

## CHAPTER 6: Natural Toxins

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### 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 that are normal constituents of certain species of fish.

For fish products in the United States (U.S.) commerce there are six recognized fish poisoning syndromes that can occur from the consumption of fish or fishery products contaminated with natural toxins: Paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP), diarrhetic shellfish poisoning (DSP), amnesic shellfish poisoning (ASP), ciguatera fish poisoning (CFP) and azaspiracid shellfish poisoning (AZP). Scombrototoxin (histamine) poisoning, that can occur as a result of scombrototoxin formation in time and temperature abused fish, is not considered a natural toxin, and is covered in Chapter 7.

- **Species and geographic areas involved**

This section provides information about species of fish and geographic areas that 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, because the distribution of the source algae may vary over time. You should be alert to the potential for emerging problems.

Paralytic Shellfish Poisoning (saxitoxin) in the U.S. is generally associated with the consumption of molluscan shellfish from its northeast and northwest coastal regions. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. Certain gastropods (e.g., conch, snails and whelk) are also known to accumulate PSP toxins. They may accumulate toxins by feeding on molluscs that are toxic. In particular, moon snails and whelk are commonly found to contain PSP toxins off the northeast coast of the U.S. Abalone from South Africa and Spain have been reported to contain PSP toxins, although there have been no reports of PSP toxins in abalone off the coast of the U.S. Similarly, PSP toxins have been reported in sea cucumbers, octopi and a variety of echinoderms, targeted for human consumption in sub-tropical regions of Australia, but to date no reports have been shown in these species in U.S. waters. In the U.S., PSP toxin has been reported from the viscera of lobster and crabs are often eaten whole, therefore it is important to include toxin loads contained in the viscera and flesh for these animals. The levels of PSP toxins found in lobster tomalley and crab viscera may pose a health hazard if eaten from a heavily contaminated area. In 2008, FDA advised against the consumption of American lobster tomalley because unusually high levels of PSP toxins were detected in that organ in lobsters caught in the waters of New England. In 2002, PSP from the consumption of the flesh of puffer fish was first reported in the U.S. All cases to date have been due to fish harvested from central east coast Florida. PSP toxins have been

confirmed in southern (*Sphoeroides nebelus*), checkered (*Sphoeroides testudineus*), and bandtail (*Sphoeroides spengleri*) puffer fish. There is currently a ban on the harvesting of all puffer fish in the Florida counties of Volusia, Brevard, Indian River, St. Lucie, and Martin.

The effects of PSP are primarily neurological and can include: tingling, burning, numbness, drowsiness, incoherent speech, and respiratory paralysis. Respiratory paralysis can result in death if respiratory support is not provided in a timely manner. PSP toxin is an extremely potent toxin with a high mortality rate. The symptoms develop from ½ to 2 hours after consumption.

Neurotoxic shellfish poisoning (from brevetoxin) in the U.S. is generally associated with the consumption of molluscan shellfish from the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. NSP has also been linked to gastropods (whelk) harvested off the Florida Gulf Coast. In addition, there has been a significant occurrence of toxins similar to NSP in New Zealand and some suggestions of occurrence elsewhere.

NSP is characterized by gastrointestinal and neurological symptoms, including: tingling and numbness of the lips, tongue, and throat; muscular aches; dizziness; reversal of sensations of hot and cold; diarrhea; and vomiting. Symptoms develop from a few minutes to a few hours after consumption. There are few, if any, after effects and there have been no reported fatalities.

Diarrhetic shellfish poisoning (from okadaic acid and dinophysistoxins) is generally associated with the consumption of molluscan shellfish. There have been no documented occurrences of illness to date in the U.S. however reports of this illness can be misidentified as a bacterial or viral source and is expected to be highly under-reported. Outbreaks have been documented in Japan, Southeast Asia, Scandinavia, Western Europe, Chile, New Zealand, and eastern Canada. However, in 2008, okadaic acid levels in excess of the 0.16 ppm guidance level were recorded for

the first time in several locations along the Texas Gulf Coast during a large marine algae bloom.

DSP is characterized by gastrointestinal symptoms, including: nausea, vomiting, diarrhea, abdominal pain, headache, and fever. Symptoms develop from 30 minutes to 3 hours after consumption and last for up to 4 days. DSP is generally not considered life threatening but complications could occur as a result of severe dehydration in some patients.

