Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Contamination of fish with natural toxins from the harvest area can cause consumer illness. Most of these toxins are produced by species of naturally occurring marine algae (phytoplankton). They accumulate in fish when they feed on the algae or on other fish that have fed on the algae. There are also a few natural toxins which are naturally occurring in certain species of fish.

There are five recognized fish poisoning syndromes in the United States: paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP), diarrhetic shellfish poisoning (DSP), amnesic shellfish poisoning (ASP), and ciguatera fish poisoning (CFP). Scombrotoxin formation, the subject of Chapter 7, is not considered a natural toxin.

- Species involved

This section will provide information about species and geographic areas which have been linked to one of the five fish poisoning syndromes by historical occurrence of the syndrome. However, it is important to note that historical occurrence may be an inadequate guide to future occurrence in the case of natural toxins, since the source algae vary in their distribution. Processors need to be alert to the potential for emerging problems.

Paralytic shellfish poisoning in the U.S. is generally associated with the consumption of molluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, Dungeness crabs, tanner crabs, and red rock crabs. While the viscera of mackerel are not normally eaten, the viscera of lobster and crabs are. However, the levels of PSP toxin that are found in lobster tomale are not likely to pose a health hazard unless large quantities are eaten from a heavily contaminated area.

Neurotoxic shellfish poisoning in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

Diarrhetic shellfish poisoning is generally associated with the consumption of molluscan shellfish. There has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produces the toxin has been found there. ASP toxin has recently been identified as a problem in the viscera of Dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States. The viscera of anchovies are also eaten.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. These species are not generally

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associated with ciguatera in the northern Gulf of Mexico. Many other species of large fish-eating fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

• Natural toxin detection

FDA has established action levels for all of the natural toxins except CFP.

- PSP- 0.8 ppm (80ug/100g) saxitoxin equivalent;
- NSP- 0.8 ppm (20 mouse units/100g) brevetoxin-2 equivalent;
- DSP- 0.2 ppm okadaic acid plus 35-methyl okadaic acid (DXT 1);
- ASP- 20 ppm domoic acid, except in the viscera of Dungeness crab, where 30 ppm is permitted.

There are no validated, rapid methods that are suitable for shipboard, dockside, or commercial testing of lots of fish for any of these toxins.

• Natural toxin control

Natural toxins cannot be reliably eliminated by heat. However, severe heating processes, such as retorting, may be effective at reducing the levels of some natural toxins.

To minimize the risk of molluscan shellfish containing natural toxins from the harvest area, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on the presence of natural toxins. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times, or under certain conditions, from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been permitted. Molluscan shellfish include oysters, clams, mussels, and scallops, except where the scallop product contains the shucked adductor muscle only.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the processor's name, address, and certification number.

An established water classification system similar to the molluscan shellfish system is not in place for controlling CFP in fin fish. However, some states issue advisories regarding reefs that are known to be toxic. In areas where there is no such advisory system, fishermen and processors must depend on first-hand knowledge about the safety of the reefs from which they obtain fish.

Where PSP or ASP have become a problem in fin fish or crustaceans, states generally have closed or restricted the appropriate fisheries. In addition, removal and destruction of the viscera will eliminate the hazard.

• Escolar, puffer fish, and whelk

There are naturally occurring toxins in some species that do not involve marine algae. Escolar or oilfish (i.e. *Lepidocybium flavobrunneum, Ruvettus pretiosus*) contains a strong purgative oil, called gempylotoxin, that may cause diarrhea when consumed. FDA advises against importation and interstate marketing of these fish.

Puffer fish, or fugu, may contain tetrodotoxin. Poisonings from tetrodotoxin have usually been associated with the consumption of puffer fish from waters of the Indo-Pacific ocean regions. However, several reported cases of poisonings, including fatalities, involved puffer fish from the Atlantic Ocean, Gulf of Mexico, and Gulf of California. There have been no confirmed cases of poisonings from *Spheroides maculatus* but there is still reason for concern.

Tetramine is a toxin that is found in the salivary glands of *Neptunia* spp., a type of whelk. The hazard can be controlled by removing the glands.

FDA makes no recommendations in this Guide and has no specific expectations with regard to controls for tetrodotoxin or tetramine in processors' HACCP plans.

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

At each processing step, determine whether "natural toxins" is a significant hazard. The criteria are:

1. Is it reasonably likely that unsafe levels of natural toxins will be introduced here (e.g. does it come in on the raw material at an unsafe level)?

Tables #3-1 and 3-2 (Chapter 3) identify the species of fish for which natural toxins is known to be a potential hazard. Under ordinary circumstances, it would be reasonably likely to expect that, without proper controls, natural toxins from the harvest area could enter the process at unsafe levels at the receiving step from those species. There may be circumstances in your geographic area that would allow you to conclude that it is not reasonably likely for a particular natural toxin to occur at unsafe levels in fish from your area. You should be guided by the historical occurrence of the toxin, at levels above the established guidance levels, in your geographic area. However, you should remain alert to the potential for emerging problems.

If you are receiving fish, other than molluscan shellfish, from another processor you should not need to identify "natural toxins" as a significant hazard. This hazard should have been fully controlled by the primary (first) processor.

2. Can natural toxins which were introduced at unsafe levels at an earlier step 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).

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

- Making sure that incoming fish have not been caught in an area that has been closed because of a natural toxin problem;
- Making sure that incoming fin fish have not been caught in an area for which there is a CFP advisory or for which you have knowledge there is a CFP problem;
- Checking incoming molluscan shellfish to ensure that they are properly tagged or labeled;
- Making sure that incoming molluscan shellfish are supplied by a licensed harvester (where licensing is required by law) or by a certified dealer.

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 the receiving step 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."

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 in the process the critical control point is located.

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• 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. However, in most cases, it is not likely that the significance of this hazard will be affected by the intended use of the product. One exception is with products in which only the muscle tissue will be consumed. For example, where the finished product is only the shucked adductor muscle of the scallop, or the muscle tissue of a crab or finfish, it is reasonable to assume that the product as consumed will not contain natural toxins. Similarly, in species, such as mackerel, in which the viscera is not normally consumed, it is reasonable to assume that the product as consumed will not contain natural toxins. In either case you should then enter "No" in Column 3 of the Hazard Analysis Worksheet for each of the processing steps. For each "No" entry briefly explain in Column 4 that the product is consumed without the viscera. In this case, you need not complete Steps #12 through 18 for this hazard.

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

For each processing step where "natural toxins" 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 "natural toxins":

1. Where preventive measures, such as those described in Step #11 are available to you, the hazard of "natural toxins" can best be controlled at the receiving step.

In these cases, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the receiving step. This control approach will be referred to as "Control Strategy Example 1" in Steps #14 through 18. Note that this control strategy is identical to Control Strategy Example 1 for "pathogens from the harvest area" (Chapter 4) and Control Strategy Example 6 for "environmental chemical contaminants and pesticides" (Chapter 9). If you choose an identical control strategy for two or more of these hazards, you may combine the hazards in the HACCP Plan Form.

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 "natural toxins" 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 - SOURCE CONTROL

Critical Limit: No fish may be harvested from:

- An area that is closed to fishing by foreign, federal, state, or local authorities;

OR

- An area that is the subject of a CFP advisory;

OR

- An area for which you have knowledge that there is a CFP problem;

AND

All shellstock (in-shell molluscan shellfish) must bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). For bulk shipments of shellstock (loose shellstock), the shellstock must be accompanied by a bill of lading or other similar shipping document that contains the same information.

AND

All molluscan shellfish must have been harvested from waters authorized for harvesting by a shellfish control authority. For U.S. Federal waters, no molluscan shellfish may be harvested from waters that are closed to harvesting by an agency of the federal government.

AND

All containers of shucked molluscan shellfish must bear a label that identifies the name, address, and certification number of the packer or repacker of the product.

AND

All molluscan shellfish must be from a harvester that is licensed as required (note that licensing may not be required in all jurisdictions) or from a processor that is certified by a shellfish control authority.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

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

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "natural toxins" 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.

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What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

For molluscan shellfish:

What:

- The tags on containers of shellstock. The Bill of Lading or other similar shipping document accompanying bulk shipments of shellstock;

AND

- The harvest site listed on the tag or on the Bill of Lading or other similar shipping document;

AND

- The labels on containers of shucked molluscan shellfish;

AND

- The license of fishermen, where applicable;

AND

- The certification number of suppliers (other than fishermen) of shellstock or shucked molluscan shellfish;

For other fish:

What: The harvest area location.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

For molluscan shellfish:

How: Make visual checks;

For other fish:

How: Ask the harvester for the harvest site at the time of receipt, or obtain the information from the harvester's catch record, where applicable.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

For Molluscan Shellfish:

Frequency:

- For checking tags: every container;

AND

- For checking harvest site: every lot;

AND

- For checking labels: at least three containers randomly selected from throughout every lot;

AND

- For checking licenses: every delivery;

AND

- For checking certification numbers: every delivery.

For other fish:

Frequency: Every lot of fish received.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Who: Monitoring may be performed by a receiving or production employee or supervisor, a member of the quality control staff, or any other person who has an understanding of the nature of the controls.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

Enter the "What," "How," "Frequency," and "Who" monitoring information in Columns 4, 5, 6, and 7, respectively, of the HACCP Plan Form.

STEP #16: *ESTABLISH CORRECTIVE ACTION PROCEDURES.*

For each processing step where "natural toxins" 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 - SOURCE CONTROL

For molluscan shellfish:

Corrective Action:

- Reject shellstock that is not properly tagged or is not accompanied by a proper shipping document;

AND

- Reject shucked molluscan shellfish that is not properly labeled;

AND

- Reject molluscan shellfish that has been harvested from unapproved waters;

AND

- Reject molluscan shellfish that is not from a licensed harvester or certified processor;

AND

- Discontinue use of supplier until evidence is obtained that harvesting, tagging, and/or labeling practices have changed.

Note: If an incoming lot that fails to meet a receiving critical limit is mistakenly accepted, and the error is later detected, the following actions should be taken: 1) the lot and any products processed from that lot should be destroyed, diverted to a nonfood use or to a use in which the critical limit is not applicable, or placed on hold until a food safety evaluation can be completed; and 2) any products processed from that lot that have already been distributed should be recalled and subjected to the actions described above.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

For other fish that fail to meet the CL:

Corrective Action: Reject the lot;
AND

- Discontinue use of supplier until evidence is obtained that harvesting practices have changed.

Enter the corrective action procedures in Column 8 of the HACCP Plan Form.

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "natural toxins" is identified as a significant hazard on the HACCP Plan Form, list the records that will be used to document the accomplishment of 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 recordkeeping system for the control strategy example discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROLS

For molluscan shellfish shellstock:

Records: A receiving record that documents:
- Date of harvest;

AND
- Location of harvest by State and site;

AND
- Quantity and type of shellfish;

AND
- Name of the harvester, name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority;

AND
- Number and date of expiration of the harvester's license, where applicable;

AND
- Certification number of the shipper, where applicable.

(Note: only the primary processor [the processor that takes possession of the molluscan shellfish from the harvester] need apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.)

For shucked molluscan shellfish:

Records: Receiving record that documents:
- Date of receipt;

AND
- Quantity and type of shellfish;

AND
- Name and certification number of the packer or repacker.

For other fish:

Records: Receiving record that documents the harvest area.

Enter the names of the HACCP records in Column 9 of the HACCP Plan Form.

STEP #18: *ESTABLISH VERIFICATION PROCEDURES.*

For each processing step where "natural toxins" are 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 "natural toxins"; 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 - SOURCE CONTROL

Verification: Review monitoring and corrective action records within one week of preparation.

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

TABLE #6-1

Control Strategy Example 1 - Source control

This table is an example of a portion of a HACCP plan relating to the control of natural toxins for a fish processor in Hawaii that receives locally harvested barracuda, using Control Strategy Example 1 - Source control. It is provided for illustrative purposes only. Natural toxins 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). Table #4-1 (Chapter 4) provides guidance for source controls for molluscan shellfish.

(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			
Receiving - fresh fish	Natural toxins - CFP	No fish may be harvested from an area that is covered by a State CFP advisory, or for which there is information from fishermen, news media, academia, or other sources that there is a current CFP problem.	Identify harvest area	Ask fishermen for the harvest location	Every lot	Receiving employee	Reject lot Discontinue use of supplier until evidence is obtained that harvesting practices have changed	Receiving record	Review monitoring and corrective action records within one week of preparation

Notes: