CHAPTER 9: ENVIRONMENTAL CHEMICAL CONTAMINANTS INCLUDING PESTICIDES

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UNDERSTAND THE POTENTIAL HAZARD

This chapter concerns the potential food safety hazard of environmental chemical contaminants (heavy metals, pesticides, and industrial chemicals) residues in farm-raised (aquacultured) and wild caught seafood products.

Environmental chemical contaminants are chemical compounds that accidentally or deliberately enter the environment, often, but not always, as a result of human activities. The sources of these contaminants are wide-ranging. Some of these contaminants may have been manufactured for industrial or agriculture use and if released to the environment, they may enter the food chain. Other environmental contaminants, such as heavy metals (e.g., arsenic, cadmium, chromium, nickel, and lead) are naturally present in the environment, for example in rocks and soils. However, industrial activities may increase their mobility or increase the amount available to circulate in the environment, allowing them to enter the food chain at higher levels than would otherwise occur. Most aquatic ecosystems have a natural tendency to dilute pollution to some extent, but severe contamination of aquatic ecosystems can result in alteration in the uptake, retention, and bioaccumulation of contaminants in fish.

Contaminants can be transported to aquatic environments via municipal wastewater discharges and surface runoff from agricultural fields fertilized with animal manure and/or treated with pesticides. Although some industrial chemical compounds and pesticides have not been produced or used in the United States for several years, many still persist in soil and sediments. In general, compounds that accumulate in fish have a few things in common:

- They are persistent and do not breakdown easily in the environment.
- They can be carried long distances by air or water away from their point of application or discharge.
- Their concentrations can vary considerably in fish species due to the different habitats, life cycles, nature of feeding, ecology, and physiological nature of fish. For example, some chemicals, like PCBs, are lipophilic, meaning that they tend to combine with or dissolve in fats and oils and more likely to accumulate in the edible fatty tissues of fish.
- Their concentrations can vary considerably in individual fish of the same species and from the same location, depending on factors such as their fat content, size, age, and gender.
- They are not easily broken down, or metabolized, and may stay in animal tissue for a long time.

Environmental chemical contaminants including pesticides in fish may pose a potential human health hazard. Fish can be harvested from waters contaminated with industrial chemicals, heavy metals or pesticides present at various concentrations. These contaminants may accumulate in fish and depending on the chemical's type and amount they can cause human health problems (e.g., developmental issues, carcinogenic or mutagenic effects). The hazard is commonly associated with exposure over a prolonged period of time (chronic exposure). Illnesses related to a single exposure (consumption of one fish 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. For example, in contaminated areas, bottom-dwelling fish are likely to have higher levels of these chemicals because these substances settle to the bottom where the fish feed.

Chemicals and pesticides may also accumulate in aquacultured fish through contaminated feed ingredients, particularly if feed is not purchased from a registered/certified feed manufacturer (e.g., pesticides or heavy metals in feed ingredients derived from near-shore bait fish). Moreover, certain pesticides might be applied directly to the water in aquaculture ponds to control algae and unwanted vegetation, or to eliminate pest fish species and invertebrates.

Pesticide products can be used legally only if they are registered by the U.S. Environmental Protection Agency (EPA) and used according to conditions described on the label (See 40 CFR180 and the "Guide to Drug, Vaccine, and Pesticide Use in Aquaculture" publication of the Federal Joint Subcommittee on Aquaculture (https://freshwater-aquaculture.extension.org/wp-content/uploads/2019/08/Drug_Guide_7-5-07.pdf).

The label for each pesticide product provides instructions for application, including the use site(s) and target pest(s) for which the product is registered (40 CFR 156). Pesticides produced by foreign manufacturers and imported into the United States must comply with all requirements applicable to domestic manufacturers including registration and labeling requirements established by the EPA. Information on the regulations, guidance, and policies pertaining to pesticides can be found on EPA's internet website, https://www.epa.gov/pesticides.

New industrial processing techniques enable valuable proteins, antioxidants, minerals, and oils to be obtained from fish and fish parts (skin, heads, frames, viscera, and fillet cut offs) as basic raw materials to be used for novel applications e.g., dietary supplements, dietary ingredients, and flavors. The quality of products derived from fish by-products are highly dependent on the source of the raw material and the processing method. In some cases, they may contain higher or lower concentrations of environmental chemical contaminants and pesticides than the whole fish they originated from. For example, organochlorine contaminants, such as polychlorinated biphenyls (PCBs), are lipid-soluble. When producing fish oil, 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 may result in residues in or on fish. These regulatory levels apply equally to domestic and to imported seafood in interstate commerce. Refer to the list in the Appendix 5. State, tribal, local, or foreign authorities may also utilize the federal tolerances or action levels in their deliberations concerning the possible need to either issue local advisories to consumers recommending limits on consumption of all or certain species of commercial importance, locally harvested fish, or close waters for commercial harvesting of all or certain species of fish.

In the case of molluscan shellfish, shellfish control authorities (e.g., state, tribal, and foreign regulatory authorities) consider the degree of chemical contamination as part of the established classification of harvesting areas. As a result of these harvest area classifications, harvesting of oysters, clams, mussels, and scallops is allowed from some waters and not from others. Shellfish control authorities exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been permitted. Other significant elements of shellfish control authorities' efforts to control the harvesting of molluscan shellfish include requirements that:

- containers of 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));
- molluscan shellfish harvesters be licensed;
- processors that ship, reship, shuck, or repack molluscan shellfish be certified; and
- containers of shucked molluscan shellfish bear a label with the processor's name, address, and certification number.

