

Hazard Analysis Worksheet

STEP #10: *Understand the potential hazard.*

Environmental chemical contaminants and pesticides in fish pose a potential human health hazard. Fish are harvested from waters that are exposed to varying amounts of industrial chemicals, pesticides, and toxic elements. These contaminants may accumulate in fish at levels that can cause illness. The hazard is most commonly associated with long-term exposure to these contaminants; illnesses associated with a single exposure (one meal) are very rare. Concern for these contaminants primarily focuses on fish harvested from fresh water, estuaries, and near-shore coastal waters (e.g. areas subject to shoreside contaminant discharges), rather than from the open ocean. Pesticides used near aquaculture operations may also contaminate fish.

• Control of chemical contaminants

Federal tolerances, action levels, and guidance levels are established for some of the most toxic and persistent contaminants that are found in fish. These levels are listed in Table #9-1. States often use the Federal tolerances, action levels, and guidance levels for deciding whether to issue consumption advisories or to close waters for commercial harvesting of all or certain species of fish.

In the case of molluscan shellfish, State 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, 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.

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; and, 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 their name, address, and certification number.

STEP #11: *Determine if this potential hazard is significant.*

At each processing step, determine whether “environmental chemical contaminants and pesticides” is a significant hazard. The criteria are:

1. Is it reasonably likely that unsafe levels of environmental chemical contaminants or pesticides will be introduced at the receiving step (e.g. does the raw material come in with an unsafe level of an environmental chemical contaminant or pesticide)?

Tables #3-1 and 3-2 (Chapter 3) identify the species of fish for which “environmental chemical contaminants and pesticides” is 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. There may be circumstances in your geographic area 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 from your area. You should be guided by the historical occurrence of environmental chemical contaminants and pesticides, at levels above the established tolerances, action levels, or guidance levels, in fish from your geographic area.

Except in the case of molluscan shellfish, the hazard of “environmental chemical contaminants and pesticides” should be fully controlled by the primary processor. For this reason, secondary processors of fish other than molluscan shellfish need not identify this hazard as a significant hazard.

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2. Can unsafe levels of environmental chemical contaminants and pesticides, which were introduced 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)

“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 prevent or eliminate (or is adequate to reduce the likelihood of occurrence to an acceptable level) unsafe levels of environmental chemical contaminants and pesticides that are reasonably likely to occur. Preventive measures for environmental chemical contaminants and pesticides can include:

- Making sure that incoming fish have not been harvested from waters that are closed to the commercial harvest of that specie due to environmental chemical contaminants or pesticides;
- Making sure that incoming fish have not been harvested from waters that are under a consumption advisory by a federal, state 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 tolerances, action levels, or guidance levels. Note: many consumption advisories are not based on such a determination.
- Checking incoming molluscan shellfish to ensure that they 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;
- Receipt of the aquacultural grower’s lot-by-lot certification of harvesting from uncontaminated waters, coupled with appropriate verification (see Step #18 - Verification);
- Review, at time of receipt of aquacultured fish, of environmental chemical contaminant and pesticide test results of soil and water or fish flesh samples, and monitoring of present land use practices in the area immediately surrounding the production area (tests and monitoring may be performed by the aquacultural grower, a State agency, or a third party organization);

- On-farm visits to the aquacultural grower to collect and analyze soil and water samples or fish samples for environmental chemical contaminants and pesticides, and to review present land use practices in the area immediately surrounding the production area;
- Environmental chemical contaminant and pesticide testing of fish flesh at time of receipt;
- Receipt of evidence (e.g. third party certificate) that the producer operates under a third party-audited Quality Assurance Program for environmental chemical contaminants and pesticides (e.g. the National Aquaculture Association’s Fish Producers Quality Assurance Program).

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s). In the case of an integrated operation, where fish processing and grow-out are performed by the same firm, it may be possible and desirable to exercise preventive measures early in the process (ideally when the grow-out site is selected), rather than at receipt of the fish at the processing plant. Such preventive measures will not be covered in this chapter.

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

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.

• 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 unlikely that the significance of this hazard will be affected by the intended use of the product.

STEP #12: *Identify the critical control points (CCP).*

For each processing step where “environmental chemical contaminants and pesticides” 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 #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 “environmental chemical contaminants and pesticides”:

Is the raw material an aquacultured product?

