18 AAC 34 Seafood Processing and Inspection
Proposed Amendments FAQs

Last Updated 11/27/2018

The Department of Environmental Conservation (DEC) proposes to adopt regulation changes in Title 18, Chapter 34 of the Alaska Administrative Code, dealing with seafood processing and inspection.

Amendments include revisions to cite federal rules which will be adopted by reference, rather than using old language that was previously paraphrased based on federal rules. Amendments will standardize the approach to make the standards clearer and avoid inconsistencies between the federal requirement and the written regulations. Additional changes relating to recall plans, sanitation plans, and product sampling are also proposed.

What are the main changes I should be aware of and how will the changes affect me?

First, the proposed changes streamline, update, and simplify the regulations. This should make it easier to understand requirements. In addition, the department proposes some significant substantive revisions, including:

- Adoption of 21 CFR Part 117, including provisions dealing with allergen cross-contact, employee training, and human food by-products used for animal foods;
- Development of a written recall plan;
- Changes to routine sampling for frozen, ready-to-eat, and shelf-stable products; and
- Changes to the general, inspection, and compliance article that reflect current inspection processes and practices.

How has DEC reorganized the code?

DEC has significantly reorganized the sections of the regulations dealing with Good Manufacturing Practices (GMPs). Previously, these provisions were found in Sections 060 - 105. Now, these requirements have relocated and many have been renamed to match up with the section names found in the Code of Federal Regulations (CFR) that address GMPs. Below is a table to help you track the reorganized sections:

Good Manufacturing Practices (GMP) Reorganization	
Current	**Proposed**
18 AAC 34.055 Facility plan approval	18 AAC 34.035 Permit requirements
18 AAC 34.060 Facility requirements	18 AAC 34.810 Plant & grounds
18 AAC 34.065 Chemicals and compounds	18 AAC 34.815 Sanitary operations

18 AA C 34.070 Sanitizing	18 AAC 34.815 Sanitary operations 18 AAC 34.820 Sanitary facilities & controls
18 AAC 34.075 Plumbing	18 AAC 34.820 Sanitary facilities & controls
18 AAC 34.080 Water supply & ice	18 AAC 34.820 Sanitary facilities & controls 18 AAC 34.830 Processes & controls; handling; ice
18 AAC 34.085 Toilet & handwash sink requirements	18 AAC 34.820 Sanitary facilities & controls
18 AAC 34.090 Equipment & utensils	18 AAC 34.825 Equipment & utensils
18 AAC 34.095 Waste disposal	18 AAC 34.820 Sanitary facilities & controls
18 AAC 34.100 Personnel	18 AAC 34.803 Qualifications & training 18 AAC 34.805 Personnel
18 AAC 34.105 Handling	18 AAC 34.830 Processes & controls; handling; ice

In addition to relocating the GMP sections, there were a few provisions that made more sense in different locations. In the draft regulations project, you'll note the current provision is marked, "repealed." For the following, the language is not being deleted, but is simply being relocated to a more appropriate section elsewhere in the project:

Relocated for Improved Flow	
Current	**Relocation**
18 AAC 34.050(d)	18 AAC 34.940
18 AAC 34.110(b)	18 AAC 34.112(b)
18 AAC 34.080(f)	18 AAC 34.602
18 AAC 34.125(a)	18 AAC 34.930(b)

How has DEC simplified Alaska's regulations?

The department did a thorough comparison of 18 AAC 34 and the federal requirements. In doing so, we found that some language in 18 AAC 34 duplicated in federal code. In other places, it was not entirely clear when or how some of the materials adopted by reference applied. For each of the GMP requirements, in particular, the department identified and deleted duplicate language. As well, it is now clear when Alaska has additional or more specific requirements.

What regulations include Alaska specific requirements?

Because the CFR is designed to apply to all types of food processors throughout the nation, it is necessarily broad. While this allows for new technologies and novel ways of meeting the requirements, it is important that a regulatory agency be clear with the regulated public through regulations when the agency is applying a standard or a requirement broadly. For seafood processors in Alaska, there are certain standards or requirements that DEC applies across the board, so it is appropriate to clearly state the requirement through regulation. Examples of situations where Alaska has outlined requirements in addition to or specifying an adopted federal rule include,

- Permit requirements;
- Labeling with the Alaska-issued permit number;
- Definitions of adulterated and misbranded products that are found in Alaska statute;
- Rules implementing special requirements during an oil spill;
- Specific requirements dealing with plant and grounds;
- Specific requirements dealing with sanitary facilities and controls, including plumbing, water supply, toilet and handwash sinks, and waste disposal; and
- Specific processes and controls requirements, including handling and ice supply.

How is Alaska proposing to adopt 21 CFR Part 117?

One of the more significant proposed changes is the adoption of 21 CFR Part 117, the federal rule already required by FDA that includes a few new provisions for seafood processors and updates the cGMPs. Specifically, those provisions new to seafood processors under this rule are mandatory employee education and training requirements, controlling for allergen cross-contact, and requirements for handling human food by-products that are used for animal foods. Alaska is simply updating its code to reflect national standards and many Alaskan firms are already compliant with these rules.

What are the employee education and training requirements?

Though seafood processors are already required under both federal and state regulations to train employees in sanitation, 21 CFR Part 117 now makes specific they type of training needed and now requires documentation of the training. There are three elements of the training requirements:

1. Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
2. The employees must be trained in the principles of food hygiene and food safety, including the importance of employee health and hygiene as appropriate to the food, the facility, and the individual's assigned duties.
3. Records of training must be maintained.

What is required to comply with new rules concerning food allergen cross-contact?

All seafood firms must already address allergens through labeling within their HACCP plan. Cross-contact is a bit different, though. Cross-contact becomes a concern when a firm is producing products that contain an allergen, like tuna fish sandwiches, and other products that do not, like ham sandwiches. In a case where cross-contact is a concern, firms are required to develop procedures, practices, and processes to control the hazard.

When and how do rules concerning human food by-products used as animal food apply to me?

The updated GMPs contain provisions for holding and distributing human food by-products that are used for animal food. Human food by-products used for animal food are typically: (1) distributed (sold or given away) to an animal producer to be fed directly to livestock, (2) distributed to another facility that will further process them for animal food use, or (3) further processed for animal food use at the human food facility. Requirements differ depending on what the firm is doing. For a complete discussion of these rules, the FDA has developed Guidance for Industry: Human Food By-Products for Use as Animal Food, publication #239.

What is DEC proposing regarding a written recall plan?

Though HACCP requires that a corrective action plan define how a firm will remove affected product when there is a deviation from a critical limit, situations involving misbranding or adulterated products for other reasons may not fall under HACCP. Additionally, in the rare cases where a product must be recalled, the department has found that some firms have no plan to recover product that has been distributed into commerce. For these reasons, we propose a simple, written plan that includes the procedures that describe the steps to perform the recall and at minimum assigns responsibility for:

1. Notifying the direct consignees of the food being recalled, including how to return or dispose of the affected food;
2. Notifying the public about hazards in the food;
3. Conducting effectiveness checks; and
4. Appropriately disposing of the recalled product.

Below is an example of a recall plan:

Section	***Measure***	***Firm Plan***	***Who***	***Records***
1. External Notification				
	a. Describe procedures that must be utilized to directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food.			
	b. Described the procedures that must be utilized to notify the public about any hazard presented by the food when determined to be appropriate to protect the public health.			
2. Effectiveness Checks				
	Describe procedures that must be utilized to conduct effectiveness checks to verify a recall is carried out.			
3. Product Disposition				
	Describe to be taken to appropriately dispose of recalled product.			

Will creating a recall plan be a burden to my business?

The department recognizes that creating a recall plan will require some time and resources for seafood processors. Although currently not required, most large processors already have recall plans in place as this is a good business practice. For those firms that do not have a plan in place, DEC envisions this plan to be simple and there are free templates to assist operators in creating a plan that will be ready to use should the firm ever encounter an unfortunate situation when the plan must be implemented.

There are many tools and templates available for creating these plans. Examples of free templates may be found here, though others exist online, as well.

For a small processor that has limited distribution, such as a direct-market vessel, a plan could be created in less than a few hours.

The section dealing with permit requirements is proposed to be repealed and readopted. How are the requirements changing?

There are two primary ways this section is proposed to be changed. 1) provisions dealing with plan review have been relocated to this section because it makes sense to combine the two; 2) the department is greatly reducing the amount of time and paperwork burden to operators for annual permit renewal. The changes reflect the department's current process for plan review and renewals. Clarifications have been made to make clear that if a facility is renewing their permit and there have been no changes in ownership or processes, then the operator may simply attest to this instead of the former process of having to submit a full application every three years and an abbreviated application for other years. Now, once an operator applies for an initial permit, the full application isn't required unless there are significant renovations or additions to a type of operation or process.

It seems like there are a lot of new CFRs adopted by reference. Why so many?

The CFRs that are being added to the adopted by reference section should have no effect on operations. The reason for this is that the FDA standards already apply and these standards are merely making more specific already existing regulations dealing with adulterated and misbranded products. These CFRs include provisions dealing with safe direct and indirect food additives, color additives, substances prohibited from use in food, and standards of identity.

What are the changes to the product testing requirements and why is the department proposing the changes?

Under the proposal, the requirement for refrigerated and frozen products that are ready-to-eat requires the processor to submit 12 randomly-collected product sample from the first lot produced each calendar year instead of conducting sampling following initial permitting and one sample each month thereafter. For shelf-stable products, sampling is not required.

There are three primary reasons for this proposal: 1) the language concerning "processed approved by the department" was confusing, particularly because the department does not approve processes; 2) sampling for the presence of *Listeria monocytogenes* and *Salmonella* is a measure of sanitation – process is governed by the HACCP plan, which already includes verification that ensures food is processed safely; and 3) the department recognized that sending one sample from the first lot each month is burdensome to operators.

By consolidating the sample requirement, the operator will realize efficiencies and more effective use of resources, particularly due to potential reduction in shipping costs, as all samples would be sent together once per calendar year, rather than monthly. Additionally, because one sample each month from a lot is far from being a representative sample, by increasing the number of samples that are submitted at one time, there is a greater chance that if an environmental pathogen such as *Listeria* or *Salmonella* is present it will be detected.

What are the changes regarding approved laboratories and methods?

The AOAC methods for testing have been removed because the new requirements state that processors must submit samples to a qualified laboratory. The definition for a qualified laboratory is now included the definitions.

What has changed for sanitation plan and monitoring requirements for direct market vessels and direct market land based facilities?

Direct-market vessels and direct-market land based facilities that were producing products that did not require a HACCP plan were previously required to develop a written cleaning and sanitizing schedule. When the 4th Edition of the Fish and Fishery Products Hazards and Controls Guidance was released in 2011, it specified that, because fish is an allergen, seafood firms must consider allergens as a hazard reasonably likely to occur that required a control. This meant that almost all processors subject to 18 AAC 34 were required to develop a HACCP plan, even if no other hazards were present.

What has changed with the inspection scores? When will corrections need to be made from violations that are found during an inspection?

For some time, the department has not provided a score along with an inspection report. This proposal reflects the change in practice. Critical violations must be corrected at the time of inspection. All other violations must be corrected 30 days from the date of inspection or the date that the processors is provided in the notice of violation, whichever is later. The department may agree to additional time for correction.

How do I submit comments on these proposed regulations?

Your comments on the proposed regulation changes will be greatly appreciated.

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 Lorinda Lhotka, Department of Environmental Conservation, 610 University Avenue, Fairbanks, AK 99709. Additionally, the Department of Environmental Conservation will accept comments by facsimile at (907) 451-5120 and by electronic mail at lorinda.lhotka@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system and using the comment link. The comments must be received not later than 5:00pm on February 1, 2019.

We do not respond individually to comments on proposed regulations changes. After we have a chance to review the written comments received and then consider them in deciding what changes (if any) to make in our regulations, we will prepare a summary of the comments and our responses to them, which will be mailed to everyone who submits a timely written comment on the proposed changes and

provides a return mailing address. Individual commenters will not be identified in the summary; however, the comments themselves are public records subject to public inspection.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Theresa Zimmerman by electronic mail at theresa.zimmerman@alaska.gov or by phone at (907) 465-6171 or TDD Relay Service 1-800-770-8973/TTY or dial 711 not later than January 18, 2019 to ensure that any necessary accommodations can be provided.

What if I have another question that is not answered in this FAQ?

DEC will respond to questions that are relevant to the proposed changes if the questions are received in writing at least ten days before the end of the public comment period. If questions are submitted after that, we may, but we are not required to, respond to those questions. The questions and answers will be available on the Department of Environmental Conservation's website at https://dec.alaska.gov/eh/fss.aspx . One consolidated answer may be provided for a group of questions that are similar, as appropriate.