If fish components are utilized for other products intended for human consumption (e.g., dietary supplements, dietary ingredients, and flavors), their safety and quality have to be ensured in the same manner as the whole fish. The application of food safety and quality control systems, including

HACCP and GMPs, are imperative for retaining the suitability of these products as sources of human grade food. Processors of these products should implement appropriate food safety controls for the environmental chemical contaminants and pesticides hazard at the receiving step by establishing and implementing controls for incoming raw materials. If contaminants in the raw material are present at unacceptable levels, the processor may reject the product or choose to implement a validated method to remove impurities from the finished product. For example, these methods may include distillation, absorption, treatment with activated carbon and steam deodorization. The processor should demonstrate the effectiveness of the method employed to mitigate the environmental and chemical contaminants hazard and to prevent the hazard from occurring. Reduction of the presence of the chemical contaminant must be accomplished through removal techniques and not through dilution. The deliberate mixing of a product containing the contaminant at unacceptable levels with a product containing lower concentrations renders the finished product adulterated under the Federal Food, Drug, and Cosmetic Act, regardless of the final concentration of contaminant in the finished food. The processor should include and monitor appropriate controls in the HACCP plan. This chapter does not provide further information on these control measures.

- **Tolerance and action levels**

A tolerance, or maximum residue limit, is the amount of pesticide or chemical compound residue allowed to remain in or on a food product. Tolerances for pesticides are established by EPA. In the absence of an EPA tolerance, or tolerance exemption, FDA may establish an action level for such unavoidable chemical compound residues. An action level is a recommended maximum concentration of a contaminant not to exceed, and the level at and above which FDA may take regulatory action against the product and processor.

Refer to the Appendix 5 for the list of tolerance and action levels that have been established for environmental contaminants: industrial chemicals and pesticides in the edible portion of fish.

NOTE: The guidance levels for heavy metals residues in seafood are currently under revision.

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 residue levels of environmental chemical contaminants or pesticides will be introduced at this processing step (e.g., do such chemical contaminants or pesticides come in on the raw material)?**

   NOTE: A "residue'' can be defined as a chemical compound or its breakdown product(s) that unintentionally remains or contaminates food as a result of exposure to this chemical.

   For information on hazards associated with fish you processed refer to the Chapter 3. Tables 3-2 and 3-3 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 of any type of fish. However, there may be circumstances that would allow you to conclude that it is not reasonably likely for fish you received for processing to contain unsafe levels of environmental chemical contaminants and pesticides. The historical and current information on industrial and agriculture activities, monitoring data collected on occurrences of environmental contaminants and pesticides in fish, and the water body where fish are harvested from can be considered in assessing the potential hazard. The processor should seek assistance of federal, state, tribal, territorial, local, or foreign health or environmental authorities as they may have this information available for the area where fish are harvested commercially.

   If you are receiving fish, other than molluscan shellfish, from another processor, you do not need to identify environmental chemical contaminants and pesticides as a significant hazard. The primary (first) processor should have appropriate control measures and procedures in place to manage this hazard adequately and effectively. However, the

prudent secondary processor might request records from the supplying primary processor demonstrating that the product has been processed in compliance with the HACCP regulation, and the hazard of environmental contaminants and pesticides has been addressed by the primary processor. Documentation may include, but is not limited to, HACCP monitoring records reflecting monitoring of environmental contaminants hazard approach, test results for chemicals reasonably likely to be present, reports from visits by the primary processor to the raw material supplier(s), etc. It is recommended that the secondary processor keeps all relevant records in files.

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?

The presence of environmental chemical contaminants and pesticides residues is a significant hazard that occurs prior to a delivery of fish to a processing facility and should be considered by a primary processor at any processing step, but at the receiving of raw material step in particular. It is recommended that the primary processor has an understanding of the hazard and sources of environmental contamination in order to employ the appropriate control measures early in the process to prevent, eliminate or reduce the likelihood of its occurrence.

- **Preventive Measures**

Preventive measures for environmental chemical contaminants and pesticides may include the following measures:

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 and pesticides exceeding the established federal tolerances or action levels.

- Making sure that incoming fish have not been commercially harvested from the same waters that are under a consumption advisory issued by a state, tribal, territorial, local, or foreign regulatory authority based on their determination that fish harvested from these waters are reasonably likely to contain contaminants above the established federal tolerance or action levels.

  NOTE: Not all consumption advisories are based on this determination.

For aquacultured fish other than molluscan shellfish:

- Conducting on-farm visits to the aquaculture producer to review land-use practices in the area immediately surrounding the production area, to examine pesticides and chemicals storage and use on the farm, and to collect and analyze water or fish samples for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

- Reviewing, at time of receipt of each lot of the raw material, a signed certification or declaration from the farmer or other supplier (middleman, broker, collector) that clearly states that fish have been collected from uncontaminated waters, only registered pesticides have been used on the farm and as specified on the label, and the present land-use practices in the area immediately surrounding the production area do not cause contamination of fish.

- Reviewing, at time of receipt of the raw material, test results of fish tissue samples or production site water for those contaminants that are reasonably likely to be present. Tests can be done on each lot of fish or part of a regular environmental monitoring program performed by the farmer, or a state, tribal, territorial, local, or foreign authority, or a third-party organization. It would be recommended that the farmer includes information on present land-use practices in the area immediately surrounding the production area. The land use reports should be updated annually and whenever information on the land use changed and warrants a more frequent update.

- Reviewing, at time of receipt of the raw material, evidence that the raw material supplier/farm operates under a competent third-party farm certification program. The third-party farm certification program should specifically address controls and preventive measures in place to reduce the risk of environmental chemical contaminants and pesticides. The evidence can be lot by-lot or continuing a third-party certificate, or a copy of documentation indicating

that the farm is listed on an accessible, secure, and valid website administered by the third-party. The program can be administered and verified by a government competent authority or a private third-party entity.

- Conducting, at time of receipt of each lot of the raw material, residue testing for those environmental contaminants and pesticides that are reasonably likely to be present in fish tissue. The selection of chemical compounds for testing can be made based on information on prevalence of contaminants in the harvest location, farming area and land-use practices. The processor should seek assistance from federal, state, tribal, local, or foreign health or environmental authorities as they may have this information available.

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 or by a certified dealer who harvested the product from an approved area or a conditionally approved area in the open status.

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 are not covered in this guidance document.

- **Environmental Contaminants, Processing, and Intended Use of the Final Seafood Product**

Environmental chemical contaminants and pesticides are not normally expected to be significantly affected during common food processing activities (e.g., washing, sorting, grading, packing, fileting, breading, cooking, brining, and freezing) or preparation techniques (e.g., cooking, baking, grilling or microwaving). Therefore, it is unlikely that any typical processing or intended use of the final product will eliminate or reduce 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.

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

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 or agreement with the farmer, then you might identify a pre-harvest step as the CCP for the hazard of environmental contaminants and pesticides. The preventive measure for this type of control can include:

i. PROCESSOR'S ON-FARM VISIT

- Conducting on-farm visits to the aquaculture grower (farm) to review general farm conditions and any farm management and biosecurity programs (e.g., Good Aquaculture Practices, Best Management Practices) in place.

- Conducting an evaluation of present land use practices on the farm-site and in the area immediately surrounding the farm production area, including, but not limited to:

  - What types of crops, if any, are grown in the area near the farm 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 sur-rounding the farm production site?

- Based on the observations made, samples of fish or pond water can be collected for environmental chemical contaminants and pesticides that are reasonably likely to be present.

- A person representing the processor should conduct a general inspection of each supplying farm at least once per grow-out cycle or more frequently as needed. A report should be made from each visit carried out at each individual farm.
- The report should include:
    - date of the visit,
    - name of person visiting the farm,
    - observations (e.g., agriculture land use, potential sources of chemical contamination, urban, agriculture runoffs, storage of toxic chemicals including fuels, lubricants, pesticides, and other agriculture chemicals),
    - a number, type of samples (fish and/or water) and location of sample collection, and tests recommended, and
    - areas that need improvement or correction.

The reports should be kept as part of the processor's HACCP records. The processor should have a procedure in place to document any follow-up enhancement or corrective steps taken by the farmer.

The farm visit should be coupled with an appropriate verification to ensure that the strategy implemented at the farm is operative and effective, and the environmental contaminants and pesticides hazard is adequately controlled. This strategy should also include testing for chemical compound residues reasonably likely to be present. Refer to the control strategy "On-farm Visits" in the chapter 11 (the version: June 2021) for additional information on conducting the farm visit and specific components to be considered during the visit.

Example 1:

This control approach is a control strategy referred to in this document as "Control Strategy Example 1 – On – Farm Visits."

An aquacultured tilapia processor that regularly purchases from the same grower (farmer) should visit the grower before the fish are harvested. The processor should review farming conditions including storage of pesticides, chemical products and present land-use at the farm-site and in the adjacent areas. The processor should combine this control approach and monitoring procedure with an appropriate verification strategy and collect and analyze water or fish samples for those environmental chemical contaminants and pesticides that are reasonably likely to be present to demonstrate that the critical limit is effective and working properly to control the hazard. The processor should then set the CCP at the pre-harvest step.

b. If you do not have such a relationship or agreement with the farmer, 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:

i. SUPPLIER'S CERTIFICATION OR LETTER OF GUARANTEE

Reviewing, at time of receipt of each lot of the raw material, a signed certification or declaration, or letter of guarantee from the farmer or other supplier (middleman, broker, or collector) that clearly states that fish has been collected from waters that are not contaminated with pesticides and environmental chemicals, only registered pesticides have been used on the farm and as specified on the label, and the present land-use practices in the area immediately surrounding the farm production area do not cause contamination of fish. This control measure should be coupled with a proper verification including an appropriate verification testing strategy that is sufficient to demonstrate that the critical limit is effective and working properly to control the hazard.

Example 2:

This control approach is a control strategy referred to in this document as "Control Strategy Example 2 - Supplier's (Farm or Middleman or Collector) Certification or Letter of Guarantee."

- A primary processor of aquaculture trout that **purchases raw material directly from a contract farm** should receive a lot-by-lot certificate or letter of guarantee from the farmer. The certificates would state that fish were not harvested from contaminated waters, only registered pesticides have been used on the farm, and the present land-use practices in the area immediately surrounding the production area would not result in residues exceeding the established tolerance or action levels.

  The processor should combine this control strategy and monitoring procedure with appropriate verification testing strategy for environmental chemical contaminants and pesticides that are reasonably likely to be present. The verification should demonstrate that the critical limit is effective and working properly to control the hazard. The processor should set the CCP at receiving.

- A primary processor of aquaculture trout that **purchases raw material from a number of farms through a middleman or collector** should request to 1) receive a lot-by-lot certificate or letter of guarantee from each farm the raw material was collected from that clearly states that fish were not harvested from contaminated waters, only registered pesticides have been used on the farm, and the present land-use practices in the area immediately surrounding the production area would not result in residues exceeding the established tolerance or action levels, 2) request that the middleman or collector provides a list of farms he bought trout from with affiliated lot numbers. This would allow the processor to trace the product back to a farm and pond level.

  The processor should combine this control strategy and monitoring procedure with an appropriate verification testing strategy for environmental chemical contaminants and pesticides that are reasonably likely to be present. The verification should demonstrate that the critical limit is effective and working properly to control the hazard. The processor should set the CCP at receiving.

ii. RECORD OF TESTING AND MONITORING

Reviewing, at time of receipt, test results of fish tissue samples for those contaminants that are reasonably likely to be present. Tests can be done on each lot of fish or be the part of environmental monitoring program performed regularly by the farmer, or a state, tribal, territorial, local, or foreign authority, or a third-party organization.

It is recommended that the processor acquires records of the pond water or the source water testing for those contaminants that are reasonably likely to be present **from all new suppliers**. Tests can be performed by the farmer or be the part of environmental monitoring program performed regularly by a state, tribal, territorial, local, or foreign authority, or a third-party organization.

It is recommended that the farmer includes information on present land-use practices at the farm site and in the area immediately surrounding the farm (agricultural and industrial). The land use reports should be updated annually and whenever information on the land use changed and warrants more frequent updates. This control measure should be coupled with an appropriate verification to ensure that the strategy implemented is effective and the environmental contaminants and pesticides hazard is adequately controlled.

Example 3:

This control approach is a control strategy referred to in this document as "Control Strategy Example 3 - Record of Testing and Monitoring."

