

CHAPTER 9: Environmental Chemical Contaminants and Pesticides

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UNDERSTAND THE POTENTIAL HAZARD.

Environmental chemical contaminants and pesticides in fish pose a potential human health hazard. Fish can be harvested from waters that are contaminated by varying amounts of industrial chemicals, including heavy metals and pesticides. These contaminants may accumulate in fish at levels that can cause human health problems (e.g., carcinogenic and mutagenic effects). The hazard is most commonly associated with exposure over a prolonged period of time (chronic exposure). Illnesses related to a single exposure (one meal) are very rare. Concern for these contaminants primarily focuses on fish harvested from aquaculture ponds, freshwater bodies, estuaries, and near-shore coastal waters (e.g., areas subject to shoreside contaminant discharges), rather than from the open ocean. Environmental chemicals and pesticides may also accumulate in aquacultured fish through contaminated feed ingredients (e.g., pesticides in oil-containing feed ingredients derived from near-shore bait fish).

Although some pesticides have not been produced or used in the United States for many years (e.g., dichloro-diphenyl-trichloroethane (DDT) and polychlorinated biphenyls (PCBs)), many are very persistent and tend to accumulate in soil and sediments. Once pesticides are introduced into the environment, they may travel beyond their point of application or discharge.

Certain pesticides are applied directly to the water in aquaculture ponds to control weeds and algae and to eliminate fish and invertebrates. These products can be used legally only if they are registered with the U.S. Environmental Protection Agency (US EPA)

and used according to conditions described on the label (40 CFR 180 and the "Guide to Drug, Vaccine, and Pesticide Use in Aquaculture," the Federal Joint Subcommittee on Aquaculture (<http://aquanic.org/jsa/wgqaap/drugguide/drugguide.htm>)).

Many contaminants accumulate in the edible fatty tissues of fish. Concentrations of these contaminants can vary considerably in individual fish of the same species from the same location, depending on factors such as their fat content, size, age, and gender.

In the case of components or extracts of whole fish (e.g., dietary supplements, dietary ingredients, and flavors), the component or extract may contain higher or lower concentrations of environmental chemical contaminants and pesticides than the whole fish from which it was derived. For example, organochlorine contaminants, such as PCBs, are oil soluble. When producing fish oil and fish meal, any PCBs present will become more concentrated in the oil fraction and less concentrated in the water fraction, as compared with the levels in the whole fish.

• **Control of chemical contaminants**

Federal tolerances and action levels are established for some of the most toxic and persistent contaminants that can be found in fish. These levels are listed in Table 9-1. State, tribal, local, or foreign authorities may use the federal tolerances or action levels to decide whether to issue local advisories to consumers recommending limits on consumption of all or certain species of locally harvested fish (some of which may be commercially important) or to close waters for commercial harvesting of all or certain species of fish.

In the case of molluscan shellfish, state, tribal, territorial and foreign government agencies, called shellfish control authorities, consider the degree of chemical contamination as part of their classification of harvesting waters. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters and not 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.

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.

Processors of seafood components and extracts may choose to control environmental chemical contaminants and pesticides at receipt (e.g., by screening raw materials). If contaminants in the raw material are present at unacceptable levels, processors may reject the product or choose to implement refining steps that reduce the contaminants to acceptable levels in the finished product. These steps may include distillation, absorption, and steam deodorization. You should validate the effectiveness of these refining steps at reducing environmental and chemical contaminants to an acceptable level and include appropriate controls in your Hazard Analysis Critical Control Point (HACCP) plan. No further information on these control measures is provided in this guidance document.

- **Tolerance and action levels**

Table 9-1, "Environmental Chemical Contaminants and Pesticides Tolerance and Action Levels," lists the tolerance and action levels that have been established for environmental chemical contaminants and pesticides in the edible portion of fish (wet weight).

TABLE 9-1

ENVIRONMENTAL CHEMICAL CONTAMINANTS AND PESTICIDES TOLERANCE AND ACTION LEVELS

Tolerance Levels			
DELETERIOUS SUBSTANCE	LEVEL IN EDIBLE TISSUE	FOOD COMMODITY	REFERENCE
PCBs	2 ppm	All fish	21 CFR 109.30
Carbaryl	0.25 ppm	Oysters	40 CFR 180.169
Diquat	2 ppm	Fish	40 CFR 180.226
Diquat	20 ppm	Shellfish	40 CFR 180.226
Diuron and its metabolites	2 ppm	Farm-raised, freshwater finfish	40 CFR 180.106
Endothall and its monomethyl ester	0.1 ppm	All fish	40 CFR 180.293
Fluridone	0.5 ppm	Finfish and crayfish	40 CFR 180.420
Glyphosate	0.25 ppm	Fish	40 CFR 180.364
Glyphosate	3 ppm	Shellfish	40 CFR 180.364
2,4-D	0.1 ppm	Fish	40 CFR 180.142
2,4-D	1 ppm	Shellfish	40 CFR 180.142
Action Levels			
DELETERIOUS SUBSTANCE	LEVEL IN EDIBLE TISSUE	FOOD COMMODITY	REFERENCE
Aldrin and dieldrin ¹	0.3 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Benzene hexachloride	0.3 ppm	Frog legs	"Compliance Policy Guide," Sec. 575.100
Chlordane	0.3 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Chlordecone ²	0.3 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Chlordecone ²	0.4 ppm	Crabmeat	"Compliance Policy Guide," Sec. 575.100
DDT, TDE, and DDE ³	5 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Methylmercury ⁴	1 ppm	All fish	"Compliance Policy Guide," Sec. 540.600
Heptachlor and Heptachlorepoxyde ⁵	0.3 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Mirex	0.1 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
<p>1. The action level for aldrin and dieldrin is for residues of the pesticides individually or in combination. However, in calculating a total, amounts of aldrin or dieldrin found at below 0.1 ppm are not counted.</p> <p>2. Previously listed as Kepone, the trade name of chlordecone.</p> <p>3. The action level for DDT, TDE, and DDE is for residues of the pesticides individually or in combination. However, in calculating a total, amounts of DDT, TDE, and DDE found below 0.2 ppm are not counted.</p> <p>4. See Chapter 10 for additional information.</p> <p>5. The action level for heptachlor and heptachlor epoxide is for the pesticides individually or in combination. However, in calculating a total, amounts of heptachlor and heptachlor epoxide found below 0.1 ppm are not counted.</p>			

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether environmental chemical contaminants and pesticides are a significant hazard at a processing step:

1. Is it reasonably likely that unsafe levels of environmental chemical contaminants or pesticides will be introduced at this processing step (e.g., do such contaminants and pesticides come in on the raw material)?

Tables 3-2 and 3-3 (Chapter 3) identify the species of fish for which environmental chemical contaminants and pesticides are a potential hazard. Under ordinary circumstances, it would be reasonably likely to expect that, without proper controls, unsafe levels of environmental chemical contaminants and pesticides could enter the process at the receiving step from those species. However, there may be circumstances that would allow you to conclude that it is not reasonably likely for unsafe levels of environmental chemical contaminants and pesticides to occur in fish harvested from your area. You should be guided by the historical occurrence of environmental contaminants and pesticides, at levels above established tolerance and action levels, in fish from the area in which your fish are caught. This information may be available from federal, state, tribal, territorial, local, or foreign health or environmental authorities in the area where your fish are caught.

If you are receiving fish, other than molluscan shellfish, from another processor, you would not need to identify environmental chemical contaminants and pesticides as a significant hazard. This hazard should have been fully controlled by the primary (first) processor.

2. Can unsafe levels of environmental chemical contaminants and pesticides that were introduced earlier be eliminated or reduced to an acceptable level at this processing step?

Environmental chemical contaminants and pesticides should be considered a significant hazard at any processing step where a preventive measure is or can be used to eliminate the hazard or to reduce the likelihood of its occurrence to an acceptable level. Preventive measures for environmental chemical contaminants and pesticides can include:

For wild-caught fish other than molluscan shellfish:

- Making sure that incoming fish have not been harvested from waters that are closed to commercial harvest because of concentrations of environmental chemical contaminants or pesticides exceeding the federal tolerance or action levels;
- Making sure that incoming fish have not been harvested (for commercial purposes) from the same waters that are under a consumption advisory by a state, tribal, territorial, local, or foreign regulatory authority based on a determination by the authority that fish harvested from these waters are reasonably likely to contain contaminants above the federal tolerance or action levels. Note that many consumption advisories are not based on such a determination.

For aquacultured fish other than molluscan shellfish:

- Reviewing, at time of receipt, the producer's lot-by-lot certification that harvest is from uncontaminated waters, coupled with appropriate verification;
- Reviewing, at time of receipt, test results of fish tissue samples or production site water for those contaminants that

are reasonably likely to be present, and obtaining information on present land use practices in the area immediately surrounding the production area (tests and monitoring may be performed by the aquacultural producer, a state, tribal, territorial, local, or foreign authority, or a third-party organization);

- Conducting on-farm visits to the aquacultural producer to collect and analyze water or fish samples for those environmental chemical contaminants and pesticides that are reasonably likely to be present, and to review present land use practices in the area immediately surrounding the production area;
- Reviewing, at time of receipt, evidence (e.g., a third-party certificate) that the producer operates under a third-party-audited Quality Assurance (QA) program for environmental chemical contaminants and pesticides (e.g., the National Aquaculture Association's Fish Producers Quality Assurance Program);
- Conducting, at time of receipt, environmental chemical contaminant and pesticide testing of fish tissue for those contaminants that are reasonably likely to be present.

For molluscan shellfish, both aquacultured and wild caught:

- Checking incoming molluscan shellfish to ensure that containers are properly tagged or labeled;
- Screening incoming molluscan shellfish to ensure that they are supplied by a licensed harvester (where licensing is required by law) or by a certified dealer.

These preventive measures are ordinarily employed either at the receiving step or at the pre-harvest step. In the case of an integrated operation, where fish cultivation and processing are performed by the same

firm, it may be possible and desirable to exercise preventive measures early in the process (ideally when the cultivation site is selected), rather than at receipt of the fish at the processing plant. Such preventive measures will not be covered in this guidance document.

- **Intended use**

For environmental chemical contaminants and pesticides, it is unlikely that the intended use of the product will affect the significance of the hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for the hazard of environmental chemical contaminants and pesticides:

Is the raw material an aquacultured product other than molluscan shellfish?

1. If the raw material is an aquacultured product other than molluscan shellfish, do you have a relationship with the producer that enables you to visit the farm before receipt of the fish?
 - a. If you have such a relationship with the producer, then you should identify the pre-harvest step as the CCP for environmental chemical contaminants and pesticides. The preventive measure for this type of control is:
 - Conducting on-farm visits to the aquacultural producer to collect and analyze water or fish samples for those environmental chemical contaminants and pesticides that are reasonably likely to be present, and to review present land use practices in the area immediately surrounding the production area.

Example:

An aquacultured catfish processor that regularly purchases from the same

producers should visit the producers before the fish are harvested. The processor should collect and analyze water or fish samples for those environmental chemical contaminants and pesticides that are reasonably likely to be present and should review present land use at the pond site and in the adjacent areas. The processor should then set the CCP for environmental chemical contaminants and pesticides at the pre-harvest step.

This control approach is a control strategy referred to in this chapter as “Control Strategy Example 1 - On-Farm Visits.”

- b. If no such relationship exists with the producer, then you should identify the receiving step as the CCP for environmental chemical contaminants and pesticides. At the receiving step, you should exercise one of the following preventive measures:

- Reviewing, at time of receipt, the supplier’s lot-by-lot certification of harvesting from uncontaminated waters, coupled with appropriate verification.

Example:

An aquacultured shrimp processor that purchases raw material through various brokers should receive lot-by-lot certificates from the suppliers. The certificates would state that shrimp were not harvested from contaminated waters that would cause the levels in shrimp to exceed the established tolerance or action levels. The processor should combine this monitoring procedure with quarterly raw material testing for those environmental chemical contaminants and pesticides that are reasonably likely to be present for

verification and should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as “Control Strategy Example 2 - Supplier’s Certification.”

- Reviewing, at time of receipt, test results of water or fish tissue samples for those contaminants that are reasonably likely to be present and obtaining information on the present land use practices in the area immediately surrounding the production area (the aquaculture producer, a state, tribal, territorial, local or foreign authority, or a third-party organization may perform tests and monitoring).

Example:

A farm-raised catfish processor purchases catfish from producers with which the processor has no long-term relationship. The processor requires all new suppliers to provide the test results of water samples or fish tissue for those contaminants that are reasonably likely to be present and reports on present agricultural and industrial land use at and near the pond site. The land use reports are updated annually and whenever information on the land use change warrants a more frequent update (the aquaculture producer, a state, tribal, territorial, local or foreign authority, or a third-party organization may perform tests and monitoring). The processor should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as “Control Strategy Example 3 - Records of Testing and Monitoring.”

- Conducting, at time of receipt, analysis of fish tissue for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

Example:

An aquacultured shrimp processor that purchases raw material through various brokers should screen all incoming lots of shrimp for those environmental chemical contaminants and pesticides that are reasonably likely to be used in the production area. The processor should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as “Control Strategy Example 4 - Chemical Contaminant Testing.”

- Reviewing, at time of receipt, evidence (e.g., a continuing or lot-by-lot third-party certificate) that the producer operates under a third-party-audited QA program that covers environmental chemical contaminants and pesticides. The certificate should outline the audit steps and summarize the water and/or fish test results.

Example:

An aquacultured trout processor that regularly purchases raw trout from the same producer should obtain a third-party certificate, valid for 1 year (i.e., a continuing certificate), that attests that the producer operates under a QA program that controls environmental chemical contaminants and pesticides or should receive a lot-by-lot certificate issued by the third party. The processor should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as “Control Strategy Example 5 - QA Program.”

Is the raw material molluscan shellfish (aquacultured or wild caught) or wild caught fish other than molluscan shellfish?

1. If the raw material is molluscan shellfish or wild-caught fish other than molluscan shellfish, you should identify the receiving step as the CCP for environmental chemical contaminants and pesticides. At the receiving step, you should exercise the following preventive measures:
 - a. For wild-caught fish other than molluscan shellfish:
 - Making sure that incoming fish have not been harvested from waters that are closed to commercial harvest because of concentrations of environmental chemical contaminants or pesticides exceeding the federal tolerance or action levels;
 - Making sure that incoming fish have not been harvested from waters that are under a consumption advisory by a state, tribal, territorial, local, or foreign regulatory authority based on a determination by the authority that fish harvested from the waters are reasonably likely to contain contaminants above the federal tolerance or action levels.

Example:

A processor purchases bluefish directly from the harvester. The processor asks the harvester where the fish were caught. The processor then compares the harvest area location with the areas that are closed to commercial fishing by state or local regulatory authorities or that are under consumption advisories that include bluefish and that are based on the reasonable likelihood that a contaminant level in fish tissue will exceed a federal tolerance or action level. The processor should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as “Control Strategy Example 6 - Source Control for wild caught Fish Other Than Molluscan Shellfish.”

b. For molluscan shellfish:

- Checking incoming molluscan shellfish to ensure that they are properly tagged or labeled;
- Checking incoming molluscan shellfish to ensure that they are supplied by a licensed harvester (where licensing is required by law) or by a certified dealer.

Example:

A processor purchases oysters directly from the harvesters. The processor should check the harvest location on the tags attached to the sacks of oysters. The processor should then compare the harvest area location with information on closed waters and check the harvesters’ state licenses. The processor should set the CCP at receiving.

This control approach is a control strategy referred to in this chapter as “Control Strategy Example 7 - Source Control for Molluscan Shellfish.”

DEVELOP A CONTROL STRATEGY.

The following guidance provides seven control strategies for environmental chemical contaminants and pesticides. It is important to note that 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
On-farm visit	✓	
Supplier’s certification	✓	
Records of testing and monitoring	✓	
Chemical contaminant testing	✓	
QA program	✓	
Source control for wild caught fish other than molluscan shellfish	✓	
Source control for molluscan shellfish	✓	✓

• CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT

Set Critical Limits.

- Environmental chemical contaminants and pesticides that are reasonably likely to be present in farm water may not be at levels so high that they are reasonably likely to result in concentrations in fish tissue above the established tolerance or action levels (refer to Table 9-1). Elevated concentrations of chemical contaminants in water can be an indication that they are reasonably likely to be present in the fish tissue. Note that US EPA has developed water quality guidance documents that may be suitable for evaluating water quality in local situations (*U.S. EPA Water Quality Standards Handbook*, Appendix I);

OR

- The levels of environmental contaminants and pesticides in fish tissue samples that are reasonably likely to be present may not exceed the established tolerance or action levels (refer to Table 9-1);

AND

- Agricultural and industrial practices in the area near the production site must not be reasonably likely to cause contamination

of the fish tissue above the established tolerance or action levels (refer to Table 9-1).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The levels of environmental chemical contaminant and pesticide residues found in water or in fish tissue for those contaminants that are reasonably likely to occur;

AND

- Agricultural and industrial practices in the area near the production site.

» **How Will Monitoring Be Done?**

- Collect and analyze water samples or fish tissue samples from each production site;

AND

- Ask questions about and observe agricultural and industrial practices in the area near the production site, such as:
 - Which types of crops, if any, are grown in the area near the production site?
 - What pesticides, if any, are used on these crops, how are they applied, and at what time of year?
 - What industrial and urban discharges, if any, enter the watershed surrounding the production site?

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

- For testing water:
 - Before first delivery from each production site;

OR

- For testing fish tissue:
 - Before each delivery;

AND

- For evaluating agricultural and industrial practices:
 - At least once per year for each production site.

» **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:

- Do not have the product shipped from the production site for processing.

AND

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

- Discontinue use of the supplier until evidence is obtained that the cause of the chemical contamination has been eliminated.

Establish a Recordkeeping System.

- Test results;

AND

- On-site audit report.

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 9-2

CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - On-Farm Visits." This example illustrates how an aquacultured catfish processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental chemical contaminants and pesticides 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., 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		
Pre-harvest	Environmental chemical contaminants and pesticides	Levels of environmental chemical contaminants and pesticides in fish tissue may not exceed established tolerance and action levels for those contaminants that are reasonably likely to be present*	Environmental chemical contaminant and pesticide levels in fish tissue for those contaminants that are reasonably likely to be present*	Collect samples and analyze for environmental chemical contaminants and pesticides*	Before each harvest	Field agent will submit samples to the contract laboratory	Do not have the product shipped for processing Discontinue use of the supplier until evidence is obtained that the cause of the chemical contamination has been eliminated	Test results	Review monitoring and correction action records within 1 week of preparation		
		Agricultural and industrial practices in the area near the pond must not be reasonably likely to cause contamination of the fish tissue above the established tolerances and action levels	Agricultural and industrial practices near the pond	Ask questions and observe agricultural and industrial practices	Once per year	Field agent	Do not have the product shipped for processing Discontinue use of the supplier until evidence is obtained that the cause of the chemical contamination has been eliminated	Field agent report	Review monitoring and correction action records within 1 week of preparation		

* Note: This plan is for illustrative purposes only. An actual plan should specify (1) in the Critical Limits column: the environmental chemical contaminants and pesticides that are reasonably likely to be present and the critical limits to be applied to each contaminant; and (2) in the Monitoring columns: the contaminants for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each contaminant.

- **CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION**

Set Critical Limits.

- A certificate accompanying all lots received (lot by lot) that indicates that fish were not harvested from contaminated waters that could cause the levels in fish tissue to exceed the established federal tolerance and action levels (refer to Table 9-1).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Presence of a certificate indicating harvesting from uncontaminated waters.

» **How Will Monitoring Be Done?**

- Visual check for the presence of a certificate.

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

- Each lot received.

» **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;
OR
- Hold the lot until a certificate can be provided;
OR
- Hold and analyze the lot for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

AND

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

- Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls.

Establish a Recordkeeping System.

- Copy of the certificate;
AND
- Receiving record showing lots received and the presence or absence of a certificate.

Establish Verification Procedures.

- Visit all new aquacultured fish producers within the year and all existing fish suppliers at a predetermined frequency (e.g., 25% per year) to collect and analyze water or fish tissue samples, as appropriate, for those environmental chemical contaminants and pesticides that are reasonably likely to be present, and review agricultural and industrial practices in the production area;
OR
- Collect a representative sample of the raw material, in-process product, or finished product at least quarterly, and analyze it for those environmental chemical contaminants and pesticides that are reasonably likely to be present;
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 9-3

CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Supplier's Certification." This example illustrates how an aquacultured shrimp processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental chemical contaminants and pesticides 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., aquaculture drugs, food and color additives, and metal fragments).

**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) HOW	(6) FREQUENCY	(6) WHAT				
Receiving	Environmental chemical contaminants and pesticides	Certificate accompanying all lots received indicates that fish were not harvested from contaminated waters that could cause the levels in fish tissue to exceed the established federal tolerance and action levels	Visual check	Each lot received	Presence of a certificate	Receiving dock employee	Reject lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls	Copy of the certificate Receiving record	Review monitoring, corrective action, and verification records within 1 week of preparation Visit all new aquacultured fish producers within the year and 25% of existing suppliers each year to collect and analyze water samples, and review agricultural and industrial practices in the area

- **CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING**

Set Critical Limits.

- Reports of analyses of the water from all new suppliers that show that levels of those environmental chemical contaminants and pesticides that are reasonably likely to be present are not so high that they are reasonably likely to result in levels in the fish tissue that exceed the established federal tolerance and action levels (refer to Table 9-1). (The aquaculture producer, a state, tribal, territorial, local, or foreign authority, or a third-party organization may perform tests.) Note that US EPA has developed water quality documents that may be suitable for evaluating water quality in local situations (*U.S. EPA Water Quality Standards Handbook*, Appendix I);
OR
- Reports of analyses of fish tissue for each delivery that show that levels of those environmental chemical contaminants and pesticides that are reasonably likely to be present are below the established federal tolerance and action levels (the aquaculture grower, a state, tribal, territorial, local, or foreign authority, or a third-party organization may perform tests);
AND
- Reports from all suppliers that show that agricultural and industrial practices in the area near the aquaculture production site are not reasonably likely to cause contamination of fish tissue above the established federal tolerance or action levels (the aquaculture producer, a state, tribal, territorial, local, or foreign authority, or a third-party organization may perform monitoring).

Establish Monitoring Procedures.

- » **What Will Be Monitored?**
- Test results of water or fish tissue for those environmental chemical contaminants and

pesticides that are reasonably likely to be present;

AND

- Monitoring results for agricultural and industrial practices.
- » **How Will Monitoring Be Done?**
- Visual check of test results and monitoring reports.
- » **How Often Will Monitoring Be Done (Frequency)?**
- For results of water testing:
 - All new suppliers;OR
- For results of fish tissue testing:
 - Each delivery;AND
- For reports of evaluation of agricultural and industrial practices:
 - At least once every year.
- » **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 over the operation after a critical limit deviation:

- Discontinue use of the supplier until evidence is obtained that the supplier will comply with the testing and evaluation controls.

Establish a Recordkeeping System.

- Test results;
- AND
- Reports of evaluation of agricultural and industrial practices.

TABLE 9-4

CONTROL STRATEGY EXAMPLE 3 - RECORDS OF TESTING AND MONITORING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3 - Records of Testing and Monitoring." This example illustrates how a farm-raised catfish processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental chemical contaminants and pesticides 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., aquaculture drugs, food and color additives, and metal fragments).

**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) HOW	(6) FREQUENCY	(7) WHO				
Receiving	Environmental chemical contaminants and pesticides	Reports of analyses of the water from all new suppliers that show that levels of environmental chemical contaminants and pesticides that are reasonably likely to be present are not so high that they are likely to result in levels in fish tissue that exceed the established federal tolerance or action levels*	Visual check	At first delivery	Quality control staff	Reject the lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the testing and evaluation controls.	Test results	Review monitoring and corrective action records within 1 week of preparation	
			Visual check	Once per year	Quality control staff	Reject the lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the testing and evaluation controls	Reports of agricultural and industrial practices	Review monitoring and corrective action records within 1 week of preparation	

* Note: This plan is for illustrative purposes only. An actual plan should specify (1) in the Critical Limits column: the environmental chemical contaminants and pesticides that are reasonably likely to be present and the critical limits to be applied to each contaminant; and (2) in the Monitoring columns: the contaminants for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each contaminant.

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.
- **CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING**

Set Critical Limits.

- No lot may exceed the federal tolerance or action levels for those environmental chemical contaminants and pesticides that are reasonably likely to be present (refer to Table 9-1).

Establish Monitoring Procedures.

- » **What Will Be Monitored?**
 - Fish tissue for those environmental chemical contaminants and pesticides that are reasonably likely to be present.
- » **How Will Monitoring Be Done?**
 - Obtain samples and analyze for environmental chemical contaminants and pesticides.
- » **How Often Will Monitoring Be Done (Frequency)?**
 - Each lot received.
- » **Who Will Do the Monitoring?**
 - Any person who is qualified by training or experience to perform the analyses.

Establish Corrective Action Procedures.

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

- Reject the lot.

AND

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

- Discontinue use of the supplier until evidence is obtained that the cause of

the chemical contamination has been eliminated.

Establish a Recordkeeping System.

- Test results.

Establish Verification Procedures.

- Periodically verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Chemists, or equivalent method, or by analyzing proficiency samples);

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 9-5

CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANT TESTING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4 - Chemical Contaminant Testing." This example illustrates how an aquacultured shrimp processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental chemical contaminants and pesticides 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., aquaculture drugs, food and color additives, and metal fragments).

**Example Only
See Text for Full Recommendations**

(1)	(2)	(3)	(4)			(6)	(7)	(8)	(9)	(10)
			WHAT	HOW	FREQUENCY					
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING							
Receiving	Environmental chemical contaminants and pesticides	No lot of shrimp may exceed the established tolerance or action levels for environmental chemical contaminants and pesticides that are reasonably likely to be present*	Chemical residue levels in shrimp tissue that are reasonably likely to be present*	Obtain samples and analyze for environmental chemical contaminants and pesticides*	Each lot received	Receiving employee will submit sample to quality control staff	Reject the lot Discontinue use of the supplier until evidence is obtained that the cause of the chemical contamination has been eliminated	Test results	Annual methods comparison to AOAC methods Review monitoring and corrective action records within 1 week of preparation	

* Note: This plan is for illustrative purposes only. An actual plan should specify (1) in the Critical Limits column: the environmental chemical contaminants and pesticides that are reasonably likely to be present and the critical limits to be applied to each contaminant; and (2) in the Monitoring columns: the contaminants for which analysis will be conducted, the protocol for sample collection, and the analytical method to be used for each contaminant.

- **CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM**

Set Critical Limits.

- A certificate indicating that the producer operates under a third-party-audited QA program that covers environmental chemical contaminants and pesticides. The certificate may accompany each lot of incoming aquacultured fish or may be issued for each producer of incoming aquacultured fish as a continuing certification.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Certificate indicating operation under a third-party-audited QA program.

» **How Will Monitoring Be Done?**

- Visual check for the presence of a certificate.

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

- Each lot received is checked for the presence of a certificate. Certificates may be issued on continuing (not less often than annually) or lot-by-lot basis.

» **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;
OR
- Hold the lot until a certificate can be provided;
OR
- Hold and analyze the lot for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

AND

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

- Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls.

Establish a Recordkeeping System.

- Third-party certificates;
AND
- Records showing lots received and the presence or absence of a certificate.

Establish Verification Procedures.

- Review the third-party-audited QA program and results of audits annually;
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 9-6

CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

This table is an example of a portion of a HACCP plan using "Control Strategy Example 5 - QA Program." This example illustrates how an aquacultured trout processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purpose only.

Environmental chemical contaminants and pesticides 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., aquaculture drugs, food and color additives, and metal fragments).

**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				
Receiving	Environmental chemical contaminants and pesticides	Certificate indicating that the producer operates under a third-party-audited QA program that covers environmental chemical contaminants and pesticides	Presence of a third-party certificate	Visual check for the presence of a certificate	Each lot	Receiving dock employee	Reject the lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls	Certificate Receiving record	Review the third-party-audited QA program and results of audits annually Review monitoring, corrective action, and verification records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL FOR WILD CAUGHT FISH OTHER THAN MOLLUSCAN SHELLFISH**

Set Critical Limits.

- No fish may be harvested from an area that is closed to commercial harvesting by state, tribal, territorial, local, or foreign authorities because of concentrations of environmental chemical contaminants or pesticides exceeding the federal tolerance or action levels;

AND

- No fish may be harvested from an area that is under a consumption advisory by a, state, tribal, territorial, local, or foreign regulatory authority based on a determination by the authority that fish harvested from the waters are reasonably likely to contain contaminants above the federal tolerance or action levels. Note that many consumption advisories are not based on such a determination.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Location of harvest and whether the harvest area is subject to closure or consumption advisory.

» **How Will Monitoring Be Done?**

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

AND

- Ask the state, tribal, territorial, local, or foreign authorities in which your fish are harvested whether there are closures or consumption advisories that apply to the areas from which your fish are harvested.

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

- Every lot received.

» **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;

OR

- For fish harvested from an area under a consumption advisory based on federal tolerance or action levels:
 - Sample the lot and analyze it for the appropriate environmental chemical contaminant or pesticide. Reject the lot if the results exceed the federal tolerance or action level.

AND

Take the following corrective action to regain control over 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 records that document the location and whether the harvest area is subject to closure or consumption advisory.

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 9-7

CONTROL STRATEGY EXAMPLE 6 - SOURCE CONTROL FOR WILD CAUGHT FISH OTHER THAN MOLLUSCAN SHELLFISH

This table is an example of a portion of a HACCP plan using "Control Strategy Example 6 - Source Control for Wild Caught Fish Other Than Molluscan Shellfish." This example illustrates how a wild caught bluefish processor can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental contaminants and pesticides from the harvest area 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., scombrototoxin (histamine), metal fragments).

**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				
Receiving	Environmental chemical contaminants and pesticides	No fish may be harvested from an area that is closed to commercial harvesting by state, or local authorities because of concentrations of environmental chemical contaminants or pesticides exceeding the federal tolerance or action levels No fish may be commercially harvested from an area that is under a consumption advisory by a state, local, or local regulatory authority based on a determination by the authority that fish harvested from the waters are reasonably likely to contain contaminants above the federal tolerance or action levels	Location of harvest and whether the harvest area is subject to closure or consumption advisory	Ask the harvester for the harvest location, and ask state and local authorities the status of the area	Each lot received	Receiving dock employee	Reject the 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

- **CONTROL STRATEGY EXAMPLE 7 - 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), the type and quantity of shellfish, and the harvester's or harvester's vessel information (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 other 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), the 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 receives molluscan shellfish directly from the harvester) needs to 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?**

- The information contained on tags on containers of incoming shellstock or on the bill of lading or other similar shipping document accompanying bulk shipments of shellstock and whether the harvest area is authorized for harvest by a shellfish control authority;

AND

- The license of the harvester;

OR

- The information contained on labels on containers of incoming shucked molluscan shellfish.

» **How Will Monitoring Be Done?**

- Perform visual checks;

AND

- Ask the relevant shellfish control authority whether the harvest area is authorized for harvest.

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

- For checking tags:
 - Every container;

AND

- For checking harvester licenses:
 - Every delivery;

OR

- For checking labels:
 - At least three containers randomly selected from throughout 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 over 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 9-8

CONTROL STRATEGY EXAMPLE 7 - SOURCE CONTROL FOR MOLLUSCAN SHELLFISH

This table is an example of a portion of a HACCP plan using "Control Strategy Example 7 - Source Control for Molluscan Shellfish." The example illustrates how a processor of shellstock oysters received directly from a harvester can control environmental chemical contaminants and pesticides. It is provided for illustrative purposes only.

Environmental contaminants and pesticides from the harvest area 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 and pathogens from the harvest area).

**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) HOW	(6) FREQUENCY	(7) WHO				
Receiving	Environmental chemical contaminants and pesticides	All 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	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	
			Perform visual checks and ask the shellfish control authority whether the area is authorized for harvest	Every lot		Reject lots from unapproved waters Discontinue use of the supplier until evidence is obtained that harvesting practices have changed			
			License of harvester	Every delivery		Reject lots from unlicensed harvesters Discontinue use of the supplier until evidence is obtained that the harvester is properly licensed			

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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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NOTES: