



The Step-by-Step Guide to the Licensed Processing of Fish and Fishery Products

On December 18, 1995, The Food and Drug Administration (FDA) published as a final rule 21CFR 123, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products" that requires processors of fish and fishery products to develop and implement Hazard Analysis Critical Control Point (HACCP) systems for their operations. The regulation became effective December 18, 1997.

The FDA also published the "Fish and Fishery Products Hazards and Controls Guide" ("the Guide") in September 1996, to assist processors in the development of their HACCP plans, and to provide information to help them identify hazards that may be associated with their products and formulate control strategies for those hazards. The current guide was developed to coincide with the issuance of the final regulation.

The intent of this handout is to provide the basic requirements and guidance for food processors wishing to enter the business of processing fish and fishery (seafood) products for wholesale business. This "Step by Step Guide" contains tools to get you started, links for informational resources, and important contact information to help you along the way to becoming a licensed processor of seafood products. Failure to adhere to these requirements may lead to the foods being deemed adulterated and subjected to a state or federal recall.

Oregon seafood processors are subject to Oregon's food statutes and administrative rules. Additionally, firms are held to the Seafood HACCP regulations set-forth by 21CFR part 123: Fish and Fishery Products, which requires processors of such products to develop and implement HACCP systems for their operations.

WHAT ARE FISH AND FISHERY PRODUCTS? See 21 CFR 123.3(d) and (e)

Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life other than birds or mammals, and all mollusks intended for human consumption. Species include but are not limited to: alligator, frog, aquatic turtle, jellyfish, sea cucumber, sea urchin, and the roe of such animals.

Fishery product means any human food product in which fish is a characterizing ingredient.

WHAT DOES PROCESSING AND PROCESSORS MEAN? See 21 CFR 123.3(k) and (l)

Processing means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

The regulations in this part do not apply to:

- Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
- Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.
- The operation of a retail establishment.

Processor means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processor

includes any person engaged in the production of foods that are to be used in market or consumer tests.

STEP 1: CONTACT THE OREGON DEPARTMENT OF AGRICULTURE (ODA) FOOD SAFETY PROGRAM

Call the Food Safety Program at (503) 986-4720 to locate an inspector in your facility zip code. Review the following regulations:

- **21 CFR Part 117:** Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (Seafood processors are exempt from Subparts C & G if they follow the Seafood HACCP regulations. Seafood processors still must meet the requirements of subparts A, B, and F (for the records required by subpart A). <https://oda.fyi/CFRTtitle21-117>
- **21 CFR Part 123:** Fish and Fishery Products <https://oda.fyi/CFRTtitle21-123>

If you are planning to conduct low acid canning or pickling of seafood products, you need to review the following regulations:

- **21 CFR Part 113:** Low Acid Canning <https://oda.fyi/CFRTtitle21-113>
- **21 CFR Part 114:** Acidified Foods <https://oda.fyi/CFRTtitle21-114>

STEP 2: CONTACT THE INSPECTOR AND PROVIDE A DETAILED DESCRIPTION OF YOUR PRODUCT

Provide the following information to your local inspector.

- Product Name
- Source of Fishery Product (i.e. wild caught, farm-raised, purchased from another processor, block frozen from seafood warehouse)
- Describe the Food and Process (i.e. frozen, raw, battered and breaded fish sticks)
- Method of Receiving, Storage and Distribution (i.e. raw salmon is received and stored frozen, finished smoked salmon in vacuum packages are stored and distributed under refrigeration)
- Finished Packaging Type (i.e. air-packed in clam shell container, ROP in clear film)
- Intended Use and Consumer (i.e. cooked & ready-to-eat, raw & to be cooked, to be consumed by general public).

STEP 3: PROVIDE A HAZARD ANALYSIS AND A SEAFOOD HACCP PLAN ACCORDING TO YOUR PRODUCT AND PROCESS

Submit your seafood HACCP plan to the ODA seafood HACCP inspector to review and comment. If you do not identify any hazards, you may be asked to provide a hazard analysis. If you do not know how to conduct a hazard analysis or develop a seafood HACCP plan, you must attend and pass approved FDA seafood HACCP courses as required in 21 CFR 123.10.

STEP 4: PROVIDE A HAZARD ANALYSIS AND A SEAFOOD HACCP PLAN ACCORDING TO YOUR PRODUCT AND PROCESS

Submit your Hazard Analysis (HA) and/or your seafood HACCP plan to your local ODA Seafood HACCP to review and comment. If you do not identify any hazards in your processing steps, you will be asked to provide the HA.

STEP 5: CREATE A LABEL FOR YOUR PRODUCTS

All seafood products must, at a minimum, be labeled with a common or usual name of the product, list of ingredients, net weight, company name, and address of the manufacturer.

- See the ODA Food Safety labeling handout as a guide to developing your label. <https://oda.direct/FoodLabeling>
- Submit your food label(s) for ODA seafood HACCP inspector to review and comment.

STEP 6: SCHEDULE A CONSULTATION WITH THE ODA SEAFOOD HACCP INSPECTOR

Plan review of your facility is not required but highly recommended. Your facility must be inspected and approved prior to being licensed for processing. Plan reviews and consultations are a free of charge service. The consultation visit will include an evaluation of the food preparation area to ensure that it meets all applicable health, food safety, construction and sanitation requirements per OAR Division 25, and if applicable the Code of Federal Regulations: <https://oda.fyi/OAR603-025>

STEP 7: PROVIDE THE TOOLS AND DEVELOP PRODUCTION RECORDS SHOWING ADHERENCE TO THE PROCESS

You will need special equipment to accurately monitor your critical control points (CCPs). You may need the following:

- Thermometer
- Salinometer
- Continuous time/temp monitoring device (if the ingredients or finished product will be refrigerated)
- Clock or Timer
- Metal Detector

You will need to develop the following records:

- Production Logs for monitoring critical control points (i.e. cooking or cooling time/temp, refrigerated storage temp, brine concentration)
- Labeling Log
- Standard Sanitation Operating Procedures (SSOP) -Daily/Weekly Log
- Corrective Action Log
- Thermometer Calibration Log
- Consumer Complaint Log

STEP 8: RECALL PLAN

A recall plan is not required to obtain a license approval for seafood processing; however the ODA strongly encourages the development of a recall plan. Should you lose the 21 CFR 117 Qualified Facility Exemption under Subpart E, a recall plan is required.

STEP 9: REQUEST A FINAL ON-SITE PROCESS REVIEW AND INSPECTION FOR LICENSING

After you demonstrate completion of all the aforementioned requirements, call your inspector to arrange an initial approval inspection to license your firm.

For all new and existing structures with plumbing changes, a final plumbing approval from your local authority will be required prior to the initial licensing inspection. It is your responsibility to be in compliance with all county and municipal land use or zoning laws, ordinances, and building codes.

STEP 10: REGISTER YOUR FACILITY WITH THE FDA ACCORDING TO BIOTERRORISM ACT OF 2002

The **Public Health Security and Bioterrorism Preparedness and Response Act of 2002** (the Bioterrorism Act) directs the Food and Drug Administration (FDA) as the food regulatory agency of the Department of Health and Human Services to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies. To carry out certain provisions of the Bioterrorism Act, the FDA established regulations requiring that food facilities register with the FDA and that the FDA be given advance notice on shipments of imported foods.

Register as soon as you have been licensed by the ODA

<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions>

STEP 11: MAINTAIN ACCURATE RECORDS See 21CFR 123.9

Keep all your records together in one place, preferably in a binder. Requirements for retaining records are identified in the regulations. You may receive a visit from FDA or ODA inspectors at any time during your business hours about once year to observe your process, inspect your facility, and review processing records.

ADDITIONAL HACCP RESOURCES

- Food and Drug Administration (FDA) website: www.fda.gov
- Association of Food and Drug Officials (AFDO) website: www.afdo.org
- Seafood Network Information Center (Oregon State University): <http://seafood.oregonstate.edu>
- FDA's Seafood Hazard Guides, most current edition and the FDA's Guidance Documents and regulatory information by topic is available at:
<https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls>

SUGGESTED HACCP COURSES

I. Online Seafood HACCP, Segment 1: Basic Seafood HACCP Course hosted by Cornell University.

<https://seafoodhaccp.cornell.edu/>

II. Face-to-Face Practical Session with a qualified Instructor by the Association of Foods and Drugs Officials (AFDO). <https://www.afdo.org/training/sha/haccp/>

- Seafood HACCP Segment 2: 1-day course
- Basic Seafood HACCP: 2 ½ to 3-day course

For more information contact the Oregon Department of Agriculture • Food Safety Program
635 Capitol St. NE, Salem, Oregon 97301-2532 • (503) 986-4720 •

<https://www.oregon.gov/oda/food-safety/Pages/default.aspx>