A farm-raised striped bass processor purchases fish from farmers with which the processor has no long-term relationship. The processor requires all new suppliers to provide the test results of fish tissue or pond water for those contaminants that are reasonably likely to be present and reports on present land use practices (agricultural and industrial) at the farm site and in the area immediately surrounding the farm. The land use reports should be updated annually and whenever information on the land use changed and warrants a more frequent update. Tests and monitoring can be performed by the farmer, a state, tribal, local or foreign authority, or a third- party organization. The processor should set the CCP at receiving.

iii. CHEMICAL CONTAMINANTS TESTING BY PROCESSOR

Conducting, at time of receipt of each lot of aquacultured fish, residue testing for those environmental chemical contaminants and pesticides that are reasonably likely to be present in fish tissue. The selection of chemical compounds for testing can be made based on information on prevalence of contaminants in the harvest location, farming area and land-use practices. The processor should seek assistance from federal, state, tribal, local, or foreign health or environmental authorities as they may have this information available.

This control measure should be coupled with an appropriate verification to ensure that the strategy implemented is effective and the environmental contaminants and pesticides hazard is adequately controlled.

Example 4:

This control approach is a control strategy referred to in this document as "Control Strategy Example 4 - Chemical Contaminants Testing by Processor."

An aquacultured eel processor that purchases raw material through various brokers (middleman or collector) should screen all incoming lots of eel for those environmental chemical contaminants and pesticides that are reasonably likely to be used on the farm and/or in the area immediately surrounding the farm. The processor should set the CCP at receiving.

iv. THIRD-PARTY FARM CERTIFICATION PROGRAM

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

Each supplier should be assigned a unique code/number for the purpose of identification.

The third-party farm certification program can be administered by a government competent authority, a single individual, an organization, or other private entity that is acting separately and independently from the processor. Through the certification, the third-party would affirm that they have assessed, audited, inspected, or otherwise determined that an aquaculture farm has met their program requirements and controls the environmental contaminants and pesticides hazard.

The processor should evaluate the third-party certification program periodically (e.g., once a year or once during the grow-out cycle) to determine if the necessary safety points are addressed

in the certification scheme and whether a certification scheme is implemented in accordance with described criteria. The processor should consider the assessment of inspection or audit reports and any analytical test results.

Refer to the control strategy "Third-party Farm Certification Program" in the chapter 11 (the version: June 2021) for additional information on the program specific components to be considered by a processor when utilizing the third-party certification program.

Example 5:

This control approach is a control strategy referred to in this document as "Control Strategy Example 5 – Third-Party Certification Program."

An aquacultured barramundi processor that regularly purchases raw material from the same third-party certified farm should obtain evidence (continuing or lot by-lot a third- party certificate, website listing) that the farm operates under a qualified third-party farm certification program. The certificate or other documentation should be valid for the dates of the grow-out period and in case of a continuing certification for one (1) year. The certification should attest that the program the farm operates under covers food safety components, specifically environmental chemical contaminants and pesticides hazard controls. The processor should set the CCP at receiving.

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

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. SOURCE CONTROL FOR WILD-CAUGHT FISH (OTHER THAN MOLLUSCAN SHELLFISH)

- Ensure that incoming fish have not been harvested from waters that are closed to commercial harvest because of concentrations of environmental chemical contaminants and pesticides exceeding the federal tolerance or action levels;

- Ensure that incoming fish have not been harvested from waters that are under a consumption advisory by a state, tribal, local, or foreign regulatory authority based on a determination by the authority that commercial fish harvested from the water body are reasonably likely to contain contaminants at concentrations above the federal tolerance or action levels.

This control measure should be coupled with appropriate verification to ensure that the strategy implemented is effective and the environmental contaminants and pesticides hazard is adequately controlled.

Example 6:

This control approach is a control strategy referred to in this document as "Control Strategy Example 6 - Source Control For Wild-caught Fish (Other Than Molluscan Shellfish)."

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

b. SOURCE CONTROL FOR MOLLUSCAN SHELLFISH (Aquacultured and wild caught)

- Ensure incoming molluscan shellfish are properly tagged or labeled;
- Ensure incoming molluscan shellfish are supplied by a licensed harvester or by a certified dealer.

Example 7:

This control approach is a control strategy referred to in this document as "Control Strategy Example 7 - Source Control for Molluscan Shellfish (Aquacultured and Wild caught)."

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.

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 contaminants testing	✓	✓
Third-party farm certification program	✓	✓
Source control for wild caught fish other than molluscan shellfish	✓	
Source control for molluscan shellfish	✓	✓

The primary (first) processor is required to have control measures in place to adequately control this hazard. However, the prudent secondary processor might request certification from the supplying primary processor, demonstrating that the product has been processed in compliance with the HACCP regulation, and the hazard of environmental contaminants and pesticides has been addressed by the primary processor. The secondary processor might also request additional information, e.g., records of test results for contaminant residues reasonably likely to be present, HACCP monitoring records of environmental contaminants and pesticides hazard, a supplier certificate or letter of guarantee, reports from a third-party or the primary processor's visit to the raw material supplier. It is recommended that the secondary processor keeps these records.

If the secondary processor uses imported seafood products for further processing, he might consider implementing one of the affirmative steps listed under 21CFR 123.12 "Special Requirements For Imported Products" or use another means to verify that the original primary processor controlled the environmental contaminants and pesticides hazard.

- **CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISIT**

Set Critical Limits

- Conduct an on-farm visit to review general farm conditions and any farm management and biosecurity programs (e.g., Good Aquaculture Practices, Best Management Practices) in place to control the environmental contaminants and pesticides hazard.

  AND

- Review the present agricultural and industrial practices on the farm-site and in the area immediately surrounding the farm production site for potential environmental chemical contaminants. The land-use must not be reasonably likely to cause contamination of the fish;

  AND

- Sampling:

  - The concentration of environmental contaminants and pesticides in fish tissue samples that are reasonably likely to be present should not exceed the established tolerance or action levels (refer to the Appendix 5);

    OR

- The concentration of environmental contaminants and pesticides in pond water samples are sufficiently low to preclude fish tissue from exceeding limits in Appendix 5. Elevated concentrations of chemical contaminants in water can be an indication that they are reasonably likely to be present in the fish tissue.

NOTE: US EPA has developed water quality guidance documents that may assist in evaluating water quality in local situations (U.S. EPA Water Quality Standards Handbook, https://www.epa.gov/wqs-tech/water-quality-standards-handbook).

Establish Monitoring Procedures

➢ What Will Be Monitored?

- Written and signed report from on-site farm visit that provides evaluation of present land use and agricultural and industrial practices on the farm-site and in the area immediately surrounding the farm production site;

  AND

- Test results for environmental chemical contaminants and pesticide residues (that are reasonably likely to occur) in fish tissue or pond water.

➢ How Will Monitoring Be Done?

- Review on-site farm visit report surveying agricultural and industrial practices on the farm site and in the area near the farm production site (refer to the section "Identify Critical Control Points" above for more information on on-site farm visits);

  AND

- Collect and analyze samples of fish tissue or pond water from each production site.

➢ How Often Will Monitoring Be Done (Frequency)?

- For on-site farm visit and survey of agricultural and industrial practices:
    - At least once per grow-out cycle for each aquaculture farm site;

    AND

- Sampling:
    - For testing fish tissue:
        - At least once per grow-out cycle for each aquaculture farm site;

        OR

    - For testing water:
        - At least once per grow-out cycle for each aquaculture farm site.

➢ Who Will Do the Monitoring?

- Assigned employee who has training and understanding of the environmental contaminants and pesticides hazard and qualifications to collect samples.

Establish Corrective Action Procedures

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

- Reject the product if the on-site visit document is not present or not current;

  OR

- Isolate and hold until the on-site farm document is provided and/or the farm lot(s) in question are sampled and tested for potential environmental chemical contaminants and/or pesticide residues;

  AND

- Do not buy or have the product shipped from this 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 supplier has appropriate controls in place.

Establish a Recordkeeping System

- On-site farm visit report;

  AND

- Test results.

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.

  AND

- If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Collaboration (AOAC) International (https://www.aoac.org/about-aoac-international/) or equivalent method, or by analyzing proficiency samples.

TABLE 9 – 1

Control Strategy Example 1 – ON FARM VISITS

This table **provided for illustrative purpose only** is an example of a portion of a HACCP plan using "Control Strategy Example 1 - On-Farm Visits." This example illustrates how an aquacultured tilapia processor can control environmental chemical contaminants and pesticides. **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. This information can be provided in a footnote or in a separate document.**

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**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Pre-harvest	Environmental chemical contaminants and pesticides	Farm visit to review farming conditions and evaluate the land use practices Levels of environmental chemical contaminants and pesticides in fish tissue may not exceed EPA and FDA established tolerance and action levels for contaminants that are reasonably likely to be present. 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	Written and signed report from on-site farm visit conducted within a grow-out cycle of the harvest and shipment of fish to the processor Test results for environmental chemical contaminants and pesticides residue (that are reasonably likely to occur) in fish tissue or pond water. Report of agricultural and industrial practices near the pond	Review on-site farm visit document **AND** Collect samples and analyze for environmental chemical contaminants and pesticides	At least once per grow-out cycle for each aquaculture farm	Assigned employee trained in aquaculture food safety	Reject the product if the report is not present or current **OR** Isolate and hold until on-site visit report provided or the farm lot in question is sampled and tested for environmental chemical contaminates and pesticides residues **AND** Do not have the product shipped from the production site for processing. **AND** Discontinue use of the supplier until evidence is obtained that appropriate controls are in place.	On-site visit report including on-farm pesticide usage program and procedures	Review monitoring, verification, and corrective action records within 1 week of preparation If testing is performed in the processor's laboratory periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment.

- **CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION OR LETTER OF GUARANTEE**

Set Critical Limits

A certificate or letter guarantee provided by the farmer or other supplier(s) (e.g., middlemen, collector or broker) for each lot of incoming raw material declaring 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 Appendix 5).

NOTE: If a raw material is outsourced from countries with known environmental contamination problems, the prudent processor makes sure that the product meets food safety requirements and is in compliance with US FDA laws and regulations. The processor may consider implementation of affirmative steps listed under 21CFR 123.12 Special Requirements for Imported Products**.**

Establish Monitoring Procedures

➢ What Will Be Monitored?

- Presence of a certificate signed by the farmer or authorized farmer's representative, or other supplier (e.g., middleman, collector) specifying that fish were harvested from uncontaminated waters.

➢ How Will Monitoring Be Done?

- Visual check for the presence of a certificate or letter of guarantee.

➢ How Often Will Monitoring Be Done (Frequency)?

- Each lot received.

➢ Who Will Do the Monitoring?

- Any person who has training and understanding of the principles 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 or letter of guarantee can be provided;

  OR

- Hold and analyze the lot for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

  NOTE: If testing is performed, the following specific information should be recorded: the protocol for sample collection, chemicals for which analyses were conducted, and the analytical method used.

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 or letters of guarantee;

  AND

- Receiving record showing lots received and the presence or absence of a certificate or letter of guarantee.

Establish Verification Procedures

- Visit all new aquacultured fish growers within the year and all existing fish suppliers at a predetermined frequency to review agricultural and industrial practices in the area immediately surrounding the production site and/or collect and analyze fish tissue or water samples, as appropriate, for those environmental chemical contaminants and pesticides that are reasonably likely to be present;

  OR

- Collect a representative sample of the raw material, in-process product, or finished product at established frequency, and analyze it for those environmental chemical contaminants and pesticides that are reasonably likely to be present. Specify the protocol for sample

collection, chemical compounds for which analysis will be conducted, and the analytical method to be used;

AND

- If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Collaboration (AOAC) International (https://www.aoac.org/about-aoac-international/) or equivalent method, or by analyzing proficiency samples;

AND

- If raw material is collected and delivered by a middleman, request a list of farms the middleman bought trout from with affiliated lot's numbers.

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 – 2

Control Strategy Example 2 – SUPPLIER'S CERTIFICATION OR LETTER OF GUARANTEE

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

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)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Environmental chemical contaminants and pesticides	Certificate or letter of guarantee accompanying each lot received indicating 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	Presence of a certificate or letter of guarantee	Visual check	Each lot received	Receiving employee trained in aquaculture food safety	Reject lot if certificate or letter of guarantee is absent Discontinue use of the supplier until evidence is obtained that the supplier will comply with the certification controls	Copy of the certificate or letter of guarantee Receiving record	Review monitoring, corrective action, and verification records within 1 week of preparation Visit all new aquacultured fish growers within the year and all existing fish suppliers at a predetermined frequency to review agricultural and industrial practices in the area and collect and analyze water samples **OR** Collect a representative number of samples of the raw material, in-process product, or finished product at established frequency and analyze for those chemicals that are reasonably likely to be present If raw material collected and delivered by a middleman, request a list of farms they bought trout from with affiliated lot numbers.

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

Set Critical Limits

For all new suppliers:

- Records of analyses of the pond water or the source water that show that concentrations of environmental chemicals and pesticides present could not cause the levels in fish tissue to exceed the established federal tolerance and action levels. Tests can be performed by the farmer or be part of environmental monitoring performed regularly by a state, tribal, territorial, local, or foreign authority, or a third-party organization.

For all new suppliers and current suppliers:

- Reports of test results of fish tissue samples for those contaminants that are reasonably likely to be present. Tests can be done on each lot of fish delivered to the processor or be the part of environmental monitoring performed regularly by the farmer, or a state, tribal, territorial, local, or foreign authority, or a third-party organization.

  AND

- Annual reports from all suppliers (new and current) demonstrating that present land use practices (agricultural and industrial) at the farm site and in the area near the farm are not reasonably likely to cause contamination of fish tissue above the established federal tolerance or action levels. The monitoring can be performed by the farmer, or a state, tribal, local, or foreign authority, or a third-party organization.

Establish Monitoring Procedures

➢ What Will Be Monitored?

- **For all new suppliers**: Test results of fish tissue and water for those environmental chemical contaminants and pesticides that are reasonably likely to be present;

- **For all current suppliers**: Test results of fish tissue for those environmental chemical contaminants and pesticides that are reasonably likely to be present;

  AND

- Report of monitoring 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 of raw material at first delivery;

  AND

- For results of fish tissue testing:
  - All suppliers-for each lot of raw material;

  AND

- For reports of evaluation of agricultural and industrial practices
  - All suppliers-once a year and whenever information on the land use changed.

➢ Who Will Do the Monitoring?

- Any person who has training and understanding of the principles 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

- Report of test results;

  AND

- Report of evaluation of agricultural and industrial practices.

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.

  AND

- Collect a representative sample of the raw material, in-process product, or finished product at established frequency, and analyze it for those environmental chemical contaminants and pesticides that are indicated in the supplier's test report. Specify the protocol for sample collection, chemical compounds for which analysis will be conducted, and the analytical method to be used.

Table 9 – 3

Control Strategy Example 3 – RECORDS OF TESTING AND MONITORING

This table **provided for illustrative purpose only** 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 striped bass processor can control environmental chemical contaminants and pesticides. **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.**

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**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Environmental chemical contaminants and pesticides	**For all new suppliers**: Reports of analyses of the pond or source water that show that concentrations of environmental chemical contaminants and pesticides present could not cause levels in fish tissue to exceed the established federal tolerance or action levels **For all suppliers**: Reports of test results of fish samples for those contaminants that are reasonably likely to be present	Reports of analyses for environmental chemical contaminants and pesticides that are reasonably likely to be present	Visual check	**For all new suppliers** (water test): At first delivery **For all suppliers** (fish tissue test): Each lot received	A person who has training and understanding of the principles of the controls	Reject the lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the testing and evaluation controls.	Water and/ or fish tissue results	Review monitoring and corrective action records within 1 week of preparation Collect a representative sample of the raw material, in-process product, or finished product at established frequency, and analyze it for those environmental chemical contaminants and pesticides that are indicated in the supplier's test report.
Receiving	Environmental chemical contaminants and pesticides	**For all suppliers**: Reports that show agricultural and industrial practices at the farm and in the area near the farm site	Reports of agricultural and industrial practices evaluation	Visual check	Once per year	A person who has training and understanding of the principles of the controls	Reject the lot Discontinue use of the supplier until evidence is obtained that the supplier will comply with the testing and evaluation controls	Report of agricultural and industrial practices	Review monitoring and corrective action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 4 - CHEMICAL CONTAMINANTS TESTING BY PROCESSOR**

Set Critical Limits

No lot of fish may contain residues of environmental chemical contaminants and pesticides that exceed the established federal tolerance or action levels (refer to the Appendix 5).

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 a representative number of samples of raw material supplied by each farm or fishing vessel and analyze for environmental chemical contaminants and pesticides using validated analytical methods.

➢ 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

- If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Collaboration (AOAC) International (https://www.aoac.org/about-aoac-international/) 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 – 4

Control Strategy Example 4 – CHEMICAL CONTAMINANTS TESTING BY PROCESSOR

This table **provided for illustrative purpose only** is an example of a portion of a HACCP plan using "Control Strategy Example 4 – Chemical Contaminants Testing By Processor." This example illustrates how an aquacultured eel processor can control environmental chemical contaminants and pesticides. **An actual plan should specify (1) in the Critical Limits column: the environmental chemical contaminants and pesticides that are tested for and tolerance or action level 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**.

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)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Environmental chemical contaminants and pesticides	No lot of fish may contain residues of environmental chemical contaminants and pesticides that exceed the established federal tolerance or action levels	Environmental chemical contaminants and pesticide residue levels in fish tissue that are reasonably likely to be present	Obtain representative samples and analyze for environmental chemical contaminants and pesticides	Each lot received	A person who is qualified by training or experience to collect samples and perform the analyses	Reject the lot Discontinue use of the supplier until evidence is obtained that the cause of the chemical contamination has been eliminated	Test results	Review monitoring, verification, and corrective action records within 1 week of preparation If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using AOAC or equivalent method)

- **CONTROL STRATEGY EXAMPLE 5 – THIRD-PARTY FARM CERTIFICATION PROGRAM**

Set Critical Limits

- Documentation indicating that the supplier of raw material (farm) operates under a third-party farm certification program. The program should include adequate controls for environmental chemical contaminants and pesticides and measures implemented to prevent this hazard from occurring. The third-party farm certification program with the food safety component can be administered and verified through a qualified government competent authority or a private third-party entity (A list of third-party certification bodies that have been accredited under the FDA's Accredited Third-Party Certification Program is available at the FDA Data Dashboard https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program-public-registry-accredited-third-party-certification.

- The documentation confirming that the supplier operates under a third-party farm certification program and implements adequate controls for environmental chemical contaminants and pesticides that may include:

    - a valid certificate that accompanies each lot of incoming raw material or

    - a valid certificate issued for each supplier of raw material by a third-party declaring that the company currently operates continually under their program (the continuing certification), and

    - a copy of documentation indicating that the company is listed on an accessible secure and valid web site administered by the competent authority or third-party (real-time listing).

Each supplier of raw material should be assigned a unique code/number for the identification purpose.

NOTE: Overall, a third-party program should provide reasonable assurances that the supplier of raw material is managed responsibly, meets the established criteria, and there is a high level of confidence in the safety of the product.

While the supplier may be under a third-party farm certification program, **it remains the processor's responsibility to ensure and verify their products do not contain environmental contaminants and pesticides** exceeding tolerance and action levels established by FDA and EPA.

Establish Monitoring Procedures

➢ What Will Be Monitored?

- Certificate or documentation indicating the farm operates under a third party farm certification program.

➢ How Will Monitoring Be Done?

- Visual check for the presence of a certificate or documentation.

➢ How Often Will Monitoring Be Done (Frequency)?

- Each lot received is checked for the presence of a certificate or documentation that the farm operates under a third-party farm certification program. Documents may be issued on a lot-by-lot or continuing basis (i.e., at least once during each grow-out period).

➢ Who Will Do the Monitoring?

- Any person who has training and understanding of the principles of the controls and fundamentals of the third-party farm certification program.

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 the certificate or documentation can be provided;

  OR

- Hold and analyze the lot for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

NOTE: If testing is performed, the following information should be recorded: the protocol for sample collection, the list of chemicals for which analyses were conducted, and the analytical method used for testing each chemical compound.

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 certificate or a copy of online supplier listing;

  AND

- Receiving record showing lots received and presence or absence of a certificate or online supplier listing;

  AND

- Testing results for environmental chemicals and/or pesticides that are reasonably likely to be present, conducted by the third -party certifier showing that its program criteria are effective as applicable;

  AND

- A report of evaluation of the third-party farm certification program with emphasis on the controls of environmental contaminants and pesticides hazard.

Establish Verification Procedures

- Evaluate the adequacy of the food safety component identified in the third-party farm certification program initially and at least once a year to determine if:

  - The program addresses the food safety hazard for chemical contaminants and pesticides

  - The program is properly implemented and verified;

  AND

- Review results from farm inspection and verification audits conducted by the third-party and any testing for environmental chemical and pesticide residues carried out at least 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 – 5

Control Strategy Example 5 – THIRD-PARTY FARM CERTIFICATION PROGRAM

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

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**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Environmental chemical contaminants and pesticides	Certificate or documentation indicating that the farm operates under a third-party farm certification program and adequately addresses the hazard of environmental chemical contaminants and pesticides	Presence of a third-party certificate **OR** Documentation showing the farm listing on third-party website (e.g., a government administered program)	Visual check	Each lot	Receiving trained employee in food safety and third-party documentation requirements for this critical limit	Reject the lot **OR** Hold the lot until the certificate or documentation is provided **OR** Hold and analyze the lot for those chemical contaminants and pesticides that are reasonably likely to be present **AND** Discontinue use of the supplier until evidence is obtained that the supplier complies with the documentation requirement	Third-party certificate or a copy of on-line farm listing by the third-party entity Receiving records Testing results for chemical contaminants and pesticides that are reasonably likely to be present conducted by the third-party certifier. Report of the third-party program evaluation	Evaluate the adequacy of the of the third-party farm certification program-food safety component and its implementation initially and at least once a year. Review results of farm inspection and verification audits conducted by the third-party and test results carried out on the farm, at least annually. Review monitoring, verification, and corrective action 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 fishing by the state, tribal, territorial, local, or foreign authorities because of the determination that concentrations of environmental chemical contaminants or pesticides in water bodies can result in residues in fish tissue exceeding the federal tolerance or action levels (refer to the Appendix 5);

  AND

- No fish may be harvested from a commercial fishing area that is under a consumption advisory by the state, tribal, territorial, local, or foreign regulatory authority based on the determination that fish harvested are reasonably likely to contain contaminants above the federal tolerance or action levels.

  NOTE: Consumption advisories may not be based on this conclusion.

Establish Monitoring Procedures

➢ What Will Be Monitored?

- The status of the harvest location of fish identified on harvest vessel records are not under closure for commercial harvest or subject to a consumption advisory for environmental chemical contaminants and/or pesticides.

➢ How Will Monitoring Be Done?

- Obtain the harvester's declaration certifying that the harvest area location is not under closure for commercial fishing or a consumption advisory;

  OR

- Obtain the harvester's records for fish delivered that identify the harvest area location;

  AND

- Check the website or contact the state, tribal, territorial, local, or foreign authorities whether there have been any closures or consumption advisories that apply to the areas from which fish delivered to your facility have been collected at the time of harvest.

➢ How Often Will Monitoring Be Done (Frequency)?

- Every lot of fish 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;

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 through record review of harvest locations.

Establish a Recordkeeping System

- Receiving records that document the location and status (closure for commercial fishing or consumer advisory) of the harvest area.