Amnesic shellfish poisoning (from domoic acid) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. In these regions, domoic acid has been identified in the viscera of Dungeness (*Cancer magister*), tanner, and red rock crab. Domoic acid has also been identified in several fish species including anchovies (*Engraulis mordax*), Pacific sanddab (*Citharichthys sordidus*), chub mackerel (*Scomber japonicas*), albacore tuna (*Thunnus alalunga*), jack smelt (*Atherinopsis californiensis*), and market squid (*Loligo opalescens*) along the west coast of the U.S. It has not yet been a problem in the Gulf of Mexico, although the planktonic algae that produce the toxin have been reported in coastal waters, and more recently detected in menhaden (*Brevoortia partonus*) collected from Louisiana. Although this planktivorous species is not currently commercially harvested for human food in the Gulf of Mexico, it is used in dietary supplements, feed products, and occasionally caught recreationally and eaten by locals.

ASP is characterized by gastrointestinal symptoms, including: nausea, vomiting, abdominal cramps, and diarrhea. These symptoms develop within 24 hours of consumption. In severe cases, neurological symptoms also appear, including: dizziness, headache, seizures, disorientation, short-term memory loss, respiratory difficulty, and coma. These symptoms usually develop within 48 hours of consumption. These marine toxins described above 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 fish poisoning (from ciguatoxin (CTX)) is associated with consumption of toxin-contaminated subtropical and tropical reef fish. The toxin is introduced to the marine food chain by microscopic algae and moves up the food chain as small plant-eating reef fish eat the toxic algae and are then eaten by larger reef fish. The toxin accumulates in the flesh of certain predatory reef fish species. Although ciguatera hotspots are well recognized, there is not an even distribution of toxic fish within a given reef; fish caught side by side may have widely differing contamination levels. Ciguatoxic fish may be found in tropical or subtropical areas around the world between 35° north latitude and 35° south latitude and are common in several areas in the Caribbean Sea, Pacific Ocean, Indian Ocean, and in the Flower Garden Banks area in the northern Gulf of Mexico. Reef fish associated with CFP include: barracuda (*Sphyraenidae*), amberjack (*Seriola*), grouper (Family: Serranidae), snapper (Family: Lutjanidae), po'ou (*Chelinus spp.*), jack (Family: Carangidae), travelly (*Caranx spp.*), wrasse (Family: Labridae), surgeon fish (Family: Acanthuridae), moray eel (Family: Muraenidae), roi (*Cephalopholis spp.*), and parrot fish (Family: Scaridae).

CFP is characterized by numbness and tingling of the lips and tongue, which may spread to the extremities; nausea; vomiting; diarrhea; joint pain; muscle pain; headache; reversal of sensation of hot and cold; acute sensitivity to temperature extremes; vertigo; muscular weakness; irregular heartbeat, and reduced blood pressure. Gastrointestinal symptoms may develop within 2 hours following consumption of toxic fish while neurological and cardiovascular symptoms will usually emerge within 6 hours post-ingestion.

Azaspiracid shellfish poisoning (AZP) is caused by the consumption of molluscan shellfish contaminated with azaspiracids (AZA). AZP was first recognized following a 1995 outbreak in the

Netherlands, linked to consumption of mussels harvested in Ireland. Since then, several outbreaks of AZP have been reported in various regions in Europe. In 2008, two cases of AZP were reported in the US, and linked to consumption of an imported mussel product from Ireland confirmed to contain AZP toxins in excess of guidance levels. To date, AZP toxins have not been confirmed in any product harvested in the US.

AZP is characterized by severe gastrointestinal disorders including abdominal pain, nausea, vomiting, and diarrhea. Symptoms develop within minutes to hours after consumption of the contaminated shellfish and last for several days. There have been no reported fatalities.

A number of additional toxins that have been identified in molluscan shellfish have shown toxicity in mouse studies but have not been linked to human illness. Pectenotoxins (PTX) have been detected in phytoplankton and/or molluscan shellfish in Australia, Italy, Japan, New Zealand, Norway, Portugal, and Spain. Yessotoxins (YTX) have been detected in phytoplankton and/or molluscan shellfish in Australia, Canada, Italy, Japan, New Zealand, Norway, the United Kingdom, and the U.S. Cyclic imines have been found in phytoplankton and/or molluscan shellfish in Canada, Denmark, New Zealand, Norway, Scotland, Tunisia, and the U.S. PTX and YTX have been found to occur in shellfish along with the DSP toxins okadaic acid and dinophysistoxins. At this time, FDA makes no recommendations in this guidance and has no specific expectations with regard to controls for PTX, YTX and cyclic imines in processors' Hazard Analysis Critical Control Point (HACCP) plans.

- **Natural toxin detection**

The FDA has established action levels for natural toxins as follows:

- PSP - 0.8 ppm (80 ug/100 g) saxitoxin equivalents;
- NSP - 0.8 ppm (20 mouse units/100 g) brevetoxin-2 equivalents;
- DSP - 0.16 ppm total okadaic acid

equivalents (i.e., combined free okadaic acid, dinophysistoxins, acyl-esters of okadaic acid and dinophysistoxins);

- ASP - 20 ppm domoic acid, except in the viscera of dungeness crab, where the action level is 30 ppm;
- CFP - 0.01 ppb P-CTX-1 equivalents for Pacific ciguatoxin and 0.1 ppb C-CTX-1 equivalent for Caribbean ciguatoxin;
- AZP - 0.16 ppm azaspiracid equivalents.

There are currently no NSSP-accepted rapid test methods for NSP, ASP, DSP, CFP or AZP, and only one rapid test method has been validated (for PSP).

- **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 in shellfish meats. Shellfish control authorities may also use cell counts of the toxin-forming algae in the harvest waters to classify shellfish harvest areas. 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. In this context, molluscan shellfish include oysters, clams, mussels, and scallops, except where the scallop product contains the shucked adductor muscle only.

Other significant elements of shellfish control authorities' efforts to control the harvesting of molluscan shellfish include requirements that (1) containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type

and quantity of shellfish, the harvester, harvest location, and the date of harvest (21 CFR 123.28(c)); (2) molluscan shellfish harvesters be licensed (note that licensing may not be required in all jurisdictions); (3) processors that ship, reship, shuck, or repack molluscan shellfish be certified; and (4) containers of shucked molluscan shellfish bear a label with the processor's name, address, and certification number.

An established water classification system similar to that in use for the molluscan shellfish system is not in place for controlling CFP in finfish. 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 their own knowledge of local reporting of illnesses associated with reefs from which they obtain fish.

Where PSP or ASP has become a problem in finfish or crustaceans, states generally have closed or restricted the appropriate fisheries or have issued consumption advisories. In addition, removal and destruction of the viscera will eliminate the hazard, and this is at times required by state public health authorities. In 2008, FDA advised against the consumption of American lobster tomalley, but not the lobster meat itself, because unusually high levels of PSP toxins were detected in the lobster tomalley of lobsters caught in the waters of New England.

- **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* or *Ruvettus pretiosus*) contains a strong purgative oil (wax ester), called gempylotoxin, that may cause diarrhea, abdominal cramps, nausea, headache, and vomiting when consumed. FDA advises against importation and interstate marketing of these fish. Additional deep sea fish species, such as orange roughy (*Hoplostethus atlanticus*), and, oreo dory (*Allocyttus spp.*, *Pseudocyttus spp.*, *Oreosoma spp.*, and *Neocyttus spp.*) are known to contain lesser amounts of the same indigestible wax esters. Sensitive individuals may



also experience symptoms from the consumption of these fish. Improperly handled escolar and oilfish also have been associated with scombrototoxin (histamine) poisoning (Covered in Chapter 7).

Puffer fish (also known as fugu, swellfish, bok, blowfish, globefish, balloonfish, or sea squab) 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 northern puffer fish (*Sphoeroides maculatus*), which was once harvested and marketed as “sea squab” on the U.S. east coast, but there is still reason for concern. There is a restriction on importation of all species of puffer fish and fishery products containing puffer fish. See Import Alert #16-20 at the internet location [http://www.accessdata.fda.gov/cms\\_ia/importalert\\_37.html](http://www.accessdata.fda.gov/cms_ia/importalert_37.html). Some puffer fish are also subject to contamination with PSP toxins, covered earlier in this chapter.

Tetrodotoxin has been implicated in illnesses from the consumption of additional species besides puffer fish, for example, certain species of xanthid crabs, marine gastropods, and goby fish. Reports of these illnesses have been mainly limited to Asia, and involve species unlikely to be imported into the U.S.

