Technical Committee Meeting
Agenda
October 31, 2013

1. Call to Order – Jeff Backlund, Chair

2. Introductions - Recognize Chair, Vice-chair and Members

3. Adoption of Agenda

4. Antitrust Policy

5. Regulatory Issues
   a. FSMA
      i. Comments - Preventive Controls, Foreign Supplier Verification, 3rd Party Certification
   b. ADEC
      i. Proposed changes to 18 AAC 34
      ii. Water Quality Criteria

6. Technical Issues
   a. Non-Commercially Sterile - RTE Foods
      i. Scope
      ii. Task Force Activity
         1. Risk Assessment
         2. Terminal Process
         3. Priorities and Timeline
   b. Ikura Nutrition Facts

7. BRC - Issue 7 timeline; Unannounced audits

8. EU Labeling comments

9. FDA SeaDO Update

10. Next Meeting Date and Topics

11. Adjourn
Seafood Products Association
Basic Principles of Antitrust

The Seafood Products Association (SPA) fully subscribes to the letter and spirit of the federal antitrust laws and to the principals of free and open competition upon which these laws are based. SPA is committed to the proposition that all SPA meetings and other activities are held in such a way as to assure strict compliance with requirements and prohibitions of the antitrust laws, and to avoid even the appearance of any Association activity that might raise a question under the antitrust law.

Prohibited Topics for Discussion
SPA will not knowingly tolerate any discussion among members at any Association meeting of selling prices, discounts, freight allowances, terms of warranties, other terms of sale or acquisition costs, apart from discussions concerning governmental programs relating directly to those areas. Other topics of discussion that are not permitted at meetings include: sales or production quotas, sales territories, allocation of customers or products, boycotts, refusals to deal, market sales or reciprocal dealing. Meetings will be conducted in accordance to a published agenda. Changes to the agenda may be made by agreement of the committee members present.

Review by Counsel
All directions given or actions taken by the Board of Directors or committees of the Association are subject to review and approval by counsel, in order to assure compliance with antitrust and other legal requirements.

Terms of Membership
SPA will not deny membership to any person or firm where trade might be unlawfully restrained as a result thereof. Nor will a member be expelled for reasons that would be insufficient to justify the denial of membership.

Data Reporting
Whenever SPA becomes involved in the reporting of statistical data relating to their respective industries, the data will be designed to provide appropriate information that will assist members in making business decisions. Participation in any statistical reporting programs will always be on a voluntary basis.

Any data provided will pertain to past, rather than present or future, transactions and will be reported in aggregate form so as not to permit identification of the terms of any specific transactions or the terms offered by any specific firm.

Research Activities
In any collective research activities undertaken by SPA and its constituent organization, care will be taken that the research activities do not in any way restrain competition.

Independent Decisions
SPA will not sponsor, approve or knowingly be a part of any agreements, whether expressed or implied, which in any way restrict members’ freedom to make independent, competitive decisions.

Consultation with Staff and Counsel
Questions about SPA programs or activities can be freely discussed with the Associations’ staff and counsel. Members are, of course, always free to consult their own counsel concerning SPA activities.
November 12, 2013

Division of Dockets Management (HFA – 305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

Submitted electronically via:  http://www.regulations.gov

Re: [Docket No. FDA-2011-N-0920]; Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food;

Dear Sir/Madam:

The Seafood Products Association (SPA) represents member companies on technical and regulatory issues related to the safety, quality and legality of the food products they manufacture. SPA works collaboratively with other industry associations and stakeholders to advocate sound, science-based public policy that is purposeful, effective and practical in application.

The SPA respectfully provides the following comments in response to the Docket referenced above regarding the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.

Comments are presented in chronological order with referenced sections of the applicable proposed rules bolded and underlined. Any specific changes recommended for the regulatory text are tracked with strikethrough for recommended deletions, and underlined for additions. Comments are presented first for Part 117, followed by comments for proposed changes to other affected parts of Title 21.

Subpart A

§117.1 – Applicability and status.

Comment:  Section 117.1(a) provides criteria for determining whether a food is adulterated. 117(a)(1) proposes that “(1) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food;...” However section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA) deems food adulterated “(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food;...” There is a clear difference between criteria in 117(a)(1) used to describe adulterated food and the referenced criteria in 402(a)(3) of the FFDCA. In short, Part 117(a)(1) describes manufacturing conditions, and 402(a)(3) describes actual adulterated product.

Recommendation:  SPA recommends revising the 117(a)(1) to read “Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food has been manufactured under such conditions that it is unfit for food; or”
§117.3 – Definitions.

Comment: In the context of the proposed rules, “cross-contact” refers to the unintentional incorporation of a food allergen into a food. “Cross-contact” is commonly and mistakenly used interchangeably with the term “Cross contamination”.

Recommendation: Change the defined term in §117.3 from “Cross-contact” to “Allergen cross-contact”. Also change instances of “Cross-contact” in the proposed rule to “Allergen cross-contact”.

*****

Comment: The use of the term “food-packaging” is used throughout the proposed rule with reference to controlling allergen cross-contact or contamination. However, the term “food-packaging” is not defined and therefore may be difficult to distinguish from other uses of the term “packaging” throughout the proposed rule.

Recommendation: A definition for “food-packaging”, or “primary packaging” should be added to §117.3 as “food that comes in direct contact with the product”. The term should then be used consistently throughout the rule when used in reference to controlling allergen cross-contact or contamination.

§117.5 – Exemptions.

Comment: §117.5(b) and (c) provide exemptions for seafood and juice products respectively, from requirements in subpart C of the proposed rule.

However, subpart C of the regulation has added the radiological hazard that must be considered which is not included in 21 CFR 123, i.e., only biological, chemical and physical.

SPA does not believe the inclusion of another hazard category by name, i.e. “radiological hazard” is necessary for facilities subject to part 123. Events that potentially create a radiological hazard are extremely rare and processors typically have a crisis management program to respond to such unique events or would be prompted to re-assess their plans. Also, the Fish and Fishery Products Hazards and Controls Guidance, Chapter 9 Environmental Chemical Contaminants and Pesticides includes the consideration of “contaminants that may accumulate in fish at levels that can cause human health problems (e.g., carcinogenic and mutagenic effects).” As described, these contaminants would include radionuclides associated with radiological hazards.

*****

Comment: Regarding the exemption in §123.5(b), the agency has requested comments on how to determine if a facility, owner, operator or agent is in compliance with part 123, in order to qualify for the exemption from subpart C of part 117. Requiring compliance with subpart C of part 117 for facilities covered by part 123 if those facilities were determined not to be in compliance with part 123 would not serve any practical purpose or provide any meaningful public health benefit since the facility would likely also be non-compliant with subpart C of part 117. In nearly every facility, there may be conditions that could be considered non-compliant to some degree, as commonly noted on FDA form 483 at the conclusion of inspections. These conditions are typically corrected expediently and voluntary compliance is achieved. If egregious non-compliant conditions that could result in a public health issue are not corrected, the agency can utilize enforcement tools (such as administrative detention,
registration suspension, or mandatory recall) that would prevent distribution of products that could result in serious adverse health consequences or death of humans or animals. Therefore it should be recognized that a facility that has not come into voluntary compliance with part 123 is likely to be subject to enforcement actions that will ensure compliance, or no longer be able to manufacture and distribute food as a registered food facility, and would therefore also no longer be subject to part 117 requirements. We believe the statutory intent for compliance is satisfied by the enforcement tools that ensure compliance with part 123, as well as other exempted facilities required to be “in compliance with” parts 113 and 120.

*****

Comment: §117.5(k) provides an exemption from Subpart B of the proposed rule for “farms” as defined in §1.227 of this chapter. By providing this exemption for raw agricultural commodities in §117.5 (k), FDA recognizes that historical practices for transporting raw commodities have been effective in controlling allergen cross-contact and contamination in finished products given the subsequent processing steps that are subject to GMPs, and will be subject to hazard analysis and preventive controls after the rule is finalized. This also provides justification for FDA to provide an exemption from Subpart B for harvest and immediate transport of raw fishery commodities, since they are also subject to subsequent processing GMPs and HACCP requirements under Part 123 that have demonstrated effective control for allergen cross-contact and contamination in finished fishery products.

Recommendation: SPA strongly recommends the addition of §117.5(l), providing an exemption for harvest and immediate transport of raw fishery commodities, using excerpted language from section 123.3 of this chapter as follows:

“Subpart B of this part does not apply to harvesting or transporting fish or fishery products, without otherwise engaging in “processing” as defined in §123.3. This includes practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.”

Subpart B

§117.10 – Personnel.

Comment: §117.10(c) Education and training. SPA acknowledges the importance of proper training in effective food safety and sanitation programs. Just as HACCP and Preventive Controls programs are specific to the facility, process and product, the application of GMPs is likewise subject to these variables. Therefore the GMP training requirements must recognize and accommodate flexible training elements that are tailored to each plant operation. The determination of which elements of training are necessary for an operation, the specific staff required to undergo training, and the frequency of training should be risk based. We concur with FDA that appropriate training and/or education is essential, but should not be overly prescriptive, which may result in less effective application of plant specific GMPs. Due to the essential role of proper training and education to the effective application of GMPs, SPA encourages FDA to develop guidance on appropriate elements of training and education, and may want to use the bulleted items in section XI.M.3. (FR p. 3729) of the preamble as elements of the guidance, rather than incorporating them into the regulation.

Recommendation: SPA generally agrees with the proposed text of 117.10(c), as modified in Table 11 of the preamble, and as edited below; “Personnel responsible for identifying sanitation failures or food contamination must have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of
clean and safe food, as applicable to the plant operation. Food handlers and supervisors must receive appropriate training in proper food handling techniques and food-protection principles applicable to their assigned duties, and should be informed of the danger of poor personal hygiene and insanitary practices.”

§117.35 – Sanitary operations.

Comment: §117.35(d)(1) covers requirements for food contact surfaces used for manufacturing/processing or holding low-moisture foods. It does not accommodate initial processing steps prior to moisture removal where food contact surfaces will be exposed to moist (non-dry) conditions. It also does not recognize that food contact surfaces may not appear to be “sanitary” when raw materials handled at initial processing steps have not yet undergone subsequent processes designed to eliminate microorganisms of public health concern.

Recommendation: SPA recommends consideration of the following language for §117.35(d)(1);
“(1) Food-contact surfaces used for manufacturing/processing or holding low-moisture food must be in a clean, dry, sanitary condition before use and after any interruption during which the food contact surfaces may have become contaminated. Finished product low-moisture food contact surfaces must be maintained in a clean, dry and sanitary condition at the time of use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.”

*******

Comment: Proposed §117.35(f) includes storage and handling requirements for “cleaned” portable equipment and utensils with food contact surfaces. SPA concurs that it is important that these food contact surfaces are clean and sanitary when used. Since storage of equipment or utensils could be for an extended period of time, the regulation should apply the requirements “before subsequent use” of the equipment or utensils.

Recommendation: SPA recommends consideration of the following language for §117.35(f);
(f) Storage and handling of cleaned portable equipment and utensils.
Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a manner and manner that protects food-contact surfaces from allergen cross-contact and contamination, and must be cleaned and sanitized before subsequent use.

§117.40 – Equipment and utensils.

Comment: §117.40(a)(1) on Table 11 of the preamble should refer to §117.40(a)(3), and SPA concurs that “must” is appropriate to indicate this is required.

§117.80 – Process and controls.

Comment: The proposed rule recommends current guidance in §117.80(b)(1) on inspection of raw material containers and carriers be made requirements in the final rule. We believe other requirements of 117.80(b)(1) obviate the need to make this particular element mandatory. This appears to be redundant with the fundamental requirement that “raw materials and ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against cross-contact and contamination and minimize deterioration.” This is required by the first sentence 117.80(b)(1), and would include inspection as needed of containers/carriers at receipt.

Recommendation: Delete or move to guidance the last sentence of §117.80(b)(1).

*******
Comment: The second sentence of proposed §117.80(c)(10) is redundant, as the first sentence includes the fundamental requirement (performance standard) for conducting processes in a manner that protects product from allergen cross-contact and contamination.

Recommendation: Delete or move to guidance the second sentence of §117.80(c)(10), recommending the use of risk assessment for specific processes to determine where to effectively and appropriately apply GMP procedures.

********

Comment: §117.80(c)(14) includes requirements for foods requiring control of water activity (a_w) for preventing the growth of undesirable microorganisms. The proposed language uses the term moisture interchangeably with the term water activity, and does not take into account other synergistic barriers for microbial growth and toxin formation.

Recommendation: Revise §117.80(c)(14) to read; “Food, including dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level a_w.

******

Comment: §117.80(c)(15) includes requirements for foods requiring pH control (acid and acidified foods) for preventing the growth of undesirable microorganisms. The proposed language should be consistent with relevant provisions of part 114 Acidified Foods.

Recommendation: Revise §117.80(c)(15) to read; “Food, including acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a finished equilibrium pH of 4.6 or below.

Subpart C

§117.130 – Hazard analysis.

Comment: § 117.130(c)(3)(x) identifies additional national disaster events, e.g., flood, that also could be addressed in a crisis management program rather than preventative measures.

******

Comment: The preamble discussion on §117.130(c)(3)(iii) attempts to differentiate between raw material and ingredients. The example of the food additive sucrose fatty acid esters is an obscure product and the explanation does not clearly define the difference between the two. It is recommended the definitions be clarified and a more commonly used ingredient be used as an example.

§117.135 – Preventive controls for hazards that are reasonably likely to occur.

Comment: The preamble on §117.135(c)(1) states: “Some preventive controls may not have specific parameters associated with them. For example, preventive controls for metal may include an equipment preventive maintenance program and a metal detector on the packaging line. These programs may not have specific factors that must be controlled to prevent metal contamination.” This is inconsistent with the hazard guidance for
Seafood HACCP which does require preventative controls with specific critical factors that are monitored at critical control points to prevent the hazard of metal inclusion.

******

**Comment:** The preamble on §117.135(e)(2) requests comments on whether the regulation should require a mock recall as a verification activity for the recall program. The only way to determine the effectiveness of a recall program is to conduct test runs of the written procedures and it would be prudent to include this requirement in the regulation.

§117.140 – Monitoring.

**Comment:** The preamble for §117.140 requests comments on monitoring the performance of preventative controls. The regulation is introducing many new concepts to small and medium size processors and the basic requirements will overwhelm most. Introducing the concept of performance evaluation is too complex and is not recommended for inclusion in the final rule. Also, verification requirements in proposed §117.150(d) are intended to ensure preventative controls are consistently implemented and effectively minimizing or preventing hazards that are reasonably likely to occur.

§117.145 – Corrective actions.

**Comment:** § 117.145(b)(2) would require that the owner, operator, or agent in charge of a facility “reanalyze” the food safety plan. Although this section indicates when they will use the work reanalyze, why is this word used instead of reassessment which is common to the other regulations such as §123.7(c)(5) and The discussion in this section essentially covers the need to reassess the plan when a system failure occurs.

**Recommendation:** Revise §117.145(b)(2) by replacing the term “reanalyze” with “reassess”. Also revise 117.150(f) by replacing the term “reanalysis” with “reassessment”.

§117.150 – Verification.

**Comment:** §117.150(a)(3) does not require validation for food allergen control and comments are requested. Although the controls may not be evaluated through scientific studies or by the collection of technical information, as discussed, the systems can be validated to assure they are effective in preventing allergen cross contamination, e.g., sample swabs (which are available). The discussion of preventative controls is limited to physical barriers, separation and other visual parameters. In addition, the proposed regulation does not require validation for sanitation controls. Although the strength, contact time, temperature may be established by chemical supply companies, they cannot assure the products are being used properly or are effective for the specific environment. The effectiveness of the sanitation controls can be validated by sample swabs. Reliance strictly on visual observation for potential allergen cross-contamination and sanitation controls does not appear to be appropriate since testing systems are available.

******

**Comment:** §117.150(f)(1) requires reanalysis of preventative controls when changes occur, etc., or at least every three years. It is recommended the reanalysis be conducted at least annually to be consistent with other HACCP regulations.
§117.155 – Requirements applicable to a qualified individual.

Comment: §117.155(b) would establish the qualifications for a “qualified individual.” To be qualified, the regulation requires an individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, or be otherwise qualified through job experience to develop and apply a food safety system. Section 117.155(c) would require that all applicable training be documented in records, including the date of the training, the type of training, and the person(s) trained. First, the regulator’s vast experience with Seafood HACCP has shown that job experience is not adequate to fully prepare individuals to understand and implement the requirements of the regulation. [For example, it is highly unlikely job experience will qualify and individual to meet the requirements of 117.130(c)(1)].

Second, it is very unlikely that individuals have documented their past job training to the degree necessary to prove it is equivalent to a standardized curriculum. There are exceptions, but in general these two points prevail. For these reasons, it is recommended the qualified individual must attend an organized training course that utilizes the standardized curriculum.

Subpart F

§117.320 – Verification.

Comment: The preamble for §117.320 suggests the agency may request food safety plans be submitted to the agency for review prior to inspections. The resources required for processing and reviewing submissions are not available to the agency and would add be of little value, given they would be viewed out of context of the processor’s operations, and most likely would be out-of-date by the time they are reviewed. This procedure is not recommended.

Appendix

The proposed rule requests comments on requirements for environmental and finished product testing. As we know, HACCP was developed in the early years of space travel because it was common knowledge sampling could not be relied upon to assure product safety. The regulation should only require finished product testing when used as a verification procedure for appropriate products, e.g., quarterly water phase salt testing of smoked fish. The regulation should not be prescriptive and require environmental sampling for all processors. As deemed necessary by the products and processes, responsible companies use sampling as a verification of their sanitation program.

Should the agency determine that inclusion of environmental sampling program (EMP) requirements for appropriate RTE food facilities benefits public health and determines that EMP should be added to the proposed rules, we strongly encourage FDA to consider the following:

- Regulatory provisions for EMP should be modeled after the FSIS Listeria Compliance Guideline, including the use of indicator organisms such as Listeria spp.
- Develop a compliance policy guideline with unambiguous policy on interpretation of EMP monitoring results
- The agency recognizes that an effective EMP will occasionally identify indicator organisms in the environment, but this does not mean that the facility’s sanitation programs are insufficient, provided the facility takes the appropriate corrective actions. Conversely, when a significant number of EMP samples
are negative for the indicator organism, this does not necessarily mean that the facility’s EMP is insufficient.

- FDA inspectors should be required to take additional training to ensure they understand agency policy with regard to the evaluation of facility EMP.

Thank you for consideration of our comments.

Sincerely,
Seafood Products Association

Kenneth Lum
President
November XX, 2013

Division of Dockets Management (HFA – 305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

Submitted electronically via: http://www.regulations.gov

Re: [Docket No. FDA-2011-N-0143]; Foreign Supplier Verification Programs for Importers of Food for Humans and Animals;

Dear Sir/Madam:

The Seafood Products Association (SPA) represents member companies on technical and regulatory issues related to the safety, quality and legality of the food products they manufacture. SPA works collaboratively with other industry associations and stakeholders to advocate sound, science-based public policy that is purposeful, effective and practical in application.

The SPA respectfully provides the following comments in response to the Docket referenced above regarding the proposed rule for Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.

Section I

A. Background and Legal Authority

Issue:
Section 805(b) of the FD&C Act [in Section 301(a) of FSMA] directs FDA to issue guidance to assist importers in developing Foreign Supplier Verification Programs (FSVP). FDA plans to issue the guidance with recommendations on how to comply with FSVP along with the final rule rather than the proposed rule. Comments were requested.

Comment:
This strategy appears to be a means to expedite dissemination of the information to the importing industry. However, it does not provide the industry an opportunity to review and comment before it is finalized. The primary concern is whether the guidance will actually be recommendations on how to comply with the regulation, or if the guidance will become mandatory for the industry to follow. The concern is based on past history of the agency. For example, the FDA’s Fish and Fishery Products Hazards and Controls Guidance document was originally promoted as recommendations for compliance with 21 CFR Part 123 Fish and Fishery Products; however, it has essentially become mandatory and any slight deviation from the guidance has not been deem acceptable. Without an opportunity to review of the guidance information, what assure can the agency provide the importing industry that it will
only be guidance and flexibility will be allowed to meet the FSVP requirements? Also, without prior review, the value of the document may be questionable, i.e., it may not reflect the real world mechanics and issues of the import community.

It is recommended the agency provide the guidance document in advance of implementation to allow comments.

Section II

A. Definitions

Issue:
Section 1.500 defines “foreign supplier” and equates the term to “facilities” in the proposed preventative controls in human food section of the FD&C Act to mean an establishment that manufacturers, processes, packs or holds food, etc."

Comment:
There are foreign companies (e.g., brokers) that consolidate products from several different suppliers (manufacturers, processors, etc.) but never take physical position of the products, and simply arrange the export of the products and never take physical position of the products, and simply arrange the export of the products to the United States. The consolidating company is listed on the standard export documentation but not the suppliers. In these arrangements, the exporter will not reveal the product sources for fear the importer will purchase directly from the actual source, rather than the intermediate broker. There may be other such examples where the supplier is not identified.

Will such companies be considered “foreign suppliers” and subject to the proposed regulation?

Issue:
Section 1.500 definition of an “importer” includes the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

Comment:
As specified elsewhere in the proposed regulation, an “importer” must provide assurance the foreign supplier is producing the food in compliance with the regulation, including:

- Review of the compliance status of foods and foreign suppliers;
- Analysis of hazards reasonably likely to occur with foods;
- Determination of performance of foreign supplier verification activities;
- Reassessment of the FSVP;
- Ensuring the required information is submitted at entry; and
- Maintenance of records.

An U.S. agent or representative for a foreign processor is typically a third-party individual who is not an employee of the foreign supplier, consignee or importer. As such, the U.S. agent or representative does not have access to the degree of information required by the regulation or the ability to perform the above functions. Such individuals typically have no financial interest in the food, consignee or importer and are not aware of the daily operations of the foreign supplier, consignee or importer.
The original intent of the U.S agent concept under the *Bioterrorism Act of 2002* was to identify foreign food exporters (and domestic companies) and provide a means or a conduit to facilitate the agency’s ability to communicate with the foreign processor in times of emergencies, to obtain information on processing procedures (e.g., low acid canned food registration and processing filings), be invoiced for FDA costs associated with reconditioning activities and other considerations.

Further, the regulation will make the U.S. agent or representative responsible for the FSVP requirements when “a food has not been sold or consigned to a person in the United States at the time of entry.” It is theoretically impossible for an U.S. agent or representative to take responsibility and comply with FSVP requirements when they are not involved in the daily operations of the supplier or importer and have no knowledge of the on-going business transactions. It is questionable why the agency allows product to be entered into the United States with an identified owner or consignee at the time of entry and doesn’t propose to hold them responsibility for the FSVP requirements. Surely, someone other than the U.S. agent or representative has a financial interest in the entry and it’s more logical to hold that entity responsible for FSVP, i.e., the owner of the product.

It is recommended the definition of importer should exclude the U.S. agent or representative.

**Issue:**

Regarding the requirements of importers, the agency requested comment on whether the FSVP requirements should apply to importers who are part of the same corporate structure as the foreign supplier and subject to a single integrated, company-wide food safety system.

**Comment:**

The procedures should not be modified for the described business arrangement. Sophisticated companies with highly developed food safety programs will most likely take advantage of the Voluntary Qualified Importer Program (VQIP) in the future and will no doubt be required to provide equivalent assurance of compliance. Other such integrated companies may not participate in VQIP. There is no perceived reason to make an exception for all importers with integrated, company-wide food safety system. Exceptions allows for inconsistencies in interpretation, implementation and enforcement of the requirements.

Such an exemption could also result in fraudulent schemes to make it appear as if the supplier and importer are integrated companies. Historically, various components of the importing industry are notorious for abusing the privilege to import products into the United States and taking advantage of the agency’s limited resources to investigate fraudulent schemes.

It is recommended the regulation be applicable to the entire exporting and importing industry rather than making exceptions to specialized segments.
D. Personnel

Issue:
Section 1.503 would require a “qualified individual” to perform the FSVP requirements. Section 1.500 definition of a “qualified individual” proposes to allow an importer to use a third-party auditor that is qualified, but not accredited in accordance with Section 808 of the FD&C Act to be their designated “qualified individual.” Comments were requested.

Comment:
The proposed allowance is an acceptable alternative provided the individual’s qualifications include documented education, training and experience in performing food safety analyses to establish the competency of the auditor. The agency should consider establishing the standard training curriculum or other criteria to ensure the competency of such auditors. Implementation of the import verification requirements under 21 CFR Part 123 Fish and Fishery Products determined the import community had a difficult time complying with the regulation, and still does after 15 years as evident by current regulatory actions involving importers. One possible reason is there is no mandatory training requirement for importers and there is a lack of knowledgeable individuals to provide assistance to the industry. The proposed regulation will create a great demand for industry assistance to meet the challenge of complying with FSVP requirements; this would provide a potential source of “qualified individuals”

It is recommended the regulation should allow qualified auditors—-but not accredited auditors—-perform the FSVP requirements provided they meet the above criteria.

M. Small Importers and Small Foreign Suppliers

Issue:
Section 1.512 proposes to exempt very small importers and very small foreign suppliers, defined as having no more than $500,000 in annual sales value. The proposed regulation indicates the intent is to limit the volume of food imported under the FSVP procedures. Comments were requested.

Comment:
The stated justification for the exemption defeats the purpose of the proposed regulation. The new requirements are designed to enhance the safety of the food supply and there should be no exemptions to the regulation based on volume of business. Granted, the proposed regulation will be a difficult challenge for the smaller importers and exporters and compliance would be slow coming. Rather than establishing exemptions, perhaps a phase-in process could be included in the proposed regulation for the smaller companies. This approach has been used in implementing other food safety regulations.

Theoretically, under the proposal, the agency would need to implement procedures for industry’s reporting of data and procedures for the agency to verify the supplier’s and importer’s annual volume of sales. Reporting and verification activities will cause an additional workload burden for the agency. Verification of sales data may be possible for importers through interagency cooperation with the IRS but this couldn’t be accomplished for
foreign suppliers. Without verification, the agency provides an opportunity for fraudulent reporting under the exemption.

It is recommended the regulation apply to the entire exporting and importing industry rather than making exceptions to specialized segments.

B. Applicability and Exemptions

**Issue:**
Section 1.501(b) would exempt certain juice and seafood facilities from the FSVP requirements. Reportedly, consideration will be given to rulemaking to revise the regulations applicable to seafood and juice due, in part, to GAO’s report on the seafood regulation that concluded there is no requirement for onsite audit of foreign suppliers to verify the preventative controls are being followed.

**Comment:**
The lack of onsite verification is an acknowledge weakness of the affirmative action procedures in the other food safety regulations. Consistency amongst all applicable regulations is a reasonable expectation.

Re-evaluation of the seafood and juice regulations appears to be justified to establish consistency.

**Issue:**
Comments were requested regarding facilities that may be subject to FSVP as well as the proposed regulations for preventative controls for human food and the future preventative controls for animal feed. Comments were requested whether the FSVP supplier verification requirements (procedures) should apply to the other regulations.

**Comment:**
Considering the fact that a facility may be subject to two or three of the regulations, the requirements should be consistent amongst the regulations.

The agency is encouraged to have the comparable requirements for all regulations.

E. Review of Food and Foreign Supplier Compliance status

**Issue:**
Section 1.504 states the importer will be responsible for determining the compliance status of the foreign supplier through the review of warning letters, FDA Form 483s, establishment inspection reports, recall notices, import alerts and documents related to seizures and injunctions.

**Comments:**
While access to warning letters is relatively easy at the FDA website, the other documents referenced in the proposal are not. The other cited sources of compliance information would
require submission of Freedom of Information Act (FOIA) requests. Such requests are dependent upon available agency staffing. Most likely, the requirement would result in an overwhelming number of FOIA requests and it is questionable whether the agency is prepared to meet the challenge of the additional workload to provide the information in a timely manner. This could result in prolonged delays in obtaining the information to facilitate the importer’s decision about a foreign supplier’s compliance status. Also, information is not released under a FOIA request if the inspection and/or sample results are under evaluation and potentially subject to regulatory action so there is no guarantee information will be available.

Further, due to time delays, the importer could not be assured of the current, official status of the supplier’s compliance status. For example, corrective actions may have been completed and verified by FDA but not reflected in the information provided. Also, import alerts are not necessary updated in a timely manner and do not always identify the actual names of the foreign supplier subject to the import alerts.

The proposed regulation has good intentions to assist the importer in sourcing products from compliant suppliers. However, the sources of agency information necessary to make an evaluation are rather limited or difficult to obtain.

F. Hazard Analysis

**Issue:**
Section 1.505(b) requires the importer to evaluate hazards that are reasonably likely to occur. The proposed regulations questions whether potential hazards intentionally introduced for economic reasons should be considered reasonably likely to occur, e.g., melamine. Comments were requested.

**Comment:**
Evaluating intentional hazards would be a difficult task for the industry, even amongst HACCP experienced individuals since it has not been included in other food safety regulations. Significant resources may be spent evaluating such hazards that are best spent implementing the core requirements of FSVP.

It is impossible to determine the next deviant action perpetrated by immoral individuals. Situations like the melamine event occur on a random basis, are unpredictable and are due to the unethical behavior of individuals. An unethical foreign processor that will knowingly adulterate or misbrand their product is not going to include and assess the act as a reasonably likely to occur hazard in their preventative controls program. (There is also the issue of how a company would address the other pillars of preventative controls for such an event, e.g., monitoring, verification procedures.) As with volcanic eruptions, earthquakes and other natural disasters, cases of intentional adulteration or misbranding are unpredictable and can only be managed when they occur. The best approach is for a prudent supplier or import to have food security and crisis management pre-requisite programs that specifies what actions will be taken when such an event occurs.

It is recommended intentionally introduced hazards be excluded from the regulation.
**Issue:**
Section 1.505(c) would require the hazard evaluation to consider transportation practices.

**Comments:**
The seafood and juice regulations do not require the facility to include transportation in the hazard evaluation; it is included in the proposed preventative controls for human food regulation. The agency recognized they cannot regulate the vast common carrier industry and that is the reason it was not included in the seafood and juice regulations. A company typically evaluates how their products will be distributed to the market place during the development of a product. However, the company can’t easily monitor and verify compliance of the requirements and must rely upon the integrity of the transportation industry to follow the designated procedures, e.g., proper refrigeration and freezer monitoring. Failure will most likely be detected by the importer upon receipt of the shipment. Resolution of the problem is a matter of the business relationships and negotiations between the supplier, transportation company and importer. Prudent suppliers and importers should have pre-requisite programs for inspection of out-going and in-coming transportation vehicles for sources of product contamination.

It is recommended transportation practices be excluded from the regulation and be left to the business relationship between the parties, and best practices.

**G. Foreign Supplier Verification and Related Activities**

**Issue:**
The proposed regulation 1.506(e) questions whether an importer with validated preventative controls for a product should be required to conduct the supplier verification activities. That is, the importer would not need to perform supplier verification activities if they process the product to control the identified hazard after receipt. Comments were requested.

**Comment:**
This approach is a plausible exemption to the verification requirements but would be dependent upon the validity of the importers (i.e., processors) preventative controls and whether they have included all hazards reasonably likely to occur. The *Salmonella* example cited emphasizes this point.

**Issue:**
Section 1.506(f) would provide the importer an exemption if they obtain written assurance on an annual basis from its customers that they are following procedures to control the identified hazards. Essentially, the importer would defer control of hazards to their customers. Comments were requested regarding whether the written assurance should be obtained more frequently than every 3 years.

**Comment:**
Historically, in other preventative control regulations the agency has not allowed an establishment to routinely pass-on the control of a hazard to the next user, as implied in the macadamia nuts example, even with a written agreement. Just like the requirement for
importers to conduct on-site audits of high risk products because paper documents do not ensure compliance, a written agreement does not guarantee compliance. The frequency of obtaining the written agreement is not the issue. The foreign supplier or importer should be responsible for controlling the hazard, not the subsequent customers.

An exemption from hazard control is not recommended

**Issue:**
Sections 1.506(g) and (h) would allow the importer to use an FDA inspection of the foreign supplier in lieu of an audit by a “qualified individual”.

**Comments:**
Allowance of this procedure would be dependent of several factors: the FDA inspection would need to evaluate all the products in the importer's verification procedures, the agency may need to know which importers are receiving the product, the agency would need to know about any complaints received by the importer, the agency would need to provide a copy of the establishment inspection report (and any corrective action documentation submitted to the agency by the facility) to the importer on a routine basis, not under FOIA, etc. It is questionable whether the FDA could accomplish these requirements.

The option is not recommended unless further developed to ensure the agency is adequately evaluating the importer's program and providing documentation in a timely manner.

**H. Complaints, Investigations, and Corrective Actions**

**Issue:**
Section 1.507(a) would require the importer to review any complaints from consumers or customers that are related to the FSVP.

**Comment:**
As with other food safety regulations, it is reasonable that a company review complaints to determine if they relate to the adequacy of the food safety program. The information may identify a hazard that was originally identified as not reasonably likely to occur or an inappropriate critical limit or monitoring procedures. The supplier will most likely be the most appropriate party to evaluate the complaint and provide feedback to the importer.

It is reasonable to require importers to review inquiries from customers and consumers.

**Issue:**
Section 1.507(c) would require the importer to take corrective action if the supplier evaluation or sampling determined the foreign supplier was not adequately controlling the hazards, including submission to the Report Food Registry (RFR).

**Comment:**
The agency acknowledges the definition of “supplier” applies to establishments that are not required to register (e.g., raising of animals, harvesting food) and therefore not subject to RFR. Likewise, since most importers are not required to register under Section 415, they
have no current obligation to make a submission under RFR in the event of a significant (i.e., Class 1 SAHCOSHA events) adulterated or misbranded product.

Does the agency have a plan to address this potential RFR reporting gap?

I. Reassessment of FSVP

Issue:
Section 1.508 would require reassessment of the FSVP every three years.

Comment:
Consistent with other preventative control regulations, the reassessment frequency is annually or whenever changes occur that may impact on the hazard analysis and/or HACCP plan. Three years is a large time gap considering the dynamic nature of changes that occur in the food industry.

It is recommended that the reassessment be conducted annually or in the event of changes impacting on the program.

J. Identification of Importer at Entry

Issue:
Section 1.509(b) would require the importer to obtain a DUNS number to be used with each line number of the electronic filing with the Customs Border Protection to identify the importer. Also, the section of the regulation is described as “ambiguous” as to the meaning of Section 805(g) of the Food, Drug and Cosmetic Act, i.e., should a list be developed for all importers or just those in compliance.

Comment:
Considering the limited information available to the U.S. agent or representative, as previously discussed, it is equally impossible for them to make electronic submissions for an entry.

Based on the intent of the regulation, the language does not appear to be ambiguous and Section 805 was intended to result in a comprehensive list of all importers in the U.S. However, what is ambiguous is FDA’s use and maintenance of the database. Historically, such lists are subject to errors and are not maintained to prevent duplicate numbers.

Generation of a master list of importers is not objectionable provided it is maintained and used for good intentions. U.S. agents and representatives should be excluded from the data entry reporting requirement.

******
Issue:
Section 1.509(b) would require the importer to obtain a DUNS number. Based on the proposed definition of an importer, this will require an U.S. agent or representative to obtain a DUNS number.

Comment:
This will be a moot point if agents and representatives are excluded from the definition of importer. The U.S. agent or representatives—not being an integrated employee of any party in the transaction, as previously noted—will not be making electronic entries and there is no apparent reason for issuance of a DUNS number.

Currently, the FDA databases may have multiple CFN, FEI and Bioterrorism assigned numbers due to slight changes in names and addresses or fraudulent submissions. The agency needs to implement provisions to prevent the issuance of multiple DUNS numbers, either unintentional or intentionally on the part of the importer.

DUNS numbers for U.S. agents and representatives is not warranted.

O. Consequences of Failure to Comply

Issue:
Section 1.514 deems an article of food to be subject to refusal of admission if the importer fails to comply with the regulation.

Comment:
Provided that an importer is meeting all the requirements of the FSVP regulation, the agency may collect a sample and determine the food to be adulterated or misbranded. This may imply the importer’s FSVP is inadequate in identifying or controlling a hazard.

Although the product will be subject to detention/refusal, what action will the agency pursue regarding the importer’s FSVP?

Thank you for consideration of our comments.

Sincerely,
Seafood Products Association

Kenneth Lum
President
November 26, 2013

Division of Dockets Management (HFA – 305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852
Submitted electronically via: http://www.regulations.gov

Re: [Docket No. FDA-2011-N-0146]; Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certificates

Dear Sir/Madam:

The Seafood Products Association (SPA) represents member companies on technical and regulatory issues related to the safety, quality and legality of the food products they manufacture. SPA works collaboratively with other industry associations and stakeholders to advocate sound, science-based public policy that is purposeful, effective and practical in application.

The SPA respectfully provides the following comments in response to the Docket referenced above regarding the proposed rule for Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certificates. Docket No. FDA-2011-N-0146.

Section II Background

A. Legal Authority

2. Voluntary Qualified Importer Program
3. Authority To Require Import Certification for Food
5. Other Provisions of the Federal Food, Drug, and Cosmetic Act

Issue:
Sections 806(a), 808(c)(2), 801(q) and 808(c)(2) of the FD&C Act cites two purposes for certificates issued by third-party auditors/certification bodies: to establish eligibility for the Voluntary Qualified Importer Program (VQIP) participation; and Mandatory Import Certification (MIC). The proposed regulation notes the agency may expand the procedures to allow importers to use reports of regulatory audits for meeting the on-site audit requirement of foreign suppliers under the proposed Foreign Supplier Verification Program (FSVP) regulation. The primary concern with the expansion to FSVP is related to the reporting requirements and, although not stated in this proposed regulation, potential expansion to supplier approval under the proposed Preventative Controls for Human Food regulation.
Comments:
Provided the degree of reporting requirements is limited to “serious risk to public health” associated with regulatory audits conducted to determine the compliance with the FD&C Act, as noted below, the extension to FSVP should be beneficial to the importing industry. The importing industry faces a momentous challenge to conduct the on-site assessments under FSVP and audits by qualified third-party auditors/certification bodies may be a practical means to meet the requirement. To address concerns the agency should emphasize the regulatory audit reporting is limited to assessing the foreign entity’s, as defined, compliance status with the FD&C Act—not domestic suppliers—and doesn’t include other elements typical of Global Food Standard Initiative (GFSI) benchmarked standards, e.g., assessing management’s commitment to food safety, compliance with international standards.

IV. Purpose and Description of the Proposed Rule

A. Proposed Revisions to Part 1, New Subpart
1. Definitions and Scope
a. What definitions apply to this subpart (Proposed 1.600)?

Issue:
Consultation Audit definition: The proposed regulation states consultation audits are for internal use only—which implies they are not reportable to the agency—and cannot be used for importers under FSVP or in lieu of regulatory audit under 808 of the FD&C Act, i.e., VQIP and MIC requirements. Subsequently, the proposed regulation (page 45815) acknowledges Section 808 of the FD&C Act does not define “serious risk to the public health” nor gives examples of conditions. The concern is consultation audits may require reporting if conditions constitute a “serious risk to public health” which is not clearly defined.

Comment:
The agency must positively assure the industry that reporting of consultation audits will not be required, except if required under Section 415 of the FD&C Act where a “serious risk to public health” is associated with the imported food product. It is recommended the agency clearly define “serious risk to public health” as defined in Section 415.

Issue:
Eligible Entity definition: The proposed regulation requests comments on expels of specific types of entities that meet the definition and whether organizations similar to the National Organic Program (NOP) administered by the U.S. Department of Agriculture are relevant in determining whether a cooperative is an “eligible entity.”

Comment:
Cooperatives typically represent a substantial number of small operators (growers/harvesters/processors) under the direction of a single management and marketing system, e.g., Latin American coffee cooperatives with hundreds of members. The growing, harvesting and preliminary processing is common to the members of the cooperative and is under the direction of the cooperative’s management. The requirements of the proposed FSVP regulations will be extremely burdensome to these small operations, and the information from each operation would be redundant potentially inundating the agency with documentation which will sap vital resources needed for reviewing the submissions. Under this scenario, it is recommended the agency consider allowing cooperatives to be included in...
the definition of an “eligible entity.” Such an allowance would necessitate the agency providing guidance on acceptable parameters of the cooperative and may require changes in the definitions of “facility” and “facility certification” in this section.

Contrary to cooperatives, “consolidators” should not be included in the definition of “eligible entity.” In most cases, consolidators are essentially brokers that purchase products from various processors and export the goods to the U.S. Typically, the consolidators simply source products for export and do not own, manage, or have a financial interest in the actual processing operations. As such, they do not have control or knowledge of the processing procedures to verify the requirements of the proposed regulation or FSMA. In it recommended the agency should define the term “consolidator” in the final regulation or address the issue in the preamble.

**Issue:**

**Regulatory Audit definition:** The definition of “regulatory audit” in the proposed regulation includes determining whether such entity is in compliance with the provisions of the FD&C Act. Also, the definitions of “Facility Certificate” and “Food Certification” means the food and facility meets the requirements of the FD&C Act.

**Comment:**

The scope of a third-party audit may be limited to identified process(s) and/or product(s), e.g., the product’s canning operations but not the freezing operations. It’s possible the entity could be compliant in one process/product category, yet out of compliance in another process/product category. The proposed regulation implies all processes and products must be in compliance. Certification could depend upon whether one or both process/product categories are included in the scope of the audit. The agency should clarify the degree of compliance that would be required for certifications, i.e., all processes and products, or just those exported. At a minimum, it is recommended the agency ensure the regulatory audit is compliant for the specific process(s) and/or product(s) exported to the U.S.

**A. Proposed Revisions to Part 1, New Subpart 3. Requirements for Recognized Accredited Bodies**

**Section 1.620**

**Issue:**

Section 808(c)(4)(A) of the FD&C Act requires the third-party auditor/certification body to notify the agency of “serious risk to the public health” as a condition of its accreditation.

**Comment:**

As noted above, the agency should clarify the meaning of “serious risk to public health.” It is recommended the definition be equivalent to the Reportable Food Registry (RFR) provisions of FD&C Act Section 415, i.e., conditions that warrant a Class 1 recall.

Without clarification, it would appear the agency could require the submission of consultation audit reports for situations comparable to Class 1 and Class 2 recall events. Class 2 recalls do not meet the criteria and would be contrary to the definition of consultative audits which are intended for internal use, except in the event of “serious risk to public health.”
There are situations where a “serious risk to public health” may exist in a product but the product remains under the control of the processor. By definition, this does not constitute a recall because the product is under the processor’s control. Under RFR, it is not; however, the proposed regulation is not clear if this situation requires notification.

When reporting is required, the proposed regulation does not provide guidance on the procedures for notifying the agency. It is recommended the proposed regulation should reference or parallel the RFR reporting procedures.

Section 1.623

**Issue:**
Section 1.623 of the proposed regulation would require information (e.g., self-assessment reports) submitted to the agency electronically and in English (English only is also cited elsewhere in the regulation). Comment was requested regarding the English only requirement and who should be responsible for the costs of translation or interpretation services.

**Comment:**
Other regulations require documents for agency review to be in the English language (e.g., Seafood HACCP regulation) although it is sometimes difficult to understand the document’s content due to the translation into the English language. If documents are not submitted in English, it is recommended the accredited body be responsible for all translation and interpretation costs. This approach allows flexibility yet eliminates the potential costs to the agency.

Section 1.624

**Issue:**
Section 1.624(a)(2) would prohibit officers, employees or other agents of a recognized accreditation body from accepting monies, gifts, etc. except as cited, including onsite meals of a de minimis value. Comment was requested whether meals of a de minimis value should be allowed which would be consistent with agency employees.

**Comment:**
It is recommended meals of de minimis value be allowed during the course of consultation and regulator audits. The procedure may expedite the assessment and may be necessary when the facility is located in a remote area or distant from available facilities. The current definition of de minimis value for US Government employees should be used.

**Issue:**
Section 1.624(c) would require transparency in the payment of fees or reimbursement of direct costs by an accredited auditor/certification body to the accreditation body. Such information must be available at the accreditation body’s website. The concern is whether a favorable decision is made by the accreditation body due to multiple payments by the accredited auditor/certification body.
Comment:
It’s recommended the agency should clarify whether this is limited to the dates such payments are made to the accreditation body, or must they also include the actual dollar value of the payments. Posting of dollar values on a public site is a very sensitive issue for various security reasons. Perhaps, the reporting should be limited to inclusion in the annual reporting under Section 1.625.

A. Proposed Revisions to Part 1, New Subpart
5. Accreditation of Third-Party Auditors/Certification Bodies

Section 1.642

Issue:
Section 1.642 would require the accredited third-party auditor/certification body to have adequate resources. The proposed regulation discussion is focused on the number of qualified personnel and other agents.

Comment:
It is recommended the agency consider requiring accredited third-party auditors/certification bodies to be bonded, as well as the accreditation bodies. The intent is to cover any agency costs associated with the certification process in the event the company was to go bankrupt.

Issue:
Section 1.642 would require the accredited third-party auditor/certification body to have an adequate number of personnel and other agents with relevant knowledge, skills, and experience to effectively audit for compliance with applicable FDA requirements and industry standards and practices.

Comment:
While audit agents may be knowledgeable of GFSI benchmarked standards and other industry standards and practices, they may only be familiar with some relevant regulations enforced by the agency under the FD&C Act, e.g., good manufacturing practices, basic principles of HACCP. However, without extensive qualified training, it is questionable whether audit agents are prepared to assess compliance with the FD&C Act in regards to all other agency regulations and guidance that may apply to a process and product, e.g., labeling, food additives, compliance program guides. It takes several years of training for a FDA inspector to be knowledgeable of the FD&C Act requirements and additional years to become adept in specialized process and food commodities. The agency needs to be assured the audit agents are capable of assessing compliance with all relevant FD&C Act regulations applicable to the process and/or food subject to the scope of the audit. It is recommended the agency establish the requirements for audit agents. This is especially necessary for foreign accredited auditors/certification bodies that will assess an entity’s compliance with the FD&C Act.
A. Proposed Revisions to Part 1, New Subpart
6. Requirements for Accredited Auditors/Certification Bodies

Section 1.650

Issue:
Section 808(a)(7) of the FD&C Act will require the regulatory audits to assess an entity’s compliance with the FD&C Act and the audit agents must be qualified in assessing compliance with the act. Section 1.650(a)(3) of the proposed regulation requires annual food safety training.

Comment:
See Section 1.642 above. The proposed regulation is vague in the training requirements and cites technical and expert training but does not reference training in FD&C Act and regulation training.

The proposed regulation defines (see above) an “audit agent” as an individual who is qualified to conduct food safety audits. However, the qualifications are not adequately defined.

Issue:
Section 1.650(a)(5) of the proposed regulation requires the audit agent (and the accredited auditor/certification body under 1.656(c)) to notify FDA if a “serious risk to public health” is discovered during a food safety audit. This applies to both consultative and regulatory audits.

Comment:
As previously noted, it is recommended the agency clearly define a “serious risk to public health” in the regulation and to use the RFR criteria.

Issue:
Section 1.650(c) of the proposed regulation would prevent an audit agent to conduct a regulatory audit if they have conducted a “consultative” or “regulatory” audit of the entity within the preceding 13 months, except as allowed as per Section 1.663 where an insufficient number of accreditation certification bodies are in the entity’s location.

Comments:
It is recommended that an audit agent that has conducted a consultative audit of an entity be restricted from conducting a regulatory audit of the entity. This would be considered a conflict of interest or potentially creating conflicting information to the entity, e.g., the regulatory audit identifies deficiencies not noted during the consultation audit. In addition to the time element between regulatory audits (i.e., 13 months), it is recommended the agency consider limiting the number of times the audit agent can conduct a regulatory audit of the same entity (e.g., 2 or 3 times).

Section 1.652

Issue:
Section 1.652(a) and 1.652(b) discusses the requirements for food safety reports for consultation and regulatory audits, respectively. Section 1.652(a)(5) requires information on
any deficiencies observed during the audit that requires corrective action and the date on which such corrective actions were completed; Section 1.652(b)(3) also requires information on sampling and laboratory analysis, recent food recalls, recent significant changes at the facility and any food or facility certifications recently issued to the entity. “Information” is not clearly defined.

Comment:
Third-party auditors typically observe the process, review records and cite any non-conformity to a standard and the “information” included in a written report, but do not collect typically collect physical evidence in the manner FDA Inspectors document non-compliance with the FD&C Act regulations. This is especially true for “significant risk to public health” events. For example, in a typical GFSI audit, an observed process deviations would be simply reported on the audit checklist as “canning retort time did not meet the x temperature/y time of the scheduled process,” a potential Class 1 situation due to *Clostridium botulinum*. This would be classified as a major non-conformance (and audit failure) but it’s doubtful this is sufficient reporting for the agency to classify the recall and evaluate the full extent of the problem. It is recommended the agency clarify the expectations for reporting and evidence development when significant observations are made, especially when “serious risk to public health” conditions are encountered and are reportable.

Issue:
Section 1.652(b)(4) requires the audit report to include the process and food observed during the audit. The proposed regulation indicates this is necessary to assure the scope of the audit is defined for certification.

Comment:
If a processor operates various processes (e.g., canning, freezing, reduced oxygen packaging, ready-to-eat), it is recommended the agency clarify if all processes and foods must be observed and deemed compliant during the regulatory audit to achieve certification, or if certification can be limited to just those observed. The concern is the scope of the audit may deem one process and/or product is in compliance but the safety of other processes and products cannot be assured.

Section 1.656

Issue:
Section 1.656(c) of the proposed regulation requires the accredited auditor/certification body to immediately notify the agency when a “serious risk to public health” is identified, and the notification requires identification of the “FDA registration” number.

Comment:
It is recommend the agency clarify what registration number discussed in the proposed regulation is required: DUNS, UFI, FD&C Act Section 415 (bioterrorism registration) and/or CFN/FEI.

The section also requires the accredited auditor/certification body to notify FDA prior to notifying the client, the eligible entity. The proposed rule doesn’t provide adequate justification for this sequence and could cause delay in corrective action by the eligible entity. Ideally, the eligible entity should be notified immediately to facilitate evaluation of the conditions and take the necessary corrective action.
Section 657

Issue:
Section 1.657(a)(2) of the proposed regulation would require audit agents to divest all interests in FDA-related food firms.
Comment:
This would be consistent with FDA Inspector restrictions and would be appropriate for the regulation to contain this restriction.

A. Proposed Revisions to Part 1, New Subpart
9. Requirements for Eligible Entities

Section 1.680

Issue:
Section 1.680(a) states the agency may conduct an onsite audit of an eligible entity and 1.680(b) states such a food safety audit is not considered an inspection under 704 of the FD&C Act.
Comment:
An audit must determine if the entity is in compliance with the FD&C Act which is comparable to a 704 inspection. The proposed regulation has not provided adequate justification of why the agency’s food safety audit does not constitute a 704 inspection. This needs clarification since a FDA inspection may be used to meet the verification requirements under the proposed FSVP regulation.

Other

General Comment:
The proposed regulation does not discuss the anticipated agency response to a “serious risk to public health” reported by the accredited auditor/certification body. It is not known if the accredited auditor/certification body will be allowed to manage the event or will the agency initiate a comprehensive inspection of the eligible entity, including the collection of samples and documentation with the potential intent to pursue regulatory action. It is recommended the agency address the issue in the preamble.
18 AAC 34 Seafood Processing Regulation

Proposed Changes

September 2013

Department of Environmental Conservation,
Division of Environmental Health
18 AAC 34.010 is amended to read:

18 AAC 34.010. Requirements adopted by reference. The following requirements are adopted by reference:

(1) 21 U.S.C. 348(a), as revised as of 2006 [November 21, 1997];
(2) 21 U.S.C. 379c(a), as revised as of 2006 [August 13, 1993];
(3) 21 C.F.R. 101.1 - 101.108 (Food Labeling), as revised as of April 1, 2013 [2006];
(4) 21 C.F.R. 102.5 - 102.57 (Common or Usual Name for Nonstandardized Foods), as revised as of April 1, 2013 [2006];
(5) 21 C.F.R. 108.35 (Thermal Processing of Low-acid Foods Packaged in Hermetically Sealed Containers), as revised as of April 1, 2013 [2006];
(6) 21 C.F.R. 110.3 - 110.110 (Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food), as revised as of April 1, 2013 [2006];
(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, 2013 [2006];
(8) 21 C.F.R. 114.3 - 114.100 (Acidified Foods), as revised as of April 1, 2013 [2006];
(9) 21 C.F.R. 123.3 - 123.28 (Fish and Fishery Products), as revised as of April 1, 2013 [2006];
(10) 21 C.F.R. 172.160, (Potassium nitrate), as revised as of April 1, 2013 [2006];
(11) 21 C.F.R. 172.170 (Sodium nitrate), as revised as of April 1, 2013 [2006];
(12) 21 C.F.R. 172.175 (Sodium nitrite), as revised as of April 1, 2013 [2006];
(13) 21 C.F.R. 172.385 (Whole fish protein concentrate), as revised as of April 1, 2013 [2006];
(14) 21 C.F.R. 179.21 - 179.45 (Irradiation in the Production, Processing, and Handling of Food), as revised as of April 1, 2013 [2006];
(15) 21 C.F.R. 1240.60 (Control of Communicable Diseases; Molluscan Shellfish), as revised as of April 1, 2013 [2006];

(16) the state plumbing code as developed for this state under AS 18.60.705, as amended from time to time;

(17) repealed / / ; [The Seafood List, FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce 1993;]

(18) repealed / / ; [The National Sanitation Foundation’s (NSF) NSF International White Book: Listing of Proprietary Substances and Nonfood Compounds, as revised as of June 14, 2006;]

(19) National Shellfish Sanitation Program: Guide for the Control of Molluscan Shellfish, 2011 [2005] Revision, United States Department of Health and Human Services, Public Health Service, Food and Drug Administration; this document is adopted by reference as amended from time to time;

(20) American National Standard Sampling Procedures and Tables for Inspection by Attributes, ANSI/ASQC Z1.4 – 2003, as revised as of 2003;

(21) 29 C.F.R. 1910.141(c)(1)(i) and Table J-1, as revised as of July 1, 2000.

(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

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: 2011 Revision may be obtained from the United States Department of Health and Human Services, Food and Drug Administration, Office of Seafood, 5100 Point Branch Parkway, College Park, MD 20740-3835; Internet address:

http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm

[HTTP://WWW.CFSAN.FDA.GOV/~EAR/NSS2-TOC.HTML]. 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. [THE NATIONAL SANITATION FOUNDATION (NSF) INTERNATIONAL WHITE BOOK: LISTING OF PROPRIETARY SUBSTANCES AND NONFOOD COMPOUNDS IS AVAILABLE FOR DOWNLOAD AT:
HTTP://WWW.NSF.ORG/USDA/WHITEBOOK/WHITEBOOK.PDF.]

18 AAC 34.035 (a)(3)(B) is amended to read:

(B) a sanitation plan as required by 18 AAC 34.050 [OR, IF THE APPLICATION IS FOR A DIRECT-MARKET FISHING VESSEL OR A DIRECT-MARKET LAND-BASED FACILITY THAT IS NOT REQUIRED TO HAVE A HACCP PLAN BECAUSE NO HAZARDS WERE IDENTIFIED UNDER 18 AAC 34.045, A SANITATION SCHEDULE AS REQUIRED UNDER 18 AAC 34.525 AND 18 AAC 34.740];

(Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am 8/6/2006, Register 179; am __/ __/ ____.
Register ____ )
18 AAC 34.045(d) is amended to read:

(d) In addition to reviewing a HACCP Plan under 18 AAC 34.930 and 18 AAC 34.940, the department **may** require a processor with a critical violation at a point in the seafood production process that has not already been identified in the processor’s HACCP plan as a critical control point, to submit the HACCP plan to the department for review and comment.

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

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

**18 AAC 34.047. Recall plan.** (a) A processor shall develop and maintain, for department review, written procedures sufficient to notify consumers of a product recall.

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

(c) A processor shall implement the procedures in subsection (a) of this section at the direction of the department. (Effective __/__/____, Register ____)

Authority: AS 17.20.005  AS 17.20.072  AS 44.46.020

AS 17.20.065  AS 17.20.180
18 AAC 34.050(b)(2) is amended to read:

(2) this chapter, including monitoring to ensure compliance with

(A) **18 AAC 34.066** [18 AAC 34.060(7)(A)], as that section [SUBPARAGRAPH] deals with pest control [PROCEDURES USED], including a list of rodenticides, insecticides, and herbicides used and procedures followed to assure that use is restricted to knowledgeable persons to prevent misuse; restricted-use pesticides must be used in accordance with 18 AAC 90;

(B) **18 AAC 34.066** [18 AAC 34.065], as that section deals with proper labeling, storage, and use of chemical compounds;

(C) **18 AAC 34.066** [18 AAC 34.070(a)], as that section [SUBSECTION] deals with the concentration level of each sanitizer used; monitoring for compliance must include the testing frequency for hand and product dips, processing water, and sanitizing solutions for food-contact surfaces;

(D) 18 AAC 34.080, as that section deals with the condition of water that contacts food or food-contact surfaces;

(E) 18 AAC 34.085, as that section deals with the maintenance of hand sanitizing, hand washing, and toilet facilities;

(F) 18 AAC 34.090, as that section deals with cleanliness of equipment and utensils, including containers, pans, and tubs that are used to store and transport seafood products, and areas around equipment and utensils including the walls, floors, and drains; monitoring for compliance must include

(i) the cleaning frequency for non-food-contact surfaces and areas;

(ii) the cleaning and sanitizing frequency for food-contact surfaces before, during, and after processing; monitoring under this subparagraph must include the length of time between each cleaning and sanitizing during each 24 hour period; if the frequency is longer than 24 hours, the processor shall submit to the department and follow a predetermined schedule based on microbial sampling;
(iii) the identification of sanitizer type and the concentration to be used; and

(iv) the time allotted for sanitizer-to-surface contact time;

(G) 18 AAC 34.090 and 18 AAC 34.105, as those sections deal with the prevention of cross-contamination from

(i) insanitary objects to food, food packaging material, and other food-contact surfaces, including utensils, gloves, and outer garments; and

(ii) raw product to cooked product; and

(H) 18 AAC 34.100, as that section deals with instructions given to employees to assure that proper personal hygienic practices are followed, and the control of employee health conditions. (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 17.20.065  
AS 17.20.180  
AS 44.46.020

18 AAC 34.060 is repealed and readopted to read:

18 AAC 34.060. Facility requirements. (a) A processor shall ensure that each facility meets the requirements of 18 AAC 34.075 - 18 AAC 34.085 unless a waiver is approved under 18 AAC 34.915.

(b) Every facility must meet the requirements of 21 C.F.R. 110.20, adopted by reference in 18 AAC 34.010. In addition,

(1) the outside walls and the roof

(A) may be of a flexible material, such as rubberized nylon, polypropylene, polyester-based vinyl, or nylon-based vinyl, that is at least 20 mils thick, with the seams heat-welded; and

(B) must protect the facility from weather and the entry of insects, rodents, and other animals;
(2) sleeping or living quarters must be separated from processing and food or food packaging storage areas by a solid, stationary floor-to-ceiling wall to prevent direct access from these areas to the sleeping or living quarters;

(3) the facility must have lighting of at least

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

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

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

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

(4) the inside walls in

(A) 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 solid material is less than the full height of the wall, the top of the solid material must be sealed to the wall;

(B) 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, glasply panels, or another nonabsorbent, durable, smooth, and easily cleanable material designed for its intended use;

(C) 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

(D) 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;
(5) floors in

(A) 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;

(B) refrigerator and freezer areas that are subject to drippage 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

(C) 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;

(6) floor drains are required in areas where

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

(B) normal operations release or discharge water or other liquid waste onto the floor; or

(C) wastewater could contaminate a processing area. (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 34.065 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__/__/____)
18 AAC 34 is amended by adding a new section to read:

**18 AAC 34.066. Sanitary operations.** (a) Buildings, fixtures, and other physical facilities must be maintained in the manner specified in 21 C.F.R. 110.35(a), adopted by reference in 18 AAC 34.010.

(b) Substances used in cleaning and sanitizing must adhere to the requirements in 21 C.F.R. 110.35(b), adopted by reference in 18 AAC 34.010. In addition, in an area of a facility that is used for processing or for storage of food or food packaging materials, a processor may not use or store a chemical that is a sanitizer, detergent, lubricant, pesticide, or water treatment compound without department approval, based on the department finding that use and storage of the chemical does not pose a threat to public health.