Establish Verification Procedures

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.
- Periodically monitor regulatory authority (e.g., state, local, foreign) website or reports for the most current information regarding commercial fishing restrictions and consumption advisories due to environmental chemical contamination

TABLE 9 – 6

Control Strategy Example 6 – SOURCE CONTROL FOR WILD CAUGHT FISH OTHER THAN MOLLUSCAN SHELLFISH

This table **provided for illustrative purpose only** 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.

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., scombrotoxin (histamine), 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**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Environmental chemical contaminants and pesticides	No fish may be harvested from an area that is closed to commercial harvesting by state, local, or foreign authorities because of the determination that concentrations of environmental chemical contaminants or pesticides present could cause levels in fish to exceed the established federal tolerance or action levels **AND** No fish may be commercially harvested from an area that is under a consumption advisory by a state, local, or foreign regulatory authority based on a determination that fish harvested are reasonably likely to contain contaminants above the established federal tolerance or action levels	The status of harvest location of fish, whether the harvest area is subject to closure or consumption advisory	Obtain the harvester's declaration **OR** Obtain the harvester's records for fish delivered that identify the harvest area location. **AND** Check website or contact the regulatory authority to confirm the harvester's declaration or harvest area records provided	Each lot received	Receiving employee who has an understanding of the nature of the controls.	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 approval Periodically monitor website or reports of regulatory authority (e.g., state, local, or foreign) for the most current information regarding commercial fishing restrictions and consumption advisories due to environmental chemical contamination.

- **CONTROL STRATEGY EXAMPLE 7 - SOURCE CONTROL FOR MOLLUSCAN SHELLFISH (Aquacultured and Wild Caught)**

Set Critical Limits

For shellstock:

- All containers of shellstock received from a harvester must bear a tag identifying the:
    - Date and place of harvest (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);

  OR

- 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;

  OR

- All containers of shellstock received from a processor must bear a tag identifying the processor who supplied the shellstock and that discloses the:
    - Date and place they were harvested (by state and site),
    - Type and quantity of shellfish,

      AND

    - The certification number of the processor;

For shucked molluscan shellfish:

- All containers of shucked molluscan shellfish must bear a label identifying the packer or re-packer that discloses:
    - Name of the packer or re-packer,
    - Address of the packer or re-packer,

      AND

    - Certification number of the packer or re-packer 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 or from a processor that is certified by a shellfish control authority.

NOTE: Both primary and secondary processors of molluscan shellfish are required to implement source controls in their HACCP plans. Only the primary processor needs to apply controls relative to the identification of the harvester, the harvester's license, or the approval status of the harvest waters. The source controls listed in this critical limit are required under 21 CFR 123.28(c).

Establish Monitoring Procedures

➢ What Will Be Monitored?

For shellstock

- Information listed on tags, or on the bill of lading, or similar shipping document accompanying bulk shipments of shellstock which includes at a minimum;
    - Date of harvest;
    - Location of harvest by state and site;
    - Quantity and type of shellfish;
    - 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);
    - Number and date of expiration of the harvester's license, where applicable;

AND

- Certification number of the shipper, where applicable.

AND

- Receiving information on whether the harvest area is authorized for harvest by a shellfish control authority or information regarding closures of federal harvest waters by an agency of the federal government.

AND

- The harvester's license.

For shucked molluscan shellfish

- Information declared on labels on containers of incoming shucked molluscan shellfish such as:
  - Name of the packer or re-packer of the product;
  - Address of the packer or re-packer of the product;

    AND
  - The certification number of the packer or re-packer of the product.

➢ How Will Monitoring Be Done?

- Visual examination of the harvest area location through harvest records to ensure they are not from areas under a restriction, advisory or prohibition from harvesting;

  AND
- Obtain assurance from shellfish control authorities from the state or country in which your shellstock are harvested that the harvest area is open for harvest.

➢ How Often Will Monitoring Be Done (Frequency)?

- Checking incoming tags for shellstock:
  - Every container received;

    OR
- Checking the bill of lading or similar shipping document for bulk shellstock:
  - Every delivery received:

    OR
- Checking incoming labels for shucked molluscan shellfish:
  - At least three containers randomly selected from every lot received;

    AND
- Checking licenses:
  - Every delivery received.

➢ Who Will Do the Monitoring?

- Any person with training and understanding of the nature of the controls and closures.

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(s) that documents:
  - Date of harvest;
  - Location of harvest by state and site;
  - Quantity and type of shellfish;
  - Name of the harvester, name of registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority (for shellstock received directly for the harvester

only);

- 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(s) that document:
  - Date of receipt;
  - Quantity and type of shellfish;

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

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 7 – SOURCE CONTROL FOR MOLLUSCAN SHELLFISH (AQUACULTURED AND WILD CAUGHT)

This table **provided for illustrative purpose only** is an example of a portion of a HACCP plan using "Control Strategy Example 7 - Source Control for Molluscan Shellfish (Aquacultured and Wild Caught)." The example illustrates how a primary processor of shellstock oysters can control environmental chemical contaminants and pesticides hazard in shellstock oysters received directly from a harvester.

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)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	**Significant Hazard(s)**	**Critical Limits**	**What**	**How**	**Frequency**	**Who**	**Corrective Action(s)**	**Records**	**Verification**
Receiving	Environmental Chemical contaminants and pesticides	All incoming shellstock must be tagged with the date and place of harvest, type and quantity of shellfish, and name or registration number of the harvester's vessel	Information on incoming shellstock tags	Visual checks	Every sack	Receiving employee	Reject untagged sacks Discontinue use of the supplier until evidence is obtained that tagging practices have changed	Receiving record	Review monitoring and corrective action records within 1 week of preparation
		All shellstock must be harvested from waters approved or conditionally approved and in the open status	Harvest site on tags	Visual checks; Ask the shellfish control authority from the state or country in which the shellstock are harvested 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		
		All shellstock must be from a licensed harvester	Harvester's license	Visual checks for number and expiration date	Every delivery from harvester		Reject lots from unlicensed harvesters Discontinue use of the supplier until evidence is obtained that the harvester has secured a license		

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