1. If it is, is your relationship with the grower one that enables you to visit the farm before receipt of the fish?

- a. If you have such a relationship with the grower, then you may identify a pre-harvest step as the CCP for “environmental chemical contaminants and pesticides.” The preventive measure for this type of control is on-farm visits to the aquacultural grower to collect and analyze soil and water samples or fish samples for environmental chemical contaminants and pesticides, and to review present land use practices in the area immediately surrounding the production area.

Example:

A processor of aquacultured catfish that regularly purchases from the same growers could visit the growers before the fish are harvested. The processor could collect and analyze soil and water samples or fish samples for environmental chemical contaminants and pesticides and review present land use at the pond site and in the adjacent areas. The processor could then set the critical control point for environmental chemical contaminants and pesticides at the pre-harvest step.

In this case, you should enter “Yes” in Column 6 of the Hazard Analysis Worksheet for the pre-harvest step. This control approach will be referred to as “Control Strategy Example 1” in Steps #14 through 18. (Note: if you have not previously identified “environmental chemical contaminants and pesticides” as a significant

hazard at the pre-harvest step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to “Yes.”)

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

- Receipt of the aquacultural grower’s lot-by-lot certification of harvesting from uncontaminated waters, coupled with appropriate verification (see Step #18 - Verification).

Example:

A processor of aquacultured shrimp that purchases raw material shrimp through various brokers could receive lot-by-lot certificates from the growers. The certificates would state that the shrimp were not harvested from waters that were so contaminated by chemicals as to make it reasonably likely that the levels in the fish flesh would be in excess of established tolerances or action levels.

In this case, 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 2” in Steps #14 through 18.

- Review of environmental chemical contaminant and pesticide test results of soil and water samples or of fish flesh samples, and monitoring of present land use practices in the area immediately surrounding the production area (tests and monitoring to be performed by the aquacultural grower, a State agency, or a third party organization).

Example:

A processor of farm-raised catfish purchases catfish from a grower with which the processor has no long term relationship. The processor requires all new suppliers to provide the results of soil and water chemical contaminant tests, and reports on present agricultural and industrial

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land use at and near the pond site. The land use reports are updated annually. The testing and reports are done by the grower, a trade association, or the State Agriculture Department.

In this case, 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 3” in Steps #14 through 18.

- Environmental chemical contaminant and pesticide testing of fish flesh. This screening can be performed by rapid analytical methods which may indicate the presence of industrial chemicals, pesticides and/or toxic elements. If the rapid screening test indicates that contaminants are present, further testing and/or follow-up with the supplier would be necessary.

Example:

A processor of aquacultured shrimp that purchases raw material shrimp through various brokers could screen all incoming lots of shrimp for pesticides that are likely to be used around the grow-out area.

In this case, 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 4” in Steps #14 through 18.

- Receipt of evidence (e.g. continuing or lot-by-lot third party certificate) that the producer operates under a third party-audited Quality Assurance program that covers environmental chemical contaminants and pesticides.

Example:

A processor of aquacultured trout that regularly purchases raw material trout from the same grower could obtain a third party certificate, valid for one year, that attests that the grower operates under a Quality Assurance Program that covers environmental chemical contaminants and pesticides.

In this case, 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 5” in Steps #14 through 18.

2. If the product is not an aquacultured product, you may identify the receiving step as the CCP for “environmental chemical contaminants and pesticides.” At the receiving step you may exercise the following preventive measures:

Source control, including:

- Making sure that incoming fish to have not been harvested from waters that are closed to commercial harvest due to environmental chemical contaminants or pesticides;
- Making sure that incoming fish have not been harvested from waters that are under a consumption advisory by a federal, state 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 tolerances, action levels, or guidance levels. Note: many consumption advisories are not based on such a determination.
- 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.

Examples:

A processor purchases oysters directly from the harvester. The processor checks the harvest location on the tags attached to the sacks of oysters. The processor then compares the harvest area location to information on closed waters. The processor also checks the harvester’s State license.

A processor purchases flounder directly from the harvester. The processor asks the harvester where the fish were caught. The processor then compares the harvest area location to his knowledge of the areas that are closed to commercial fishing by state or local regulatory authorities or that are under consumption advisories based on federal tolerance/action level/guidance levels.

In this case, 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 6” 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 1 for “natural toxins” (Chapter 6). 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 those which are 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 “environmental chemical contaminants and pesticides” is identified as a significant hazard in 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 critical limit at the point that if not met the safety of the product is questionable. If you set a more restrictive critical limit 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 critical limit 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 critical limit. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the critical limit 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 critical limit.

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

• Control Strategy Example 1 - On-farm visit

CRITICAL LIMIT: Levels of environmental chemical contaminants and pesticides in soil and water samples must not be so high that they are likely to result in levels in the fish flesh that are above the established tolerances, action levels, or guidance levels (Note: federal guidance levels for environmental chemical contaminants and pesticides in soil and water have not been established);

OR

No lot of fish may exceed the established tolerances, action levels, or guidance levels for environmental chemical contaminants and pesticides;

AND

Agricultural and industrial practices in the area immediately surrounding the production area must not be reasonably likely to cause contamination of the fish flesh above the established tolerances, action levels, or guidance levels.

• Control Strategy Example 2 - Supplier’s certification

CRITICAL LIMIT: Certificate accompanying all lots received (lot-by-lot) that indicates that the fish were not harvested from waters that were so contaminated by chemicals as to make it reasonably likely that the levels in the fish flesh would be in excess of established tolerances, action levels, or guidance levels.

• Control Strategy Example 3 - Records of testing and monitoring

CRITICAL LIMIT: Analyses of the soil and water from all new suppliers that show that levels of environmental chemical contaminants and pesticides in the soil and water are not so high that they are likely to result in levels in the fish flesh that are above the established tolerances, action levels, or guidance levels (tests may be performed by the aquacultural grower, a State agency, or a third party organization). (Note: EPA

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has developed water quality documents that may be suitable for evaluating water quality in local situations);

OR

Analyses of fish flesh for each delivery that show that levels of environmental chemical contaminants and pesticides are below the established tolerances, action levels, or guidance levels (tests may be performed by the aquacultural grower, a State agency, or a third party organization);

AND

Annually, reports from all suppliers that show that agricultural and industrial practices in the area immediately surrounding the aquaculture production area are not reasonably likely to cause contamination of the fish flesh above the established tolerances, action levels, or guidance levels (monitoring may be performed by the aquacultural grower, a State agency, or a third party organization).

- **Control Strategy Example 4 - Chemical contaminant testing**

CRITICAL LIMIT: No lot of fish may exceed the established tolerances, action levels, or guidance levels for environmental chemical contaminants and pesticides.

- **Control Strategy Example 5 - QA program**

CRITICAL LIMIT: Third party certificate indicating that the producer operates under a third party-audited Quality Assurance program that covers environmental chemical contaminants and pesticides, either for each lot of incoming aquacultured fish or for each producer of incoming aquacultured fish.

- **Control Strategy Example 6 - Source control**

CRITICAL LIMIT: No fish may be harvested from an area that is closed to commercial fishing by foreign, federal, state, or local authorities;

AND

No fish may be harvested from an area that is under a consumption advisory by a federal, state, 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 tolerances, action levels, or guidance levels.

Note: many consumption advisories are not based on such a determination.

AND

For molluscan shellfish:

- All containers of 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, where the shellstock is not containerized, all shellstock must be accompanied by a bill of lading or other similar shipping document that contains the same information.

AND

- All molluscan shellfish must be harvested from waters approved 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 containers of molluscan shellfish must be from a fisherman 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.)

TABLE #9-1

Environmental Chemical Contaminant and Pesticide Tolerances, Action Levels, and Guidance Levels

<i>Deleterious Substance</i>	<i>Level</i>	<i>Food Commodity</i>	<i>Reference</i>
Aldrin/Dieldrin ^a	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 ^b	0.3 ppm	All fish	Compliance Policy Guide sec. 575.100
	0.4 ppm	Crabmeat	
DDT, TDE, DDE ^c	5.0 ppm	All fish	Compliance Policy Guide sec. 575.100
Diquat ^d	0.1 ppm	All fish	40 CFR 180.226
Fluridone ^d	0.5 ppm	Fin fish and crayfish	40 CFR 180.420
Glyphosate ^d	0.25 ppm	Fin fish	40 CFR 180.364
	3.0 ppm	Shellfish	
Toxic elements:			
Arsenic	76 ppm	Crustacea	FDA Guidance Document
	86 ppm	Molluscan bivalves	FDA Guidance Document
Cadmium	3 ppm	Crustacea	FDA Guidance Document
	4 ppm	Molluscan bivalves	FDA Guidance Document
Chromium	12 ppm	Crustacea	FDA Guidance Document
	13 ppm	Molluscan bivalves	FDA Guidance Document
Lead	1.5 ppm	Crustacea	FDA Guidance Document
	1.7 ppm	Molluscan bivalves	FDA Guidance Document
Nickel	70 ppm	Crustacea	FDA Guidance Document
	80 ppm	Molluscan bivalves	FDA Guidance Document
Methyl Mercury ^f	1 ppm	All fish	Compliance Policy Guide sec. 540.600
Heptachlor /Heptachlor Epoxide ^e	0.3 ppm	All fish	Compliance Policy Guide sec. 575.100
Mirex	0.1 ppm	All fish	Compliance Policy Guide sec. 575.100
Polychlorinated Biphenyls (PCB's) ^d	2.0 ppm	All fish	21 CFR 109.30
Simazine ^d	12 ppm	Fin fish	40 CFR 180.213a
2,4-D ^d	1.0 ppm	All fish	40 CFR 180.142

^a The action level for aldrin and dieldrin are for residues of the pesticides individually or in combination.

However, in adding amounts of aldrin and dieldrin, do not count aldrin or dieldrin found at below 0.1 ppm.

^b Previously listed as Kepone, the trade name of chlordecone.

^c The action level for DDT, TDE, and DDE are for residues of the pesticides individually or in combination.

However, in adding amounts of DDT, TDE, and DDE, do not count any of the three found below 0.2 ppm.

^d The levels published in 21 CFR & 40 CFR represent tolerances, rather than guidance levels or action levels.

^e The action level for heptachlor and heptachlor epoxide are for the pesticides individually or in combination.

However, in adding amounts of heptachlor and heptachlor epoxide, do not count heptachlor or heptachlor epoxide found below 0.1 ppm.

^f See Chapter 10 for additional information.

Note: the term "fish" refers to fresh or saltwater fin fish, crustaceans, other forms of aquatic animal life other than birds or mammals, and all mollusks, as defined in 21 CFR 123.3(d).

- **Tolerances, action levels, and guidance levels**

Environmental chemical contaminant and pesticide tolerances, action levels, and guidance levels for poisonous or deleterious substances in the edible portion wet weight of fish are listed in Table #9-1.

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

STEP #15: Establish monitoring procedures.

For each processing step where “environmental chemical contaminants and pesticides” 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 critical limit is being met. That is, the monitoring process should directly measure the feature for which you have established a critical limit.

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

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

What Will Be Monitored?

- **Control Strategy Example 1 - On-farm visit**

WHAT: Environmental chemical contaminant and pesticide levels in soil and water or in fish flesh;
AND
Agricultural and industrial practices near the production area.

- **Control Strategy Example 2 - Supplier’s certification**

WHAT: Presence of a certificate indicating harvesting from uncontaminated waters.

- **Control Strategy Example 3 - Records of testing and monitoring**

WHAT: Soil and water, or fish flesh, chemical contaminant test results;
AND
Agricultural and industrial practices monitoring results.

- **Control Strategy Example 4 - Chemical contaminant testing**

WHAT: Fish flesh for environmental chemical contaminants and pesticides.

- **Control Strategy Example 5 - QA program**

WHAT: Third party certificate indicating operation under third-party audited QA program.

- **Control Strategy Example 6 - Source control**

WHAT: Location and status (e.g. open, closed) of the harvest area;

AND

For molluscan shellfish:

- 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.

How Will Monitoring Be Done?

- Control Strategy Example 1 - On-farm visit

HOW: Collect and analyze soil and water samples or fish flesh samples from each production area;

AND

Ask questions about and observe agricultural and industrial practices in the production area, such as:

- What crops are grown in the area immediately surrounding the production area?

AND

- What pesticides are used on these crops, how are they applied, and at what time of year?

AND

- What industrial discharges enter the watershed surrounding the production site?

- Control Strategy Example 2 - Supplier's certification

HOW: Visual for presence of certificate.

- Control Strategy Example 3 - Records of testing and monitoring

HOW: Visual of test results and monitoring reports.

- Control Strategy Example 4 - Chemical contaminant testing

HOW: Obtain samples and analyze for environmental chemical contaminants and pesticides using rapid screening methods.

- Control Strategy Example 5 - QA program

HOW: Visual for presence of certificate.

- Control Strategy Example 6 - Source control

HOW: Ask harvester;

AND

For molluscan shellfish: visual checks.

How Often Will Monitoring Be Done (Frequency)?

- Control Strategy Example 1 - On-farm visit

FREQUENCY: For testing soil or water: before first delivery from each production area;

OR

For testing fish flesh: before each delivery;

AND

For monitoring: at least once per year for each aquaculture production site.

- Control Strategy Example 2 - Supplier's certification

FREQUENCY: Each lot received.

- Control Strategy Example 3 - Records of testing and monitoring

FREQUENCY: For soil and water test results: all new suppliers;

OR

For fish flesh test results: each delivery;

AND

For monitoring reports: at least once every year.

- Control Strategy Example 4 - Chemical contaminant testing

FREQUENCY: Each lot received.

- Control Strategy Example 5 - QA program

FREQUENCY: Each lot received checked for presence of certificate. Certificates may be issued on a lot-by-lot or continuing basis, but at least annually.

- **Control Strategy Example 6 - Source control**

FREQUENCY: Each lot received;

AND

For Molluscan Shellfish:

- 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.

Who Will Perform the Monitoring?

- **Control Strategy Example 1 - On-farm visit**

WHO: Field agent (employee or contractor) or any other person who has an understanding of chemical contaminants and their limits.

- **Control Strategy Example 2 - Supplier's certification**

WHO: Receiving dock employee, production employee, production supervisor, a member of the quality control staff, or any other personnel who has an understanding of the control measure.

- **Control Strategy Example 3 - Records of testing and monitoring**

WHO: Receiving dock personnel, production employee, production supervisor, a member of the quality control staff, or any other personnel who has an understanding of chemical contaminants and their limits.

- **Control Strategy Example 4 - Chemical contaminant testing**

WHO: Member of the quality control staff or contract laboratory.

- **Control Strategy Example 5 - QA program**

WHO: Receiving employee or supervisor, production supervisor, a member of the quality control staff, or any other person who has an understanding of the control procedure.

- **Control Strategy Example 6 - Source control**

WHO: Receiving dock personnel, production employee, production supervisor, a member of the quality control staff, or any other personnel who has an understanding of the control measure.

(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 "environmental chemical contaminants and pesticides" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the critical limit 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 critical limit 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 examples discussed in Step #12.

- **Control Strategy Example 1 - On-farm visit**

CORRECTIVE ACTION: Do not have product shipped to plant, if the CL is not met;

AND

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

- **Control Strategy Example 2 - Supplier's certification**

CORRECTIVE ACTION: Reject lot, if the CL is not met;

OR

Hold the lot until a certificate can be provided;

OR

Hold and analyze the lot for environmental chemical contaminants and pesticides. This screening can be performed by rapid analytical methods which may indicate the presence of industrial chemicals, pesticides and/or toxic elements. If the rapid screening test indicates that contaminants are present, further testing and/or follow-up with the supplier would be necessary.

- **Control Strategy Example 3 - Records of testing and monitoring**

CORRECTIVE ACTION: Reject lot, if the CL is not met;

AND

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

- **Control Strategy Example 4 - Chemical contaminant testing**

CORRECTIVE ACTION: Reject lot, if the CL is not met;

AND

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

- **Control Strategy Example 5 - QA program**

CORRECTIVE ACTION: Reject lot, if the CL is not met.

- **Control Strategy Example 6 - Source control**

CORRECTIVE ACTION: Reject lot, if the CL is not met;

OR

For fish under a consumption advisory based on a federal tolerance/action level/guidance level: Sample the lot and analyze for the appropriate environmental contaminant. Reject the lot if the results exceed the federal tolerance/action level/guidance level;

AND

For molluscan shellfish:

- 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 from that have been harvested from unapproved waters;

AND

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

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

STEP #17: *Establish a recordkeeping system.*

For each processing step where "environmental chemical contaminants and pesticides" 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 examples discussed in Step #12.

Continued

• **Control Strategy Example 1 - On-farm visit**

RECORDS: Test results;

AND

On-site audit report.

• **Control Strategy Example 2 - Supplier's certification**

RECORDS: Copy of certificate;

AND

Receiving record showing lots received and presence/absence of certificate.

• **Control Strategy Example 3 - Records of testing and monitoring**

RECORDS: Test results;

AND

Monitoring reports.

• **Control Strategy Example 4 - Chemical contaminant testing**

RECORDS: Test results.

• **Control Strategy Example 5 - QA program**

RECORDS: Third party certificate;

AND

Receiving record showing lots received and presence/absence of certificate.

• **Control Strategy Example 6 - Source control**

RECORDS: Receiving records that document the harvest location and status (e.g. open, closed) of the harvest area;

AND

For molluscan shellfish shellstock: 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;

AND

For shucked molluscan shellfish: a receiving record that documents:

- Date of receipt;

AND

- Quantity and type of shellfish;

AND

- Name and certification number of the packer or repacker.

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

STEP #18: *Establish verification procedures.*

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

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

- Control Strategy Example 1 - On-farm visit

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

- Control Strategy Example 2 - Supplier's certification

VERIFICATION: Visit all new aquacultured fish suppliers within the year and all existing fish suppliers at a predetermined frequency (e.g. 25% per year) to collect and analyze soil and/or water samples, as appropriate, for environmental chemical contaminants and pesticides, 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 for drug residues;

AND

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

- Control Strategy Example 3 - Records of testing and monitoring

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

- Control Strategy Example 4 - Chemical contaminant testing

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

- Control Strategy Example 5 - QA program

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

- Control Strategy Example 6 - 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 #9-2

Control Strategy Example 1 - On-farm visits

This table is an example of a HACCP plan relating to the control of environmental chemical contaminants and pesticides in pond-raised catfish, using Control Strategy Example 1 - On-farm visit. It is provided for illustrative purposes only. Chemical contaminants 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. aquaculture drugs and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(5) Monitoring		(6)		(7)		(8) Corrective Action(s)	(9) Records	(10) Verification
			What		How	Frequency	Who	Who	Who					
Pre-harvest	Chemical contaminants	<ul style="list-style-type: none"> Levels of environmental chemical contaminants and pesticides in fish flesh may not exceed established tolerances, action levels, and guidance levels Agricultural and industrial practices in the area immediately surrounding the pond must not be reasonably likely to cause contamination of the fish flesh above the established tolerances, action levels, or guidance levels. 	<ul style="list-style-type: none"> Environmental chemical contaminant and pesticide levels in fish flesh samples before harvest Agricultural and industrial practices near the pond 	<ul style="list-style-type: none"> Collect samples and analyze for environmental chemical contaminants and pesticides using rapid screening methods Ask questions and observe agricultural and industrial practices 	<ul style="list-style-type: none"> Before harvest Once per year 	<ul style="list-style-type: none"> Field agent will submit samples to contract laboratory Field agent 	<ul style="list-style-type: none"> Do not have product shipped to plant AND Discontinue use of supplier until evidence is obtained that the cause of the chemical contamination has been eliminated Same 	<ul style="list-style-type: none"> Test results Field agent report 	<ul style="list-style-type: none"> Review monitoring and correction action records within one week of preparation Review monitoring and correction action records within one week of preparation 					

TABLE #9-3

Control Strategy Example 2 - Supplier's Certification

This table is an example of a portion of a HACCP plan relating to the control of environmental chemical contaminants and pesticides in aquacultured salmon, using Control Strategy Example 2 - Supplier's certification. It is provided for illustrative purposes only. Chemical contaminants 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. aquaculture drugs, chemical contaminants, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(5) Monitoring		(6)		(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who	How	Frequency					
Receiving	Environmental chemical contaminants and pesticides	Certificate accompanying all lots received indicates that the fish were not harvested from waters that were so contaminated by chemicals as to make it reasonably likely that the levels in the fish flesh would be in excess of established tolerances, action levels, or guidance levels.	Presence of a certificate	Visual	Each lot received	Receiving dock employee	Reject lot	<ul style="list-style-type: none"> Copy of certificate Receiving record 	<ul style="list-style-type: none"> Review monitoring, corrective action, and verification records within one week of preparation Visit all new suppliers and 25% of existing suppliers each year and collect soil and/or water samples and review agricultural and industrial practices in the area 				

TABLE #9-4

Control Strategy Example 3 - Records of testing and monitoring

This table is an example of a portion of a HACCP plan relating to the control of environmental chemical contaminants and pesticides in farmed-raised trout, using Control Strategy Example 3 - Records of testing and monitoring. It is provided for illustrative purposes only. Chemical contaminants 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. aquaculture drugs and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(5) Monitoring		(6) Frequency	(7) Who	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Who	How	Who					
Receiving	Environmental chemical contaminants and pesticides	<ul style="list-style-type: none"> Analyses of fish flesh for each delivery that show that levels of environmental chemical contaminants and pesticides are below the established tolerances, action levels, or guidance levels (tests may be performed by the aquacultural grower, a State agency, or a trade association) Annually, reports from all suppliers that show that agricultural and industrial practices in the area immediately surrounding the production area are not reasonably likely to cause contamination of the fish flesh above the established tolerances, action levels, or guidance levels (monitoring may be performed by the aquacultural grower, a State agency, or a trade association) 	<ul style="list-style-type: none"> Levels of environmental chemical contaminants and pesticides in soil and water samples Agricultural and industrial practices near the production area 	<ul style="list-style-type: none"> Visual Visual 	<ul style="list-style-type: none"> Each delivery Once per year 	<ul style="list-style-type: none"> Quality control staff Quality control staff 	<ul style="list-style-type: none"> Reject lot, AND Discontinue use of supplier until evidence is obtained that the source of the chemical contamination has been eliminated Same 	<ul style="list-style-type: none"> Test results Monitoring reports 	<ul style="list-style-type: none"> Review monitoring and correction action records within on week of preparation Review monitoring and correction action records within on week of preparation 			

TABLE #9-5

Control Strategy Example 4 - Chemical contaminant testing

This table is an example of a HACCP plan relating to the control of environmental chemical contaminants and pesticides in pond-raised shrimp, using Control Strategy Example 4 - Chemical contaminant testing. It is provided for illustrative purposes only. Chemical contaminants 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. aquaculture drugs, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(6) Monitoring	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What		How					
Receiving	Environmental chemical contaminants and pesticides	No lot of fish may exceed the established tolerances, action levels, or guidance levels for environmental chemical contaminants and pesticides	Fish flesh for chemical residues	Obtain samples and analyze for environmental chemical contaminants and pesticides using rapid screening methods	Each lot received	Receiving employee will submit sample to quality control staff	<ul style="list-style-type: none"> Reject lot AND <ul style="list-style-type: none"> Discontinue use of supplier until evidence is obtained that the cause of the chemical contamination has been eliminated 	Test results	Review monitoring and corrective action records within one week of preparation	

TABLE #9-6

Control Strategy Example 5 - QA program

This table is an example of a HACCP plan relating to the control of environmental chemical contaminants and pesticides for an aquacultured trout processor, using Control Strategy Example 5 - QA program. It is provided for illustrative purposes only. Chemical contaminants 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. aquaculture drugs and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(5) Monitoring		(6) Frequency	(7)		(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Who	How	Who						
Receiving	Environmental chemical contaminants and pesticides	Third party certificate indicating that the producer operates under a Quality Assurance Program that covers environmental chemical contaminants and pesticides	Presence of third party certificate	Visual, for presence of certificate	Receiving dock employee	Each lot checked to see if covered by certificate, which is renewed annually	Reject lot	<ul style="list-style-type: none"> • Certificate • Receiving record 	<ul style="list-style-type: none"> • Review monitoring and corrective action records within one week of preparation 				

TABLE #9-7

Control Strategy Example 6 - Source control

This table is an example of a portion of a HACCP plan relating to the control of environmental chemical contaminants and pesticides in wild-caught flounder, using Control Strategy Example 6 - Source control. It is provided for illustrative purposes only. Guidance for processors of molluscan shellfish using source control is provided in Table #4-1 (Chapter 4).

Chemical contaminants 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. parasites and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)			(6) Monitoring	(7) Who	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency					
Receiving	Environmental chemical contaminants and pesticides	No fish may be harvested from an area that is closed to commercial fishing by foreign, federal, state, or local authorities No fish may be harvested from an area that is under a consumption advisory by a federal, state, 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 tolerances, action levels, or guidance levels. Note: many consumption advisories are not based on such a determination.	Location of harvest area	Ask harvester	Each lot received	Receiving dock employee	Reject lot	Receiving record	Review monitoring and corrective action record within one week of preparation	

Notes: