Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Parasites (in the larval stage) consumed in uncooked, or undercooked, unfrozen 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, Opisthorchis spp., Heterophyes spp., Metagonimus spp., Nanophyetes salminicola and Paragonimus spp.*) are of most concern in seafood. Some products that have been implicated in human infection are: 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 recent survey of U.S. gastroenterologists has confirmed that seafood-borne parasitic infections occur in the U.S. with sufficient frequency to make preventive controls necessary 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 pathogens is provided in Chapters 16 and 17. Regulatory requirements for retorting (low acid canned foods) are contained in 21 CFR 113. This Guide does not provide further guidance 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 fat content 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 than roundworms.

Freezing and storing at -4˚F (-20˚C) or below for 7 days (total time), or freezing at -31˚F (-35˚C) or below until solid and storing at -31˚F (-35˚C) or below for 15 hours, or freezing at -31˚F (-35˚C) or below until solid and storing at -4˚F (-20˚C) or below for 24 hours is sufficient to kill parasites. FDA's Food Code recommends these freezing conditions to retailers who provide fish intended for raw consumption. Note: these conditions may not be suitable for freezing particularly large fish (e.g. thicker than six inches).

The effectiveness of hydrostatic pressure in the elimination of parasites from fish flesh is being studied.

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 skeins, but generally not within the eggs themselves. For this reason, eggs that have been removed from the skein 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.

Continued

STEP #11: ***DETERMINE IF THE HAZARD IS SIGNIFICANT.***

Determine if "parasites" is a significant hazard at each 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 #3-1 and 3-2 (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 will market the fish for consumption without cooking by the end user (e.g. raw).

Species that normally have parasites as a result of consuming infected prey, apparently do not have the same parasite hazard when raised on pelleted food 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 and by-catch fish may have a parasite hazard, even when wild caught fish of that species do not normally have a parasite hazard. Species of fish other than those identified in Tables #3-1 and 3-2 may have a parasite hazard in certain localized areas. You should consider this possibility in your hazard analysis.

If the finished product is fish eggs that have been removed from the skein and rinsed, it is not reasonably likely that it will contain parasites. You need not consider such product as having a parasite hazard. However, unrinsed fish eggs or fish eggs that remain in the skein ordinarily will have a parasite hazard if the species is identified in Tables #3-1 or 3-2 as having a parasite hazard.

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

2. Can the parasite hazard be eliminated or reduced to an acceptable level here? (Note: If you are not certain of the answer to this question at this time, you may answer "No." However, you may need to change this answer when you assign critical control points in Step #12.)

Parasites should also be considered a significant hazard at any processing step where a preventive measure is or can be used to eliminate (or reduce the likelihood of occurrence to an acceptable level) parasites that are reasonably likely to come in with the raw material. Preventive measures for parasites can include:

- Retorting (covered in 21 CFR 113);
- Cooking (covered in Chapter 16);
- Pasteurizing (covered in Chapter 17);
- Freezing (covered in this chapter);
- Brining or pickling (not a complete control);
- Candling and physical removal (not a complete control);
- Trimming away the belly flap (not a complete control).

List such preventive measures in Column 5 of the Hazard Analysis Worksheet, at the appropriate processing step(s).

If the answer to either question 1 or 2 is "Yes" the potential hazard is significant at that step in the process and you should answer "Yes" in Column 3 of the Hazard Analysis Worksheet. If neither criterion is met you should answer "No." You should record the reason for your "Yes" or "No" answer in Column 4. You need not complete Steps #12 through 18 for this hazard for those processing steps where you have recorded a "No."

You should also consider the likelihood that, without proper controls, parasites would survive your cooking process. Some cooking processes (e.g. retorting) may be exceptionally lethal to parasites, because the process is designed to kill more heat-stable bacterial pathogens. In such cases, even significant underprocessing would not jeopardize the safety of the product relative to parasites, and it may not be necessary to identify "parasites" as a significant hazard.

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where the critical control point is located.

- Intended use

In determining whether a hazard is significant, you should also consider the intended use of the product, which you developed in Step #4. If the fish is intended to be cooked by the consumer before consumption, then you do not need to consider the hazard significant even if the species is listed as having a potential parasite hazard in Table #3-1 or 3-2. Similarly, if you have assurance that the fish will be processed by a subsequent processor, restauranteur or institutional user (e.g. prison, nursing home) in a way that will kill the parasites, you do not need to identify parasites as a significant hazard.

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

It is important to note that, at certain levels in certain species of fish, parasites constitute filth, and, as a result, cause the fish to be adulterated. See Compliance Policy Guide section 540.590. However, since these defect action levels relate to a filth issue, preventive controls to assure that they are not exceeded need not be included in your HACCP plan.

STEP #12: *IDENTIFY THE CRITICAL CONTROL POINTS (CCP).*

For each processing step where "parasites" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "parasites":

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

   a. If it does, you may identify the heating step as the CCP.

      In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the heating step, and enter "No" for the receiving step. In addition, for the "No" entry, note in Column 5 that the hazard is controlled by the heating step. (Note: if you have not previously identified "parasites" as a significant hazard at the heating step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) See Chapters 16 (cooking) and 17 (pasteurizing) for further guidance on this control strategy.

      Example:
      A hot-smoked salmon processor could set the critical control point for parasites at the hot-smoking step, and would not need to identify the receiving step as a critical control point for this hazard.

   b. If the process does not contain a heating step, you should identify a freezing step as the CCP.

      In this case you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the freezing step, and enter "No" for the receiving step. In addition, for the "No" entry, note in Column 5 that the hazard is controlled by the freezing step. (Note: if you have not previously identified "parasites" as a significant hazard at the freezing step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) This control approach will be referred to as "Control Strategy Example 1" in Steps #14 through 18.

Continued

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 critical control point for this hazard.

It is important to note that you may select a control strategy that is different from that which is suggested above, provided that it assures an equivalent degree of safety of the product.

Proceed to Step #13 (Chapter 2) or to Step #10 of the next potential hazard.

HACCP Plan Form

STEP #14: *SET THE CRITICAL LIMITS (CL).*

For each processing step where "parasites" is identified as a significant hazard on the HACCP Plan Form identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the CL at the point that if not met the safety of the product will be questionable. If you set a more restrictive CL you could, as a result, be required to take corrective action when no safety concern actually exists. On the other hand, if you set a CL that is too loose you could, as a result, allow unsafe product to reach the consumer.

As a practical matter it may be advisable to set an operating limit that is more restrictive than the CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL would require you to take corrective action. You should set operating limits based on your experience with the variability of your operation and with the closeness of typical operating values to the CL.

Following is guidance on setting critical limits for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

Critical Limit: Freezing and storing at -4˚F (-20˚C) or below for 7 days (total time);

OR

Freezing at -31˚F (-35˚C) or below until solid and storing at -31˚F (-35˚C) or below for 15 hours;

OR

Freezing at -31˚F (-35˚C) or below until solid and storing at -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 six inches).

Enter the critical limit(s) in Column 3 of the HACCP Plan Form.

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "parasites" is identified as a significant hazard on the HACCP Plan Form, describe monitoring procedures that will ensure that the critical limits are consistently met.

To fully describe your monitoring program you should answer four questions: 1) What will be monitored? 2) How will it be monitored? 3) How often will it be monitored (frequency)? 4) Who will perform the monitoring?

It is important for you to keep in mind that the feature of the process that you monitor and the method of monitoring should enable you to determine whether the CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

You should monitor often enough so that the normal variability in the values you are measuring will be detected. This is especially true if these values are typically close to the CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL has been violated.

Following is guidance on establishing monitoring procedures for the control strategy example discussed in Step #12. Note that the monitoring frequencies that are provided are intended to be considered as minimum recommendations, and may not be adequate in all cases.

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

What: Freezer temperature;
AND
Length of time fish is held at freezer temperature or held frozen, as appropriate.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

How: Use a recording thermometer, digital time/temperature data logger, or similar device;
AND
Visual check on time and solid frozen condition, as appropriate.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

For temperature:

Frequency: Continuous monitoring, with visual check at least once during the cycle, but no less than once per day.

For time:

Frequency: Start and end of each freezing cycle;
OR
Time when fish is solid frozen and end of freezing cycle for each freezing cycle.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

Who: Monitoring may be performed by the freezer operator, a production supervisor, a member of the quality control staff, or any other person who has an understanding of the monitoring device and the critical limit.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "parasites" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL has not been met.

These procedures should: 1) ensure that unsafe product does not reach the consumer; and, 2) correct the problem that caused the CL deviation. Remember that deviations from operating limits do not need to result in formal corrective actions.

Following is guidance on establishing corrective action procedures for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

Corrective Action: Take one or more of the following actions as necessary 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;

AND
Refreeze and store the product at -4˚F (-20˚C) or below for 7 days (total time), or refreeze at -31˚F (-35˚C) or below until solid and store at -31˚F (-35˚C) or below for 15 hours, or refreeze at -31˚F (-35˚C) or below until solid and store at -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 six inches).

Continued

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "parasites" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the monitoring procedures discussed in Step #15. The records should clearly demonstrate that the monitoring procedures have been followed, and should contain the actual values and observations obtained during monitoring.

Following is guidance on establishing a record keeping system for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

Records: Temperature recorder chart, digital time/temperature data logger printout, with notations for start and end of freezing cycle or time when fish is solid frozen and end of freezing cycle, as appropriate.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "parasites" is identified as a significant hazard on the HACCP Plan Form, establish verification procedures that will ensure that the HACCP plan is: 1) adequate to address the hazard of "parasites"; and, 2) consistently being followed.

Following is guidance on establishing verification procedures for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - FREEZING

Verification: When digital time/temperature data loggers, or recorder thermometers are used for monitoring, check for accuracy against a known accurate thermometer (NIST-traceable) at least once per day;

AND

Review monitoring, corrective action and verification records within one week of preparation.

Enter the verification procedures in Column 10 of the HACCP Plan Form.

TABLE #5-1

Control Strategy Example 1 - Freezing

This table is an example of a portion of a HACCP plan relating to the control of parasites for a processor of frozen salmon fillets with pin bones removed, where the finished product is distributed to other processors for the production of lox, using Control Strategy Example 1 - Freezing. It is provided for illustrative purposes only. Parasites may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, aquaculture drugs, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Freezing	Parasites	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 themometers	• Continuous, with visual check at end of each freezing cycle	• Freezer operator	• Adjust freezer • Refreeze product	• Recorder chart with notations for solid frozen and end of each cycle	• Review monitoring, corrective action and verification records within one week of preparation
			• Length of time held frozen	• Visual check of when first fish is solid frozen and at end of freezing cycle	• When fish is solid frozen and at end of each freezing cycle	• Freezer operator	• Same		• Check the accuracy of the temperature recording devices daily

Notes: