requires no more than one water sample;

(3) must ensure that the water does not exceed the maximum contaminant level for total coliform bacteria set out in 18 AAC 80.300(b)(5);

(4) must sample for a contaminant listed in 18 AAC 80.300(b) at the applicable frequency set out in 18 AAC 80.310 – 18 AAC 80.335, if the department identifies a potential public health problem for inorganic or organic chemical contamination; the department will require more frequent sampling if the department determines it is necessary to serve the interests of public health and consumer protection; if required under this subsection, samples may not exceed the maximum contaminant levels set out in 18 AAC 80.300; and

(5) must sample at a point at the end of the system and tested for disinfectant residual at least once each day during the operating season; a daily log of the disinfectant residuals must be kept as required by 18 AAC 34.920.

(e) Water supplies used to deliver, chill, or hold live or unprocessed seafood must not contribute to contamination or adulteration of the seafood products and must not have a fecal coliform density of more than 14 colony-forming units (CFU) per 100 ml. These water supplies are exempt from the disinfection requirement of (d) of this section if the water is used at a location that will not allow other seafood products, food ingredients, food-contact surfaces, or food packaging materials to come into contact with the water.

(f) Water tests required under this chapter must be performed by a laboratory certified under 18 AAC 80.1100 – 18 AAC 80.1110 for drinking water analysis and compliant with reporting requirements for positive sample results described at 18 AAC 80.355. Laboratory results of water analysis, including resampling results or notices indicating that samples were too long in transit, must be maintained at the facility as required by 18 AAC 34.920.

- (g) The department will allow a land-based facility to have portable toilets or privies if
- (1) due to lack of soil, the existence of permanently frozen ground, or other geological conditions, the land-based facility is unable to install a septic system;
 - (2) the department finds that public health is protected;
 - (3) each portable toilet and privy meets the applicable requirements of 18 AAC 72;
 - (4) each portable toilet and privy is conveniently located for employee use;
 - (5) each portable toilet and privy is maintained in a sanitary manner and toilet tissue is provided;
 - (6) a handwash sink, soap, and towels are located at the entrance to the processing area; and
 - (7) handwash signs directing employees to wash their hands with soap or detergent before returning to their work stations are posted at each portable toilet or privy and at the entrance to the processing area; the signs must be printed in English and in other languages or pictures if necessary for employee understanding.
- (h) The number of toilets on a mobile processing vessel must comply with the Occupational Safety and Health Administration's general environmental controls in 29 C.F.R. 1910.141(c)(1)(i) and Table J-1, adopted by reference in 18 AAC 34.010.
- (i) Handwash sinks must be provided and
- (1) located to allow convenient use by employees in food processing areas and in, or immediately adjacent to, toilet rooms;
 - (2) accessible at all times for employee use;
 - (3) not used for purposes other than handwashing;

(4) equipped to provide water at a temperature that is comfortable to encourage and allow for employees to wash their hands thoroughly;

(5) have hand-cleaning soap or detergent at each sink; and

(6) if self-closing, slow-closing, or a metering faucet, shall provide a flow of water for at least 20 seconds without the need to reactivate the faucet.

(j) For sewage disposal from a mobile processing vessel, only a type II or type III marine sanitation device may be used. If used, marine sanitation devices must be of an adequate size for numbers of employees and must be operated in accordance with the manufacturer’s specifications and United States Coast Guard requirements.

(k) Untreated sewage from a marine sanitation device may not be discharged during processing, facility cleaning, or when within one-half mile of another vessel that can reasonably be expected to be processing or cleaning. A record of the date, time, and location of each discharge from type III marine sanitation device must be kept as required by 18 AAC 34.920.

(l) Processing waste from seafood products must be disposed of as required by 18 AAC 60 for solid waste, 18 AAC 72 for domestic wastewater, or 18 AAC 83 for wastewater.

(Eff. ___/___/___, Register ___)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020

AS 17.20.065 AS 17.20.180

Editor’s note: The subject matter addressed in 18 AAC 34.820 was formerly addressed in 18 AAC 34.070, 18 AAC 34.075, 18 AAC 34.080, 18 AAC 34.085, and 18 AAC 34.095. The history for 18 AAC 34.820 does not include the history of the earlier sections.

18 AAC 34.825. Equipment and utensils. A processor shall ensure that all equipment and utensils are adequate for the intended use and designed, installed, and maintained to facilitate cleaning and preclude adulteration of the seafood products or ingredients as required in 21 C.F.R. 117.40, adopted by reference in 18 AAC 34.010. (Eff. ___/___/___, Register ___)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

Editor's note: The subject matter addressed in 18 AAC 34.825 was formerly addressed in 18 AAC 34.090. The history for 18 AAC 34.825 does not include the history of the earlier section.

18 AAC 34.830. Processes and controls; handling; and ice supply. (a) A processor shall ensure that all operations in the manufacturing, processing, packing, and holding of seafood products are conducted in accordance with adequate sanitation principles as required in 21 C.F.R. 117.80, adopted by reference in 18 AAC 34.010, and other requirements of this section.

(b) Ice that comes into contact with seafood products must be made by the seafood processor from water that meets the requirements of 18 AAC 34.820(d) or obtained from an establishment permitted under 18 AAC 31 or this chapter to manufacture ice and handled in a sanitary manner.

(c) Vessels or vehicles, including tenders, used to transport raw seafood products must provide adequate ice or other temperature control and adequate protection against bird droppings and sun when holding or transporting seafood products.

(d) Pitching or puncturing raw seafood product using a long-handled implement is

prohibited. Hand gaff hooks are allowed if used only in a portion of the seafood product that will be discarded as waste by the processor or will not otherwise be used for human consumption.

(e) The processor shall record the condition, including quality, of incoming seafood products.

(f) Except for a direct-market fishing vessel or direct-market land-based facility, a processor shall, upon receipt and before additional processing or packaging, inspect and adequately rinse seafood products with a water supply that meets the requirements of 18 AAC 34.820(c) or (d), including those butchered or filleted in another permitted facility.

(g) A processor shall identify, by label or otherwise, and segregate seafood caught while sport fishing, subsistence fishing, or personal use fishing from commercially-caught seafood during all aspects of processing.

(h) A processor shall hold seafood products upon receipt at a temperature of not more than 45° Fahrenheit until processing of the seafood product begins. (Eff. ___/___/___, Register ___)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

Editor's note: The subject matter addressed in 18 AAC 34.830 was formerly addressed in 18 AAC 34.080 and 18 AAC 34.105. The history for 18 AAC 34.830 does not include the history of the earlier sections.

18 AAC 34.835. Storage and transportation. A processor shall ensure the proper storage and transportation of food as described in 21 C.F.R. 117. 93, adopted by reference in 18 AAC 34.010. (Eff. ___/___/___, Register ____)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

18 AAC 34.840. Holding and distribution of human food by-products for use as animal food. A processor shall ensure that human food by-products for use as animal food are stored, identified, and labeled as described in 21 C.F.R. 117. 95, adopted by reference in 18 AAC 34.010. (Eff. ___/___/___, Register ____)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

18 AAC 34.855. Defect action levels. A processor shall utilize quality control operations to reduce natural or unavoidable defects in seafood products as described in 21 C.F.R. 117.110, adopted by reference in 18 AAC 34.010. (Eff. ___/___/___, Register ____)

Authority: AS 17.20.005 AS 17.20.072 AS 44.46.020
AS 17.20.065 AS 17.20.180

The title of Article 9 is amended to read:

Article 9. General Provisions, Compliance Procedures, and Fees.

18 AAC 34.900(d) is repealed:

(d) Repealed ____/____/____.

18 AAC 34.900(e)(1)(B) is amended to read:

(B) numerous violations **that indicate a general disregard for sanitation, product safety, or wholesomeness** [INDICATED BY A LOW INSPECTION SCORE];

(Eff. 12/18/97, Register 144; am 12/2/99, Register 152; am 6/28/2001, Register 158; am 12/23/2005, Register 176; am 8/6/2006, Register 179; am 11/24/2007, Register 184; am ____/____/____, Register ____)

Authority:	AS 17.20.005	AS 17.20.072	AS 44.46.020
	AS 17.20.065	AS 17.20.180	AS 44.46.025
	AS 17.20.070		

The section heading for 18 AAC 34.920 is amended to read:

18 AAC 34.920. Records availability and retention.

18 AAC 34.920(a)(3) is amended to read:

(3) incoming seafood product records as required by **18 AAC 34.830**
[18 AAC 34.105(a)];

18 AAC 34.920(a)(4) is amended to read:

(4) drinking and processing water disinfectant records and laboratory results required by **18 AAC 34.820** [18 AAC 34.080];

18 AAC 34.920(a)(5) is amended to read:

(5) laboratory results required by **18 AAC 34.125(d) and (f)** [18 AAC 34.125(d)-(f)];

18 AAC 34.920(a)(6) is repealed:

(6) repealed ____/____/____;

18 AAC 34.920(a)(8) is amended to read:

(8) direct-market vessel water disinfectant records as specified in 18 AAC 34.520 [AND CLEANING AND SANITIZING RECORDS REQUIRED BY 18 AAC 34.525];

18 AAC 34.920(a)(9) is amended to read:

(9) records required by **18 AAC 34.820(k)** [18 AAC 34.095] regarding the discharges from a type III marine sanitation device;

18 AAC 34.920(a)(11) is amended to read:

(11) raw seafood receiving reports required by 18 AAC 34.625; [AND]

18 AAC 34.920(a)(12) is amended to read:

(12) records developed under a plan of operation that was in effect before December 18, 1997; [.]

18 AAC 34.920(a) is amended by adding new paragraphs to read:

(13) records required by 18 AAC 34.047 regarding recall procedures; and

(14) records required by 18 AAC 34.803 regarding qualifications and training.

(Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am 6/28/2001, Register 158; am 12/23/2005, Register 176; am 8/6/2006, Register 179; am ___/___/____, Register ____)

Authority:	AS 17.20.005	AS 17.20.072	AS 17.20.200
	AS 17.20.065	AS 17.20.180	AS 44.46.020
	AS 17.20.070		

18 AAC 34.930(b) is amended to read:

(b) A processor shall allow a department employee or the department's agent to inspect all portions of the facility, seafood products, food ingredients, processing equipment, labels, plans and records **required to be retained and available under this chapter** [RELATING TO CRITICAL CONTROL POINTS AND SANITATION, AND ALL OTHER RECORDS NEEDED TO DETERMINE COMPLIANCE WITH THIS CHAPTER]. **The inspector may collect samples for analytical testing of food products, of packaging, and from food-contact surfaces. A processor may not charge the department more than the average wholesale market price for a sample.**

18 AAC 34.930(f) is repealed.

(f) Repealed ___/___/____.

18 AAC 34.935 is repealed:

18 AAC 34.935. Inspection seal. Repealed. (Eff. 12/18/97, Register 144; am 12/2/99, Register 152; repealed ___/___/____, Register ____)

18 AAC 34.940(c) is amended to read:

(c) [IN ITS DISCRETION THE,] **The** department **may** [WILL]

(1) require that the processor provide the department with product for testing under 18 AAC 34.125, subject to the fees required by 18 AAC 34.905;

(2) require that the processor provide the department with copies of

(A) the HACCP plan; [,]

(B) the sanitation standard operating procedures; [PLAN,]

(C) the recall plan; and

(D) any other records the department considers necessary in evaluating compliance with this chapter;

(3) detain as described in (e) of this section any potentially violative seafood product, food ingredient, or packaging material; [OR]

(4) require a stoppage of processing and immediate correction of a critical violation; **or**

(5) require other actions that the department considers necessary to protect public health and consumers.

18 AAC 34.940(d) is repealed and readopted to read:

(d) Except where the department determines that the nature of the corrective action needed may require additional time for correction and the public's health is protected, a processor shall correct violations as follows:

(1) for a critical violation, at the time of inspection;

(2) for all other violations, 30 days from the date of inspection or the date that the processor is provided notice of the violation, whichever is later. (Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register 152; am 8/6/2006, Register 179; am 11/5/2017, Register 224; am ___/___/____, Register ____)

Authority:	AS 17.20.005	AS 17.20.180	AS 17.20.260
	AS 17.20.065	AS 17.20.200	AS 17.20.270
	AS 17.20.070	AS 17.20.230	AS 17.20.280
	AS 17.20.072	AS 17.20.240	AS 17.20.305
	AS 17.20.172	AS 17.20.250	AS 44.46.020

18 AAC 34.960 is repealed:

18 AAC 34.960. Seafood processing facility recognition program. Repealed. (Eff. 12/2/99, Register 152; repealed ___/___/____, Register ____)

18 AAC 34.990(1) is amended to read:

(1) "adequate" **has the meaning as given in 21 C.F.R. 117.3, adopted by reference in 18 AAC 34.010** [MEANS THAT WHICH IS NECESSARY TO ACCOMPLISH THE INTENDED PURPOSE, IN KEEPING WITH GOOD PUBLIC HEALTH PRACTICES, WHILE COMPLYING WITH THIS CHAPTER];

18 AAC 34.990(24) is amended to read:

(24) “facility” means the **physical infrastructure, its contents, and the contiguous land or property** [PREMISES], including all or portions of land, docks, structures, vessels, storage plants, **water supply, wastewater system, plumbing,** and equipment, whether mobile or land-based, used to prepare or process seafood products for human consumption;

18 AAC 34.990(26) is amended to read:

(26) “food” **has the meaning given in AS 17.20.370(11)** [MEANS A LIQUID OR SOLID SUBSTANCE CONSUMED BY HUMANS], including water or another beverage, a confection, condiment, food ingredient, food additive, [OR] ice, or a substance that enter into the composition of these things, whether simple, blended, mixed, or compounded;

18 AAC 34.990(31) is amended to read:

(31) “hazard” **has the meaning given in 21 C.F.R. 117.3** [MEANS A BIOLOGICAL, CHEMICAL, OR PHYSICAL PROPERTY THAT MIGHT MAKE FOOD UNSAFE FOR HUMAN CONSUMPTION];

18 AAC 34.990(51) is amended to read:

(51) “processor” means **the owner, operator, or agent in charge of a seafood processing facility who is** [A PERSON WHO PROCESSES OR IS] responsible for processing seafood intended for human consumption; [“PROCESSOR’ INCLUDES THAT PERSON’S REPRESENTATIVE;]

18 AAC 34.990(53) is amended to read:

(53) “qualified laboratory” means **a state, federal, or commercial laboratory that adheres to and operates under a documented quality management system that includes proficiency testing and has an accreditation or certification from a third party attesting to the technical competence within the laboratory to perform requested test, method, technology, matrix, or analyte combinations** [THE STATE FOOD SAFETY LABORATORY OR AN FDA LABORATORY, AND, IN ADDITION, IF THE SEAFOOD PRODUCT IS BEING THERMALLY PROCESSED A LABORATORY OPERATED BY THE NATIONAL FOOD PROCESSORS ASSOCIATION];

18 AAC 34.990(54) is amended to read:

(54) “ready-to-eat” **has the meaning given in 21 C.F.R. 117.3** [MEANS A FOOD THAT IS IN A FORM THAT IS EDIBLE WITHOUT COOKING OR ADDITIONAL PREPARATION AND THAT IS REASONABLY EXPECTED TO BE CONSUMED IN THAT FORM];

18 AAC 34.990(57) is amended to read:

(57) “sanitize” **has the meaning given in 21 C.F.R. 117.3** [A PROCESS THAT IS EFFECTIVE IN REDUCING THE NUMBER OF MICROORGANISMS PRESENT, DOES NOT ADVERSELY AFFECT A SEAFOOD PRODUCT, AND IS SAFE FOR THE CONSUMER];

18 AAC 34.990(58) is amended to read:

(58) “seafood” means any species of aquatic organism, including salt water fish, freshwater fish, amphibians, crustaceans, **and mollusks** [MOLLUSIS, AND AQUATIC PLANTS]; “seafood” includes any part or **by-product** [BY PRODUCT] of any species of aquatic organism;

18 AAC 34.990(76) is amended to read:

(76) ”water activity” **has the meaning given in 21 C.F.R. 117.3** [MEANS THE MEASURE OF THE AMOUNT OF WATER IN FOOD THAT IS AVAILABLE FOR THE GROWTH OF MICROORGANISMS, INCLUDING PATHOGENS, AS DETERMINED BY A RATIO OF THE VAPOR PRESSURE OF THE FOOD, DIVIDED BY THE VAPOR PRESSURE OF PURE WATER];

18 AAC 34.990 is amended to add a new paragraph to read:

(87) “food-contact surface” has the meaning given in 21 C.F.R. 117.3. (Eff. 12/18/97, Register 144; am/readopt 12/2/99, Register 152; am 8/6/2006, Register 179; am 11/24/2007, Register 184; am ___/___/____, Register ____)

Authority:	AS 17.20.005	AS 17.20.065	AS 17.20.250
	AS 17.20.010	AS 17.20.066	AS 17.20.260
	AS 17.20.020	AS 17.20.070	AS 17.20.270
	AS 17.20.030	AS 17.20.072	AS 17.20.280
	AS 17.20.040	AS 17.20.180	AS 17.20.290
	AS 17.20.044	AS 17.20.200	AS 17.20.305

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AS 17.20.045

AS 17.20.230

AS 17.20.340

AS 17.20.050

AS 17.20.240

AS 17.20.370

AS 44.46.020