(c) In addition to the pest control provisions in of 21 C.F.R. 110.35(c), adopted by reference in 18 AAC 34.010, a processor shall ensure that

1. restricted-use pesticides are used in accordance with 18 AAC 90;
2. commercially filled containers of pesticides that are to be used or stored in or adjacent to the premises of a facility are labeled as required by 18 AAC 90 and other applicable state or federal law, except that a small container filled or taken from a properly-labeled master container may be used if
   1. the smaller container is labeled with the common name of the material and directions for use; and
   2. the master container is retained onsite; and
3. poisonous chemicals and compounds and pesticides are not stored with food, food ingredients, food packaging materials, equipment, or utensils, except that washing, rinsing, or sanitizing compounds may be stored in a washing area.

(d) In addition to the sanitation of food contact surfaces required in 21 C.F.R. 110.35(d), adopted by reference in 18 AAC 34.010,

1. the concentration level of each chemical or compound used in sanitizing must comply with the manufacturer’s instructions;
(2) the processor shall verify the concentration of each chemical or compound is correct with a test kit, test strip, or other device;

(3) if the frequency between each cleaning and sanitizing period required in the sanitation plan under 18 AAC 34.050(b)(2)(F)(ii) is longer than 24 hours, the processor shall submit to the department and follow a predetermined schedule based on microbial sampling; and

(4) a processor may sanitize by immersion in clean water at a temperature of 170º Fahrenheit or above for at least 30 seconds if a chemical or compound is not used. (Eff. __/__/____.)

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

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 and readopted to read:

18 AAC 34.075. Plumbing. (a) Plumbing must be installed and operated in accordance with the state plumbing code under AS 18.60.705, adopted by reference in 18 AAC 34.010. Except for the toilet and sink requirements specified at 18 AAC 34.085(a), provisions in the plumbing code apply statewide to all facilities subject to this chapter, including mobile processing vessels.

(b) Plumbing must also meet the requirements of 21 C.F.R. 110.37(b), adopted by reference in 18 AAC 34.010. In addition,

(1) if necessary to prevent contamination, atmospheric breaks or backflow preventers on water lines must be used; and
(2) sewer lines, drain lines, and potable and nonpotable water lines must be color coded, tagged, or otherwise identified. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am __/__/ __)

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

18 AAC 34.080(a) is amended to read:

18 AAC 34.080. Water supply and ice. (a) In addition to the requirements in 21 C.F.R. 110.37(a), adopted by reference in 18 AAC 34.010, water [WATER] provided by a processing facility for drinking or ice making for human consumption must comply with 18 AAC 80.

18 AAC 34.080(b) is amended to read:

(b) In addition to complying with (a) of this section, a mobile processing facility that is not directly plumbed to a community public water system or a non-transient non-community [CLASS A] public water system must sample water for coliform bacterial contamination before beginning operations and once every 30 days during the operational season, and must resample the water

(1) according to the same sampling schedule [AS] required in 18 AAC 80.415, or as scheduled 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)(4) [18 AAC 80.300(b)(5)]; or

(2) if a sample is invalidated as set out in 18 AAC 80.425.

18 AAC 34.080(c) is amended to read:

(c) A processing water supply

(1) must be approved by the department, on the basis of whether public health and consumers are adequately protected;

(2) must be disinfected to maintain a measurable residual of free chlorine;
(3) may not exceed the maximum contaminant level for total coliform bacteria set out in 18 AAC 80.300(b)(4) [18 AAC 80.300(b)(5)];

(4) must be tested for compliance with other maximum contaminant levels set out in 18 AAC 80.300, if the department determines that testing serves the interests of public health and consumer protection; and

(5) if from a water system other than a community public water system or non-transient non-community [CLASS A] public water system, must be sampled

   (A) for coliform bacteria contamination before beginning operations and once every 30 days during the operational season, and must be resampled

      (i) according to the same sampling schedule [AS] required in 18 AAC 80.415, or as scheduled 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)(4) [18 AAC 80.300(b)(5)]; however, resampling requires no more than two water samples; or

      (ii) if a sample is invalidated as set out in 18 AAC 80.425; however, resampling requires no more than one water sample;

   (B) 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; [AS THE DEPARTMENT DETERMINES NECESSARY TO SERVE THE INTERESTS OF PUBLIC HEALTH AND CONSUMER PROTECTION,] the department will require more frequent sampling if the department determines it is necessary to serve the interests of public health and consumer protection; and

   (C) at a point near 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; processing water from a transient non-community [CLASS B] public water system approved by the department under 18 AAC 80 is exempt from the requirements of this subparagraph.

18 AAC 34.080(g) is amended to read:

(g) Ice that comes into contact with seafood products must be

(1) made from water that meets the requirements of (c) of this section;

(2) manufactured by the processor in a sanitary manner or [UNLESS THE ICE IS] obtained from an establishment permitted under 18 AAC 31 or this chapter to manufacture ice; and

(3) stored, transported, and handled in a sanitary manner.

(Eff. 12/18/97, Register 144; 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 17.20.072 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 34.080, to affirm the validity of that section following statutory amendments made in ch. 72, SLA 1998. The department repealed and readopted 18 AAC 34.080(a)-(c), amended (e) and (g)(1). [THE DEPARTMENT ALSO REPEALED 18 AAC 34.080(i), MOVING THE DEFINITION OF “CLASS A PUBLIC WATER SYSTEM” TO THE DEFINITIONS SECTION AT 18 AAC 34.990.] Chapter 72, SLA 1998 relocated department authority to adopt regulations in 18 AAC 34 from AS 03.05 to AS 17.20.

18 AAC 34.085 is repealed and readopted to read:

18 AAC 34.085. Toilet and handwash sink requirements. (a) The number of toilets and associated handwash sinks in a land-based facility must comply with the state plumbing code as required
by 18 AAC 34.075. 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.

(b) Toilet rooms must comply with the requirements of 21 C.F.R. 110.37(d), adopted by
reference in 18 AAC 34.010. In addition, toilet rooms must be conveniently located for employee use and
furnished with toilet tissue. Toilet rooms must have an adequate number of handwash sinks with hot and
cold running water, and must be furnished with sanitary hand towels or another drying device.

(c) In addition to the requirements of 21 C.F.R. 110.37(e) for hand-washing facilities, adopted
by reference in 18 AAC 34.010, a sign must be posted in each toilet room directing employees to wash
their hands with soap before returning to work stations. The signs must be printed in English and in other
languages or pictures if necessary for employee understanding.

(d) 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 toilet and privy meets the applicable requirements of 18 AAC 72;

(4) each toilet and privy is conveniently located for employee use;

(5) each 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 described in (c) of this section are posted at each toilet or privy and
at the entrance to the processing area.

(e) A facility that is under construction or is being extensively remodeled on December 18, 1997,
or that is built or extensively remodeled after December 18, 1997, must have handwash sinks in or
immediately adjacent to processing areas. A facility in existence on December 18, 1997, that operates at
any time on or after that date is, until extensively remodeled, not required to install handwash sinks in the
processing areas, but must provide hand sanitizers in the processing areas. A processor may meet the hand sanitizer requirement of this subsection by having in the processing areas hand sanitizers containing a sanitizing solution that complies with the manufacturer’s instructions for hand sanitizers.

(f) A handwash sink required under this section must have hot and cold running water and be equipped with a mixing valve. Self-dispensing or metering faucets must provide a flow of water for at least 20 seconds. Hand-cleaning soap must be provided at each sink. (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 34.090 is repealed and readopted to read:

18 AAC 34.090. Equipment and utensils. (a) Equipment and utensils must meet the requirements of 21 C.F.R. 110.40, adopted by reference in 18 AAC 34.010.

(b) Utensils and food-contact surfaces of equipment must be cleaned, rinsed, and sanitized according to the schedule in the sanitation plan required by 18 AAC 34.050.

(c) Processes and controls as described in 21 C.F.R. 110.80, adopted by reference in 18 AAC 34.010, must be followed for all equipment and utensils. (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 34.100 repealed and readopted to read:

18 AAC 34.100. Personnel. (a) In addition to the requirements of 21 C.F.R. 110.10, adopted by reference in 18 AAC 34.010, a processor shall take all reasonable precautions to ensure that a person with an infected wound or a disease communicable by food, including an employee with persistent
sneezing, coughing, or a runny nose, does not work in any capacity that might contaminate seafood products, food ingredients, food-contact surfaces, or food packaging materials with an infectious or toxigenic micro-organism, or that might transmit disease to others. The processor shall instruct employees to report an adverse health condition to their supervisor.

(b) A processor shall ensure that

1. each applicant to whom a conditional offer of employment is made and any employee who works in direct contact with seafood products, food ingredients, food-contact surfaces, or packaging materials reports each of the following conditions to the processor, including the date of onset as it relates to diseases that are transmissible through food, if the employee or applicant has, or is diagnosed with, that condition:

   A. vomiting;
   B. diarrhea;
   C. jaundice;
   D. sore throat with fever;
   E. a lesion containing pus, such as a boil or infected wound, that is open and draining and is
      1. on the hands or wrists, unless an impermeable cover such as a finger cot or stall, protects the lesion and a single-use glove is worn over the impermeable cover; or
      2. on other exposed portions of the body, unless the lesion is protected by an impermeable cover;
   F. *Salmonella Typhi*, within the previous three months, without the individual having received antibiotic therapy;
   G. *Shigella* spp.;
   H. Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*;
(I) hepatitis A virus;

(J) Norovirus

(2) an employee or applicant who is experiencing a symptom of a disease transmissible by food as described in (1)(A) – (1)(E) of this subsection is either excluded or restricted as listed in Table A of this section;

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Exclusion or Restriction</th>
<th>Removing Exclusion or Restriction*</th>
<th>Department of Environmental Conservation Approval Needed to Work?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vomiting</td>
<td>Exclude</td>
<td>Exclude</td>
<td>No</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>Exclude</td>
<td>Exclude</td>
<td>No</td>
</tr>
<tr>
<td>Jaundice</td>
<td>Exclude if the onset occurred within the last seven days</td>
<td>Exclude if the onset occurred within the last seven days</td>
<td>Yes, unless medical documentation is provided to the operator.</td>
</tr>
<tr>
<td>Condition</td>
<td>Exclude</td>
<td>Restrict</td>
<td>When the employee provides written medical documentation to the operator.</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>---------</td>
<td>----------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Sore Throat with Fever</td>
<td>Exclude</td>
<td>Restrict</td>
<td>When the employee provides written medical documentation to the operator.</td>
</tr>
<tr>
<td>Lesion Containing Pus</td>
<td>Restrict</td>
<td>Restrict</td>
<td>When the infected wound or boil is properly covered.</td>
</tr>
</tbody>
</table>

* An exclusion or restriction may be removed for any symptom if the excluded or restricted employee provides medical documentation to the processor that the condition is from a non-infectious condition and that the risk of transmitting a pathogenic microorganism is minimal.

(3) in addition to the requirements of (a) of this section, the processor contacts the department, verbally or electronically, within 24 hours after being notified that an employee or applicant has been diagnosed by a health practitioner as having a disease as described in (1)(F) – (J) of this subsection or is jaundiced; each notification must provide the date, name of the diagnosed disease, and the name and contact information of the food establishment reporting the diagnosed disease.

(c) In this section, “restrict” or “restriction” means to limit the activities of an employee so that there is no risk of transmitting a disease that is transmissible through food and the employee does not work with exposed food, clean food-contact surfaces, linens, or unwrapped single-service or single-use articles.

(d) A processor shall ensure that, whenever seafood products are being processed, there is in the processing facility a person responsible for identifying sanitation problems and potential food contamination who has the education and experience necessary for the production of unadulterated seafood products.

**Authority:**

- AS 17.20.005
- AS 17.20.072
- AS 44.46.020
- AS 17.20.065
- AS 17.20.180
18 AAC 34.105(b) is amended to read:

(b) In addition to the requirements of 21 CFR 110.80, adopted by reference in 18 AAC

34.010. a [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.

18 AAC 34.105(f) is amended to read:

(f) The processor shall, upon receipt and before additional processing or packaging, inspect and adequately rinse [WASH] seafood products, including those butchered or filleted in another permitted facility.

(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 34.110 is repealed and readopted to read:

18 AAC 34.110. Labeling requirements. (a) Unless a seafood product is for export only, a processor shall label seafood products as required under this section.

(b) Labels must adhere to the requirements in 21 C.F.R. 101.1 - 101.108 and 21 C.F.R. 102.5 - 102.57, adopted by reference in 18 AAC 34.010. In addition,

(c) The master carton and, if packaged for retail sale, each retail container of a seafood product must be indelibly marked at the time of sealing with the date of packaging. Before distribution, at least one area of the master carton and retail container must be labeled with

(1) the permit number reserved for and assigned to the processor under 18 AAC 34.035(c); if more than one processor is involved in manufacturing a seafood product, the permit number must be that of the processor who last handled the product before sealing; if the department
determines that use of a code serves the interests of public health and consumer protection, the department will allow a code that is on file with the department to be used instead of

(A) the date of packaging; or

(B) the processor's permit number, if the seafood product has been thermally processed; if, under this subparagraph, the department allows use of a code rather than the processor’s permit number, the code that is allowed for use must be the establishment number issued by the Seafood Products Association or a letter code issued by the department;

(2) the identity and name of the seafood product, as approved by the department, or a market or common name;

(3) a holding statement, as appropriate considering the type of seafood product, and in compliance with the following requirements:

(A) if the seafood product is not shelf-stable, the label must bear the holding statement “KEEP REFRIGERATED” or “KEEP FROZEN”;

(B) if the smoked finfish seafood product is not commercially sterile and is packaged in a reduced oxygen package or a modified atmosphere package, and if each package

(i) contains 3.5 percent water phase salt, contains, if allowed by 21 C.F.R. 172.175, adopted by reference in 18 AAC 34.010, both 3.0 percent water phase salt and not less than 100 ppm nitrite, contains other suitable barriers to control Clostridium botulinum, or is equipped with a time temperature indicator, the label must bear the holding statement “KEEP REFRIGERATED BELOW 38º F” or “KEEP FROZEN”; or

(ii) does not contain 3.5 percent water phase salt, does not contain both 3.0 percent water phase salt and not less than 100 ppm nitrite, does not contain other suitable barriers to control Clostridium botulinum, or is not equipped with a time temperature indicator, the label must bear the holding statement “KEEP FROZEN, THAW UNDER REFRIGERATION IMMEDIATELY BEFORE USE”;
(C) the holding statement must be in letters at least one-eighth inch high and comparable in size and style to other label lettering;

(D) upon application by the processor, the department will approve the removal of a holding statement as required under this paragraph

(i) for a seafood product that is not thermally processed, or for a pickled seafood product that meets the requirements of 21 C.F.R. 114.3 – 21 C.F.R. 114.100, adopted by reference in 18 AAC 34.010; and

(ii) if the testing conducted under 18 AAC 34.125 demonstrates that the seafood product meets the requirements of that section and 18 AAC 34.122 for shelf-stable seafood products; and

(4) the words “PREVIOUSLY FROZEN” if the container holds a seafood product that has been previously frozen and thawed and that will be sold without further processing; the words “PREVIOUSLY FROZEN” must appear in letters of sufficient size and prominence to be easily read under normal conditions of sale.

(d) A container of a seafood product intended for domestic processing, labeling, or repacking at another facility is exempt from the labeling requirements as specified in 21 C.F.R. 101.100, adopted by reference in 18 AAC 34.010. The processor shall ensure that distribution of that seafood product meets the requirements of 21 C.F.R. 101.100(d)(1) and (2), and (e), adopted by reference in 18 AAC 34.010.

(e) In addition to segregating food according to 18 AAC 34.105(b), a processor shall label each of the following with the words "NOT FOR SALE":

(1) a container of a seafood product that is being held or processed at a facility subject to this chapter and that is from seafood caught while sport fishing, subsistence fishing, or personal use fishing;

(2) a container of a processed seafood product that was not processed in compliance with this chapter.
(f) A processor who uses farmed salmon from other states or countries to manufacture salmon products in this state must label the product “Made with farmed salmon from [state or country].”

(g) In addition to complying with the labeling requirements of this section, a custom processor shall label smoked, custom-processed seafood as required by 18 AAC 34.310(i).

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 must meet the standards below; products that do not meet the standards are unsuitable for human consumption.

(1) For fresh or frozen seafood products other than shellfish,

(A) organoleptic: no 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;

(B) Salmonella spp.: none;

(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 decomposition detected.
(3) For smoked salmon or sablefish,
   (A) sodium nitrite: less than or equal to 200 ppm;
   (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, other than shelf-stable salted seafood product,
   (A) the product must meet the standards in subsection (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 shelf-stable salted seafood product,
   (A) the product must meet the standard in (6)(C)(ii) of this section;
   (B) the product must be produced under conditions where the product has been
   maintained at a temperature below 60º Fahrenheit during processing; and
   (C) the product must have a maximum ratio of raw product to salt of 2:1 for a
   dry brine process, or a minimum ratio of raw product to rock salt of 3:1 for a wet brine process.

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

(B) shucked and eviscerated, fresh or frozen, except oysters:

(i) a fecal coliform density of less than or equal to 100 MPN per 100 grams, or the equivalent; and
(ii) an aerobic or standard plate count of less than or equal to 100,000 colony-forming units (CFU) per gram, or the equivalent.

(9) For live, fresh, or frozen snails and shellfish, including uneviscerated shellstock,

(A) PSP: less than 80 µg; and
(B) Domoic acid: less than 20 ppm.

(10) For live, fresh, cooked, or frozen whole crab product:

(A) PSP: less than 80 µg; and
(B) Domoic acid: less than 30 ppm. (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 44.46.02

18 AAC 34.125(a) is amended to read:

(a) Except as provided in (g) of this section, the department may [AT ITS EXPENSE] test nonstatistical, nonrepresentative samples of seafood products for compliance with 18 AAC 34.122, for the presence of other marine toxins, for the presence of heavy metals, or for the presence of other
contaminants of public health significance. [A PROCESSOR MAY NOT CHARGE THE DEPARTMENT MORE THAN THE AVERAGE WHOLESALE MARKET PRICE FOR A SAMPLE.]

18 AAC 34.125(d) is amended to read:

(d) To show compliance with 18 AAC 34.122(2) [18 AAC 34.122(3)], a processor using a process that has not been approved by the department for a refrigerated or frozen ready-to-eat product shall submit samples of the product to a qualified laboratory as follows:

(1) three product samples from every production lot; each lot of product must be held by the processor until testing and approval by the department allows release; and

(2) after six consecutively acceptable lot samples under (1) of this subsection are obtained, one product sample from the first lot produced each month; the processor may release a lot of product after submitting a product sample from that lot.

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 (1) USING AOAC OFFICIAL METHOD 935.48, WHEN TESTING FOR SODIUM OR POTASSIUM NITRATE; AND]
(2) USING AOAC OFFICIAL METHOD 973.31, WHEN TESTING FOR SODIUM NITRITE.

(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 17.20.070 AS 17.20.180 AS 17.20.200 AS 17.20.072 AS 17.20.065 AS 17.20.180 AS 44.46.020

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, AND AQUATIC PLANTS: “seafood” includes any part or byproduct of any species of aquatic organism;

18 AAC 34.990(79) is repealed:

(79) repealed__/__/____;

18 AAC 34.990(80) is repealed:

(80) repealed__/__/____;

18 AAC 34.990 is amended by adding a new subsection to read:

(87) “community public water system” has the meaning given in 18 AAC 80;

18 AAC 34.990 is amended by adding a new subsection to read:

(88) “non-transient non-community public water system” has the meaning given in 18 AAC 80;
18 AAC 34.990 is amended by adding a new subsection to read:

(89) “transient public water system” has the meaning given in 18 AAC 80. (Eff. 12/18/97, Register 144; readopt 12/2/99, Register 152; am 8/6/2006, Register 179; am 11/24/2007, Register 184; am __/__/____, Register ____)

Authority:

<table>
<thead>
<tr>
<th>AS 17.20.005</th>
<th>AS 17.20.065</th>
<th>AS 17.20.250</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS 17.20.010</td>
<td>AS 17.20.066</td>
<td>AS 17.20.260</td>
</tr>
<tr>
<td>AS 17.20.020</td>
<td>AS 17.20.070</td>
<td>AS 17.20.270</td>
</tr>
<tr>
<td>AS 17.20.030</td>
<td>AS 17.20.072</td>
<td>AS 17.20.280</td>
</tr>
<tr>
<td>AS 17.20.040</td>
<td>AS 17.20.180</td>
<td>AS 17.20.290</td>
</tr>
<tr>
<td>AS 17.20.044</td>
<td>AS 17.20.200</td>
<td>AS 17.20.305</td>
</tr>
<tr>
<td>AS 17.20.045</td>
<td>AS 17.20.230</td>
<td>AS 17.20.340</td>
</tr>
<tr>
<td>AS 17.20.050</td>
<td>AS 17.20.240</td>
<td>AS 44.46.020</td>
</tr>
</tbody>
</table>
NOTICE OF PROPOSED CHANGES IN THE
REGULATIONS OF THE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

BRIEF DESCRIPTION
The Alaska Department of Environmental Conservation (ADEC) is proposing revised regulations to streamline federal and state seafood processing requirements.

The Department of Environmental Conservation proposes to adopt regulation changes in Title 18 of the Alaska Administrative Code, dealing with processing seafood products, including the following:

- 18 AAC 34.010, which includes updating requirements adopted by reference
- 18 AAC 34.035, which includes removing obsolete language
- 18 AAC 34.045, which includes removing obsolete language
- Adding a new section, 18 AAC 34.047 addressing seafood product recall plans
- 18 AAC 34.060, which includes clarifying reference to the corresponding Code of Federal Regulations (C.F.R.) and removing language duplicative of C.F.R. requirements
- Repealing 18 AAC 34.065 and 18 AAC 34.070 and adding a new section 18 AAC 34.066, Sanitary Operations, to combine relevant portions of repealed sections and make our regulation easier to read and understand in conjunction with the C.F.R.
- 18 AAC 34.075, which includes clarifying reference to the corresponding C.F.R., removing language duplicative of C.F.R. requirements, and removing obsolete language
- 18 AAC 34.080, which includes clarifying reference to the corresponding C.F.R. and updating cross-references
- 18 AAC 34.085, which includes clarifying reference to the corresponding C.F.R., removing language duplicative of C.F.R. requirements, and removing obsolete language
- 18 AAC 34.090, which includes clarifying reference to the corresponding C.F.R. and removing language duplicative of C.F.R. requirements
- 18 AAC 34.100, which includes clarifying reference to the corresponding C.F.R., removing language duplicative of C.F.R. requirements, and clarifying reporting and exclusion requirements for health conditions transmissible through food
- 18 AAC 34.105, which includes clarifying reference to the corresponding C.F.R.
- 18 AAC 34.110, which includes clarifying reference to the corresponding C.F.R. and removing language that duplicates C.F.R. requirements or other statutory provisions
- 18 AAC 34.122, which includes a substantial reorganization to make it easier to read and changing the crab PSP limit
- 18 AAC 34.990 updates to the definitions section
- Several subsections are amended to reflect changes in numbering and cross-references throughout the regulation
- Several subsections are being amended with slight wording changes to improve overall clarity of the regulation

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Brehan Kohl at Alaska Department of Environmental Conservation, 555 Cordova Street Anchorage, AK 99501. Additionally, the department will accept comments by facsimile at 907-269-7510 and by electronic mail at brehan.kohl@alaska.gov. The comments must be received no later than 4:30 p.m. on December 30, 2013.
A series of public workshops to facilitate an understanding of the regulation changes will be held. If you are unable to attend in person, you may teleconference in by dialing 1-800-315-6338, and, when prompted, enter 7643#. The times, dates, and locations are as follows:

10:00 a.m. November 8, 2013, DEC Main Floor Conference Room, 555 Cordova Street, Anchorage, Alaska.

10:00 a.m. November 19, 2013, Seafood Products Association, 1600 S. Jackson Street, Seattle, Washington.

1:00 p.m., November 20, 2013, DEC Juneau Conference Room, 2d floor, 410 Willoughby Avenue, Juneau, Alaska.

The State of Alaska, Department of Environmental Conservation complies with Title II of the Americans with Disabilities Act of 1990. If you are a person with a disability who may need a special accommodation in order to participate in this public process, please contact Deborah Pock at (907) 269-0291 or TDD Relay Service 1-800-770-8973/TTY or dial 711 ten days prior to any workshop or the final comment deadline to ensure that any necessary accommodations can be provided.

For a copy of the proposed regulation changes, contact Brehan Kohl at 555 Cordova Street, Anchorage, AK 99501 or 907-269-7636, or go to http://dec.alaska.gov/eh/fss/index.htm.

After the public comment period ends, the Department of Environmental Conservation will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulations may be different from that of the proposed regulations. You should comment during the time allowed if your interests could be affected. Written comments received are public records and are subject to public inspection.

Statutory Authority: AS 17.20.180; AS 44.46.020

Statutes Being Implemented, Interpreted, or Made Specific: AS 17.20.005; AS 17.20.010; 17.20.020-AS 17.20.072; AS 44.46.020

Fiscal Information: The proposed regulation changes are not expected to require an increased appropriation.

DATE: September 27, 2013

Larry Hartig, Commissioner,
Department of Environmental Conservation
ADDITIONAL REGULATIONS NOTICE INFORMATION
(AS 44.62.190(d))

1. Adopting agency: Department of Environmental Conservation, Division of Environmental Health

2. General subject of regulation: Seafood Processing

3. Citation of regulation (may be grouped): 18 AAC 34

4. Department of Law file number, if any: JU2012200958

5. Reason for the proposed action: Meet FDA contract/grant requirements and update/clarify old regulatory language

6. Appropriation/Allocation: 0

7. Cost of implementation to the state agency and available funding (in thousands of dollars):

<table>
<thead>
<tr>
<th></th>
<th>Initial Year</th>
<th>Subsequent Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Cost</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Capital Cost</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Federal receipts</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>General fund match</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>General fund</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>General fund/program</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>General fund/mental health</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Other funds (specify)</td>
<td>$0</td>
<td>$0</td>
</tr>
</tbody>
</table>

8. The name of the contact person for the regulations:
   Name: Jennifer Kosin
   Title: Program Coordinator, Division of Environmental Health Director’s Office
   Address: 555 Cordova Street
   Anchorage, Alaska 99501
   Telephone: (907) 269-6066
   E-mail address: jenny.kosin@alaska.gov

9. The origin of the proposed action: staff of state agency; DEC Division of Environmental Health

10. Date: September 20, 2013
     Prepared by: ____________________________
       Name (typed) Jennifer Kosin
       Title (typed) Program Coordinator
       Telephone: (907) 269-6066
Main measures of the Common Fisheries Reform adopted by the Council

The Council adopted today its position on two proposals for regulations on the common fisheries policy (CFP) reform following an early second reading agreement with the European Parliament:

– Proposal for a regulation on the CFP (12007/13) replacing the basic provisions of the common fisheries (basic regulation);

– Proposal for a regulation on the common organisation of the markets (CMO) in fishery and aquaculture products (12005/13), focusing on market policy issues (market regulation);

The European Parliament's Fisheries Committee approved the political agreement on the two proposals on 18 June 2013. Since then, a detailed legal-linguistic review took place. The regulation should be applicable after the final reading in the Plenary of the European Parliament once it has been formally signed and published in the Official Journal.

The regulation on basic provisions of the CFP and the market regulation are two of the three texts of the CFP reform "package" together with the proposal on the European Maritime and Fisheries Fund (EMFF) which will be discussed later this year between the EU institutions.
The main elements of the final compromise text on basic provisions of the CFP are as follows:

- Management of fish stocks including total allowable catches (TACs) & quotas according to the maximum sustainable yield (MSY) following from the scientific advice. This will lead to healthy fish stocks and higher quotas in a lasting manner;
- The discard of fish stocks will no longer be allowed ending the old policy which forced fishermen to waste food by discarding fish at sea. Some flexibility instruments ensuring the applicability of the measure have been included.
- Fishermen and other interest groups, as well as national administrations are at the core of developing technical and conservation measures to protect juvenile fish and vulnerable fish species with a completely new regionalised decision making approach.
- Biologically sensitive areas with spawning grounds and high populations of juvenile fish should be developed and strengthened.

For further details on the key elements see document (10395/13)

As regards the market regulation, the compromise text clarifies in particular mandatory consumer information on product marking and labeling. Mandatory information includes now the gear type used in wild capture fisheries and the requirement of a more detailed indication of the catch area. A list of gear types has been established at technical level. The Commission is also requested to report on the way forward concerning EU-eco-labels for fishery products.

In addition, the compromise text reforms the role of producer organisations which will have less administrative market intervention mechanism at hand. Focus is now given to their own marketing strategies expressed in their production and marketing plans, and a close involvement in the general policy direction, e.g. concerning discard avoidance.
Article 34
Compliance with common marketing standards

1. The products intended for human consumption for which common marketing standards are laid down may be made available on the Union market only in accordance with those standards.

2. All fishery products landed, including those that do not comply with common marketing standards, may be used for purposes other than direct human consumption, including fish meal, fish oil, pet food, food additives, pharmaceuticals or cosmetics.

Chapter IV
Consumer information

Article 35
Mandatory information

1. Without prejudice to Regulation (EU) No 1169/2011, fishery and aquaculture products referred to in points (a), (b), (c) and (e) of Annex I to this Regulation which are marketed within the Union, irrespective of their origin or of their marketing method, may be offered for sale to the final consumer or to a mass caterer only if appropriate marking or labelling indicates:

   (a) the commercial designation of the species and its scientific name;
(b) the production method, in particular by the following words "…caught…" or "…caught in freshwater.." or "…farmed…";

(c) the area where the product was caught or farmed, and the category of fishing gear used in capture of fisheries, as laid down in the first column of Annex III to this Regulation;

(d) whether the product has been defrosted;

(e) the date of minimum durability, where appropriate.

The requirement in point (d) shall not apply to:

(a) ingredients present in the final product;

(b) foods for which freezing is a technologically necessary step in the production process;

(c) fishery and aquaculture products previously frozen for health safety purposes, in accordance with Annex III, Section VIII, of Regulation (EC) No 853/2004;

(d) fishery and aquaculture products which have been defrosted before the process of smoking, salting, cooking, pickling, drying or a combination of any of those processes.
2. For non-prepacked fishery and aquaculture products, the mandatory information listed in paragraph 1 may be provided for retail sale by means of commercial information such as billboards or posters.

3. Where a mixed product is offered for sale to the final consumer or to a mass caterer that consists of the same species but which has been derived from different production methods, the method for each batch shall be stated. Where a mixed product is offered for sale to the final consumer or to a mass caterer that consists of the same species but which has been derived from a variety of catch areas or fish-farming countries, at least the area of the batch which is most representative in terms of quantity shall be stated, together with an indication that the products also come from different catch or fish-farming areas.

4. Member States may exempt from the requirements referred to in paragraph 1 small quantities of products sold directly from fishing vessels to consumers, provided that those do not exceed the value referred to in Article 58(8) of Regulation (EC) No 1224/2009.

5. Fishery and aquaculture products and their packages which were labelled or marked prior to 13 December 2014 and which do not comply with this Article may be marketed until such stocks have been used up.
Article 36

Eco-labelling reporting

After consulting Member States and stakeholders, the Commission shall, by 1 January 2015, submit to the European Parliament and to the Council a feasibility report on options for an eco-label scheme for fishery and aquaculture products, in particular on establishing such a scheme on a Union-wide basis and on setting minimum requirements for the use by Member States of a Union eco-label.

Article 37

Commercial designation

1. For the purposes of Article 35(1), Member States shall draw up and publish a list of the commercial designations accepted in their territory, together with their scientific names. The list shall indicate:

(a) the scientific name for each species, in accordance with the FishBase Information System or the ASFIS database of the Food and Agriculture Organization (FAO), where relevant;
(b) the commercial designation:

(i) the name of the species in the official language or languages of the Member State concerned;

(ii) where applicable, any other name or names that are accepted or permitted locally or regionally.

2. All species of fish which constitute an ingredient of another food may be designated as "fish", provided that the name and presentation of such food does not refer to a specific species.

3. Any changes to the list of commercial designations accepted by a Member State shall be notified forthwith to the Commission which shall inform the other Member States thereof.
Article 38

Indication of the catch or production area

1. The indication of the catch or production area in accordance with point (c) of Article 35(1) shall consist of the following:

(a) in the case of fishery products caught at sea, the name in writing of the sub-area or division listed in the FAO fishing areas, as well as the name of such zone expressed in terms understandable to the consumer, or a map or pictogram showing that zone, or, by way of derogation from this requirement, for fishery products caught in waters other than the Northeast Atlantic (FAO Fishing Area 27) and the Mediterranean and Black Sea (FAO Fishing Area 37), the indication of the name of the FAO fishing area;

(b) in the case of fishery products caught in freshwater, a reference to the body of water of origin in the Member State or third country of provenance of the product;

(c) In the case of aquaculture products, a reference to the Member State or third country in which the product reached more than half of its final weight or stayed for more than half of the rearing period or, in the case of shellfish, underwent a final rearing or cultivation stage of at least six months.

2. In addition to the information referred to in paragraph 1, operators may indicate a more precise catch or production area.
### ANNEX III

#### INFORMATION ON FISHING GEAR

<table>
<thead>
<tr>
<th>Mandatory information on the category of fishing gear</th>
<th>More detailed information on corresponding gears and codes, in accordance with Commission Regulation (EC) No 26/2004(^1) and Commission Implementing Regulation (EU) No 404/2011(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Seines</strong></td>
<td></td>
</tr>
<tr>
<td>Beach seines</td>
<td>SB</td>
</tr>
<tr>
<td>Danish seines</td>
<td>SDN</td>
</tr>
<tr>
<td>Scottish seines</td>
<td>SSC</td>
</tr>
<tr>
<td>Pair seines</td>
<td>SPR</td>
</tr>
<tr>
<td><strong>Trawls</strong></td>
<td></td>
</tr>
<tr>
<td>Beam trawls</td>
<td>TBB</td>
</tr>
<tr>
<td>Bottom otter trawls</td>
<td>OTB</td>
</tr>
<tr>
<td>Bottom pair trawls</td>
<td>PTB</td>
</tr>
<tr>
<td>Midwater otter trawls</td>
<td>OTM</td>
</tr>
<tr>
<td>Pelagic pair trawls</td>
<td>PTM</td>
</tr>
<tr>
<td>Otter twin trawls</td>
<td>OTT</td>
</tr>
<tr>
<td><strong>Gillnets and similar nets</strong></td>
<td></td>
</tr>
<tr>
<td>Set (anchored) gillnets</td>
<td>GNS</td>
</tr>
<tr>
<td>Driftnets</td>
<td>GND</td>
</tr>
<tr>
<td>Encircling gillnets</td>
<td>GNC</td>
</tr>
<tr>
<td>Trammel nets</td>
<td>GTR</td>
</tr>
<tr>
<td>Combined trammel and gillnets</td>
<td>GTN</td>
</tr>
</tbody>
</table>

---


<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surrounding nets and lift nets</strong></td>
<td>Purse seines PS</td>
</tr>
<tr>
<td></td>
<td>Lampara nets LA</td>
</tr>
<tr>
<td></td>
<td>Boat operated lift nets LNB</td>
</tr>
<tr>
<td></td>
<td>Shore-operated stationary lift nets LNS</td>
</tr>
<tr>
<td><strong>Hooks and lines</strong></td>
<td>Hand lines and pole lines (hand operated) LHP</td>
</tr>
<tr>
<td></td>
<td>Hand lines and pole lines (mechanised) LHM</td>
</tr>
<tr>
<td></td>
<td>Set longlines LLS</td>
</tr>
<tr>
<td></td>
<td>Longlines (drifting) LLD</td>
</tr>
<tr>
<td></td>
<td>Troll lines LTL</td>
</tr>
<tr>
<td><strong>Dredges</strong></td>
<td>Boat dredges DRB</td>
</tr>
<tr>
<td></td>
<td>Hand dredges used on board a vessel DRH</td>
</tr>
<tr>
<td></td>
<td>Mechanised dredges including suction dredges HMD</td>
</tr>
<tr>
<td><strong>Pots and traps</strong></td>
<td>Pots (traps) FPO</td>
</tr>
</tbody>
</table>