This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

UNDERSTAND THE POTENTIAL HAZARD

Parasites (in the larval stage) consumed in uncooked or undercooked seafood can present a human health hazard. Among parasites, the nematodes or roundworms (*Anisakis spp., Pseudoterranova spp., Eustrongylides spp.,* and *Gnathostoma spp.*), cestodes or tapeworms (*Diphyllobothrium spp.*), and trematodes or flukes (*Chlonorchis sinensis* (*C. sinensis*), *Opisthorchis spp., Heterophyes spp., Metagonimus spp., Nanophyetes salmincola,* and *Paragonimus spp.*) are of most concern in seafood. Most of these parasites cause mild-to-moderate illness, but severe symptoms can occur. Roundworms may embed in the intestinal wall and cause nausea, vomiting, diarrhea, and severe abdominal pain and sometimes may penetrate the intestine. Tapeworms can cause abdominal swelling and abdominal cramps and may lead to weight loss and anemia. Intestinal flukes (*Heterophyes spp., Metagonimus spp.,* and *Nanophyetes salmincola*) may cause abdominal discomfort and diarrhea. Some intestinal flukes may also migrate to and damage the heart and central nervous system. Liver flukes (*C. sinensis* and *Opisthorchis spp.*) and lung flukes (*Paragonimus spp.*) may migrate to the liver and lung and sometimes cause serious problems in other vital organs.

Some products that have been implicated in human parasite infection are the following: ceviche (fish and spices marinated in lime juice); lomi lomi (salmon marinated in lemon juice, onion, and tomato); poisson cru (fish marinated in citrus juice, onion, tomato, and coconut milk); herring roe; sashimi (slices of raw fish); sushi (pieces of raw fish with rice and other ingredients); green herring (lightly brined herring); drunken crabs (crabs marinated in wine and pepper); cold-smoked fish; and, undercooked grilled fish. A survey of U.S. gastroenterologists confirmed that seafood-borne parasitic infections occur in the United States with sufficient frequency to recommend preventive controls during the processing of parasite-containing species of fish that are intended for raw consumption.

- **Controlling parasites**

The process of heating raw fish sufficiently to kill bacterial pathogens is also sufficient to kill parasites. Guidance concerning cooking and pasteurizing to kill bacterial pathogens is provided in Chapters 13 (hot smoking) and 16 (cooking and pasteurization). Regulatory requirements for retorting (i.e., thermal processing of low acid canned foods) are contained in the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (hereinafter, the Low-Acid Canned Foods (LACF) Regulation). This guidance does not provide further information on retorting.

The effectiveness of freezing to kill parasites depends on several factors, including the temperature of the freezing process, the length of time needed to freeze the fish tissue, the length of time the fish is held frozen, the species and source of the fish, and the type of parasite present. The temperature of the freezing process, the length of time the fish is held frozen, and the type of parasite appear to be the most important factors. For example, tapeworms are more susceptible to freezing than are roundworms. Flukes appear to be more resistant to freezing than roundworms.

Freezing and storing at an ambient temperature of -4°F (-20°C) or below for 7 days (total time), or freezing at an ambient temperature of -31°F (-35°C) or below until solid and storing at an ambient temperature of -31°F (-35°C) or below for 15 hours, or freezing at an ambient temperature of -31°F (-35°C) or below until solid and storing at an ambient temperature of -4°F (-20°C) or below for 24 hours are sufficient to kill parasites. Note that these conditions may not be suitable for freezing particularly large fish (e.g., thicker than 6 inches).

Brining and pickling may reduce the parasite hazard in a fish, but they do not eliminate it, nor do they minimize it to an acceptable level. Nematode larvae have been shown to survive 28 days in an 80° salinometer brine (21% salt by weight).

Fish that contain parasites in their flesh may also contain parasites within their egg sacs (skeins), but generally not within the eggs themselves. For this reason, eggs that have been removed from the sac and rinsed are not likely to contain parasites.

Trimming away the belly flaps of fish or candling and physically removing parasites are effective methods for reducing the numbers of parasites. However, they do not completely eliminate the hazard, nor do they minimize it to an acceptable level.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether parasites are a significant hazard at a processing step:

1. Is it reasonably likely that parasites will be introduced at the receiving step (e.g., do they come in with the raw material)?

   Tables 3-2 and 3-3 (Chapter 3) list those species for which FDA has information that a potential parasite hazard exists. Ordinarily, you should identify the receiving step for these species as having a significant parasite hazard if you know or have reason to know that the fish will be consumed without thorough cooking by the end user or if you represent, label, or intend for the product to be consumed in that manner.

   Species of fish not listed with a parasite hazard in Tables 3-2 and 3-3 may have a parasite hazard that has not been identified if these fish are not customarily consumed raw or undercooked, or if the hazard occurs in certain localized harvest areas that are not known commercial sources of fresh fish for the U.S. You should consider this possibility in your hazard analysis.

   Species that normally have a parasite hazard as a result of consuming infected prey apparently do not have the same parasite hazard when raised only on pelleted feed in an aquaculture operation. You need not consider such aquacultured fish as having a parasite hazard. On the other hand, aquacultured fish that are fed processing waste, fresh fish, or plankton may have a parasite hazard, even when wild-caught fish of that species do not normally have a parasite hazard. Pellet fed fish that sometimes depend on wild-caught prey to supplement their diet may have a parasite hazard. In addition, fish raised in freshwater may have a parasite hazard from trematodes because these parasites enter the fish through the skin rather than in the food. You should verify the culture methods used by your aquaculture producers before eliminating parasites as a significant hazard.

   If the finished product is fish eggs that have been removed from the sac (skein) and rinsed, the fish eggs are not reasonably likely to contain parasites and you need not consider such product as having a parasite hazard. However, unrinsed fish eggs or fish eggs that remain in the sac ordinarily will have a parasite hazard if the species is identified in Table 3-2 or 3-3 as having a parasite hazard.

   If you receive the fish frozen and have documented assurance from your supplier that the fish are frozen in a way that will

kill the parasites (e.g., consistent with the guidance in this chapter), you do not need to identify the hazard of parasites as reasonably likely to occur in your product.

It is not reasonably likely that parasites will enter the process at other processing steps.

2. Can the parasite hazard that was introduced at an earlier step be eliminated or reduced to an acceptable level at this processing step?

   Parasites should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard that was introduced at an earlier step or to reduce to an acceptable level the likelihood of occurrence of the hazard. Preventive measures for parasites can include:

   - Retorting (covered in 21 CFR 113, the LACF Regulation);
   - Hot smoking (covered in Chapter 13);
   - Cooking and pasteurization (covered in Chapter 16);
   - Freezing (covered in this chapter).

- **Intended use**

If the consumer intends to cook the fish thoroughly before consumption, then you do not need to consider the hazard significant, even if Table 3-2 or 3-3 lists the species as having a potential parasite hazard. In order to eliminate parasites as a significant hazard when you are unsure of the product's intended use, you should obtain documented assurance from the subsequent processor, restaurateur, or institutional user (e.g., prison or nursing home) that the fish will be processed in a way that will kill the parasites.

Example:

A primary processor receives whole salmon from the harvest vessel and re-ices the fish for shipment to a second processor. The second processor butchers the fish for sale to the sushi market. The primary processor has documented assurance that the second processor freezes the fish before sale. The primary processor would not need to identify parasites as a significant hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for parasites:

1. Does the process contain a heating step, such as retorting, cooking, or pasteurizing that is designed to kill bacterial pathogens?

   a. If the process contains a heating step, you should identify the heating step as the CCP and would not need to identify receiving as a CCP for this hazard.

      See Chapters 13 (*Clostridium botulinum* toxin formation) and 16 (Pathogen bacteria survival through cooking or pasteurization), and the LACF Regulation (21 CFR 113) for further information on this control strategy.

      Example:

      A hot-smoked salmon processor should set the CCP for parasites at the hot-smoking step and would not need to identify the receiving step as a CCP for this hazard.

   b. If the process does not contain a heating step, you should identify a freezing step as the CCP, and would not need to identify receiving as a CCP for this hazard.

      Example:

      A salmon processor that sells the finished product for raw consumption should identify a freezing step as the CCP for parasites. The processor would not need to identify the receiving step as a CCP for this hazard.

      This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Freezing."

DEVELOP A CONTROL STRATEGY.

The following guidance provides an example of a control strategy for parasites. It is important to note that you may select a control strategy that is different from that which is suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following is an example of the control strategy included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Freezing	✓	✓

- **CONTROL STRATEGY EXAMPLE - FREEZING**

Set the Critical Limits.

- Freezing and storing at an ambient temperature of -4°F (-20°C) or below for 7 days (total time);

  OR

- Freezing at an ambient temperature of -31°F (-35°C) or below until solid and storing at an ambient temperature of -31°F (-35°C) or below for 15 hours;

  OR

- Freezing at an ambient temperature of -31°F (-35°C) or below until solid and storing at an ambient temperature of -4°F (-20°C) or below for 24 hours.

Note: These conditions may not be suitable for freezing particularly large fish (e.g., thicker than 6 inches). It may be necessary for you to conduct a study to determine effective control parameters specific to your freezing method, fish thickness, fish species, method of preparation, and target parasites.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Freezer temperature;

  AND

- Length of time fish is held at freezer temperature or held solid frozen, as appropriate:
  - For 7-day freezing critical limit:
    - Starting time of freezing and ending time of the frozen storage period;

    OR
  - For 15-hour and 24-hour freezing critical limits:
    - Time when all fish are solid frozen and ending time of the frozen storage period.

» **How Will Monitoring Be Done?**

- Use a continuous temperature-recording device (e.g., a recording thermometer);

  AND

- Perform a visual check of time and physical check of solid frozen condition, as appropriate.

» **How Often Will Monitoring Be Done (Frequency)?**

- For temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once during each freezing or storage period, but no less than once per day;

  AND

- For time:
  - Each batch, at the beginning and end of the freezing or storage period, as appropriate.

» **Who Will Do the Monitoring?**

- The device itself performs the monitoring. Any person who has an understanding of the nature of the controls may perform the visual check of the data generated by this device to ensure that the critical limits have been met consistently.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Refreeze and store the product at an ambient temperature of -4°F (-20°C) or below for 7 days (total time), or refreeze it at an ambient temperature of -31°F (-35°C) or below until solid

and store at an ambient temperature of -31°F (-35°C) or below for 15 hours, or refreeze it at an ambient temperature of -31°F (-35°C) or below until solid and store at an ambient temperature of -4°F (-20°C) or below for 24 hours. Note that these conditions may not be suitable for freezing particularly large fish (e.g., thicker than 6 inches);

OR

- Destroy or divert the product to a non-raw or non-food use.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Make repairs or adjustments to the freezer;

  OR

- Move some or all of the product in the freezer to another freezer.

Establish a Recordkeeping System.

- Record of continuous temperature monitoring;

  AND

- Record of visual checks of recorded data.

  AND

- Record of notation of the start time and end time of the freezing periods;

  AND

- Record of notation of the time the fish is solid frozen (if appropriate).

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to the National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

  AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

  AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

  AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 5-1

CONTROL STRATEGY EXAMPLE - FREEZING

This table is an example of a portion of a Hazard Analysis Critical Control Point plan using "Control Strategy Example 1 - Freezing." This example illustrates how a processor can control parasites in frozen salmon fillets with pin bones removed, where the finished product will be distributed to other processors for the production of refrigerated lox. It is provided for illustrative purposes only.

Parasites may be only one of several significant hazards for this product. Refer to Tables 3-2, and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides, aquaculture drugs, food and color additives, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			MONITORING						
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	WHAT	HOW	FREQUENCY	WHO	CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
Freezing	Parasites	Blast freeze at -31°F or below until solid, and hold at -4°F or below for 24 hours	Temperature of blast freezer and storage freezer	Recorder thermometers	Continuous, with visual check of recorded data at end of each freezing process	Freezer operator	Adjust or repair freezer Refreeze product	Recorder chart with notations for visual temperature check, time solid frozen, and time at end of storage period	Check the recorder thermometer for accuracy and damage and to ensure that it is operational before putting into service; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
			Time when all fish are visually solid frozen and time at end of storage period	Visual and physical checks	Each batch, at beginning and end of storage period				

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We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

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