Tetrodotoxin poisoning is characterized by slight numbness of the lips and tongue, tingling sensation in the face and extremities, headache, abdominal pain, nausea, diarrhea, vomiting, difficulty in walking, paralysis, respiratory distress, difficulty in speech, shortness of breath, blue or purplish discoloration of the lips and skin, lowering of blood pressure, convulsions, mental impairment, irregular heartbeat, and death. Symptoms usually develop between 30 minutes and 3 hours after consumption and may last for 20 minutes to 8 hours. If respiratory aid is not provided, death may occur within 4 to 6 hours.

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. Symptoms of tetramine poisoning include: double vision, temporary blindness, difficulty in focusing, tingling of the fingers, prostration, nausea, vomiting, diarrhea, and loss of muscle control. Symptoms usually develop within 1 hour of consumption.

FDA makes no recommendations in this guidance document and has no specific expectations with regard to controls for gempylotoxin in processors' HACCP plans. Additionally, FDA makes no specific recommendation in this guidance for control of tetrodotoxin and tetramine.

## **DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.**

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

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

Tables 3-2 and 3-3 (Chapter 3) identify the species of fish for which natural toxins are 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 for 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 information provided above and the historical occurrence of the toxin in the fish, at levels above the established guidance levels, in your geographic area. However, you should remain alert to the potential for emerging problems. Examples

of natural toxin hazards that had not until recently been known to exist are PSP in puffer fish and domoic acid in anchovies.

If you are receiving fish, other than molluscan shellfish, from another processor, you would 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 that were introduced at unsafe levels at an earlier step be eliminated or reduced to an acceptable level here?

Natural toxins should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the natural toxin hazard, which had been introduced at a previous step, or is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. Preventive measures for natural toxins can include:

For molluscan shellfish:

- 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.

For finfish other than molluscan shellfish:

- Making sure that incoming fish have not been caught in an area from which harvesting is prohibited or restricted because of a natural toxin problem;
- Making sure that incoming finfish 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.

These preventive measures are ordinarily employed at the receiving step.

- **Intended use**

In most cases, it is unlikely that the intended use of the product would determine whether the hazard is significant. One exception is with certain products for which only the muscle tissue will be consumed. For example, where the finished product is only the shucked adductor muscle of the scallop, it is reasonable to assume that the product as consumed will not contain natural toxins. In this case, you may not need to identify natural toxins 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 natural toxins. Where preventive measures, such as those described above, are available to you the hazard of natural toxins can best be controlled at the receiving step. This control approach consists of two control strategies referred to in this chapter as “Control Strategy Example 1 - Source Control for Molluscan Shellfish” and “Control Strategy Example 2 - Source Control for Fish Other Than Molluscan Shellfish” (for primary (first) processors only).

## DEVELOP A CONTROL STRATEGY.

The following guidance provides two control strategies for natural toxins. You may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following are examples of control strategies included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Source control for molluscan shellfish	✓	✓
Source control for fish other than molluscan shellfish	✓	

- **CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL FOR MOLLUSCAN SHELLFISH**

**Set Critical Limits.**

- All containers of shellstock (in-shell molluscan shellfish) received from a harvester must bear a tag that discloses the date and place they were harvested (by state and site), type and quantity of shellfish, and information on the harvester or the harvester's vessel (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 where the shellstock is not containerized, the shellstock must be accompanied by a bill of lading or similar shipping document that contains the same information;

Note: The source controls listed in this critical limit are required under 21 CFR 123.28(c).

OR

- All containers of shellstock received from a processor must bear a tag that discloses the date and place they were harvested (by state and site), type and quantity of shellfish, and the certification number of the processor;

OR

- 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 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 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, should apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters.

**Establish Monitoring Procedures.**

» **What Will Be Monitored?**

- Information contained on tags on containers of incoming shellstock or on the bill of lading or similar shipping document accompanying bulk shipments of shellstock;

AND

- Information on whether the harvest area is authorized for harvest by a shellfish control authority or information on whether federal harvest waters are closed by an agency of the federal government.

OR

- Information contained on labels on containers of incoming shucked molluscan shellfish;

AND

- The harvester's license.

» **How Will Monitoring Be Done?**

- Perform visual checks;

AND

- Ask the shellfish control authorities of the state or country in which your shellstock are harvested whether the harvest area is authorized for harvest.

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

- For checking incoming tags:

- Every container;

OR

- For checking the bill of lading or similar shipping document:

- Every delivery;

OR

- For checking incoming labels:
  - At least three containers randomly selected from every lot;

AND

- For checking licenses:
  - Every delivery.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

**Establish Corrective Action Procedures.**

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

- Reject the lot.

AND

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

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

**Establish a Recordkeeping System.**

For shellstock:

- 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 (for shellstock received directly from the harvester only);  
AND

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

AND

- Certification number of the shipper, where applicable.

For shucked molluscan shellfish:

- Receiving record that documents:
  - Date of receipt;  
AND
  - Quantity and type of shellfish;  
AND
  - Name and certification number of the packer or repacker.

**Establish Verification Procedures.**

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



TABLE 6-1

**CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL FOR MOLLUSCAN SHELLFISH**

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Source Control for Molluscan Shellfish." This example illustrates how a primary processor (processor that takes possession of the oysters from the harvester) of shellstock oysters, that is, the shellstock shipper, can control natural toxins from the harvest area in shellstock oysters received directly from a harvester. It is provided for illustrative purposes only.

Natural toxins may be only one of several significant hazards for this product. Refer to Tables 3-3 and 3-4 (Chapter 3) for other potential hazards (e.g., natural toxins, environmental chemical contaminants and pesticides, and pathogens during processing). **Example Only**  
**See Text for Full Recommendations**

(1) CRITICAL CONTROL POINT	(2) SIGNIFICANT HAZARD(S)	(3) CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	(4) MONITORING				(7) WHO	(8) CORRECTIVE ACTION(S)	(9) RECORDS	(10) VERIFICATION
			(5) WHAT	(6) HOW	(6) FREQUENCY	(6) HOW				
Receiving shellstock	Natural toxins	All incoming shellstock must be tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of the harvester's vessel	Information on incoming shellstock tags	Visual checks	Every sack	Receiving employee	Reject untagged sacks  Discontinue use of the supplier until evidence is obtained that tagging practices have changed	Receiving record	Review monitoring and corrective action records within 1 week of preparation	
			Harvest site on tags	Visual checks  Ask the shellfish control authority of the state in which the shellstock are harvested whether the area is authorized for harvest	Every lot	Receiving employee	Reject lots from unapproved waters  Discontinue use of the supplier until evidence is obtained that harvesting practices have changed			
			Harvester's license	Visual checks	Every delivery	Receiving employee	Reject lots from unlicensed harvesters  Discontinue use of the supplier until evidence is obtained that the harvester has secured a license			

- **CONTROL STRATEGY EXAMPLE 2 - SOURCE CONTROL FOR FISH OTHER THAN MOLLUSCAN SHELLFISH**

This guidance applies to primary (first) processors only.

***Set Critical Limits.***

- No fish may be received that has been harvested from:
  - An area that is closed to fishing by foreign, federal, state, tribal, territorial or local authorities (e.g., certain counties in Florida for puffer fish);
  - OR
  - An area that is the subject of a CFP or ASP consumption advisory;
  - OR
  - An area for which you have knowledge that there is a CFP problem.

***Establish Monitoring Procedures.***

- » **What Will Be Monitored?**
  - The location and status (e.g., prohibited, restricted, or unrestricted) of the harvest area.
- » **How Will Monitoring Be Done?**
  - Ask the harvesters 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)?**
  - Every lot.
- » **Who Will Do the Monitoring?**
  - Any person who has an understanding of the nature of the controls.

***Establish Corrective Action Procedures.***

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

- Reject the lot.

AND

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

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

***Establish a Recordkeeping System.***

- Receiving record that documents the location and status (e.g., prohibited, restricted, or unrestricted) of the harvest area.

***Establish Verification Procedures.***

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

TABLE 6-2

**CONTROL STRATEGY EXAMPLE 2 - SOURCE CONTROL FOR FISH OTHER THAN MOLLUSCAN SHELLFISH**

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Source Control for Fish Other Than Molluscan Shellfish." This example illustrates how a fish processor in Hawaii that receives locally harvested barracuda can control natural toxins. It is provided for illustrative purposes only.

Natural toxins 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).

**Example Only  
See Text for Full Recommendations**

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING			CORRECTIVE ACTION(S)	RECORDS	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 a valid scientific source that there is a current CFP problem	Location and status of the harvest area	Ask the fisherman for the harvest location	Every lot	Receiving employee	Reject lot Discontinue use of the supplier until evidence is obtained that harvesting practices have changed	Receiving record	Review monitoring and corrective action records within 1 week of preparation

## BIBLIOGRAPHY.

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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