Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

Unregulated/unapproved drugs administered to aquacultured fish pose a potential human health hazard. These substances may be carcinogenic, allergenic, and/or may cause antibiotic resistance in man. To control this hazard in food animals, all drugs, whether for direct medication or for addition to feed, must be approved by FDA. Under certain conditions authorized by FDA, unapproved new animal drugs may be used in conformance with the terms of an Investigational New Animal Drug (INAD) application.

Incentives for the use of animal drugs in aquatic animal species include the need to: 1) treat and prevent disease; 2) control parasites; 3) affect reproduction and growth; and, 4) tranquilization (e.g. during transit). Relatively few drugs have been approved for aquaculture. As a result, aquaculture growers may use unapproved drugs, general purpose chemicals that are not labeled for drug use, and approved drugs in a manner that deviates from the labeled instructions.

When a drug is approved by FDA's Center for Veterinary Medicine, the conditions of the approval are listed on its label. These conditions include: the species for which the drug is approved; the approved dosage; the approved route of administration; the approved frequency of use; and the approved indications for use. Only a licensed veterinarian may legally prescribe or use a drug under conditions that are not listed on the label. This restriction is more fully explained in 21 CFR 530.

Labels of approved drugs list mandatory withdrawal times, where applicable. These withdrawal times must be observed to ensure that the edible tissue is safe when it is offered for sale. Tissue residue tolerances have been established for some drugs.

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

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

1. Is it reasonably likely that unsafe levels of aquaculture drugs will be introduced at this processing step (e.g. do raw materials come in with unsafe levels of aquaculture drugs, or are they used at this step)?

Under ordinary circumstances, it would be reasonably likely to expect that unsafe levels of aquaculture drugs could enter the process during the receiving of any type of aquacultured fish, including:
- Fin fish;
- Crustaceans;
- Aquatic animals, such as alligator.

Under ordinary circumstances it would also be reasonably likely to expect that unsafe levels of aquaculture drugs could enter the process during the holding of live lobster (e.g. lobster pounds).

Under ordinary circumstances it would not be reasonably likely to expect that aquaculture drugs could enter the process during the receiving of wild-caught fish. Currently, FDA is not aware of drug use in the grow-out of molluscan shellfish. If the agency becomes aware of such use, this Guide, and, in particular, Table #3-2 (Chapter 3) will be updated accordingly. On a regional basis, it may be reasonable for you to conclude that aquaculture drug use is not a significant hazard for other species, because they are not used by producers in your region.

2. Can the presence of unsafe levels of aquaculture drugs, which are reasonably likely to occur, 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)

Continued

"Aquaculture drugs" should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level), if it reasonably likely to occur.

Preventive measures for the control of aquaculture drugs used in aquaculture operations can include:

- On-farm visits to review drug usage (other than INADs) before receipt of the product, coupled with a supplier's lot-by-lot certificate that any INADs used were used in conformance with the application requirements;
- Receipt of supplier's lot-by-lot certification of proper drug usage, coupled with appropriate verification (See Step #18 - Verification);
- Review of drug usage records (other than INADs) at receipt of the product, coupled with a supplier's lot-by-lot certificate that any INADs used were used in conformance with the application requirements;
- Drug residue testing;
- Receipt of evidence (e.g. third party certificate) that the producer operates under a third party-audited Quality Assurance Program for aquaculture drug use.

(Note: The use of Investigational New Animal Drugs (INAD) is confidential unless an exception is made by the sponsor of the drug research. Thus, review of INAD drug usage records by the processor may not be practical in certain situations. Written certification from the grower to the processor stating that any INAD drug usage is in accordance with authorizations from FDA/Center for Veterinary Medicine, will be acceptable on a lot-by-lot basis.)

Preventive measures for the control of aquaculture drugs used during the holding of live fish (e.g. lobster pounds) can include controlled application of animal drugs in a manner consistent with:

- The established withdrawal times;
- The labeled instructions for use;
- Extralabel use of FDA-approved drugs, under a veterinarian's supervision in accordance with FDA regulations and guidelines;
- The conditions specified in the FDA "low regulatory priority aquaculture drug" list;
- The conditions of an INAD application.

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s). Ordinarily this will be either the receiving step or the preharvest step. However, in the case of an integrated operation, where fish processing and grow-out, and, perhaps feed manufacture, are performed by the same firm, it may be possible and desirable to exercise preventive measures early in the process (ideally at feed manufacture), rather than at receipt of the fish at the processing plant. Such preventive measures will not be covered in this chapter. For the holding of live fish (e.g. lobster pounds) the preventive measure will usually be applied at the holding step.

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. Except in the case of an integrated aquaculture operation, this will usually be the receiving step. If none of the criteria are 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, for aquaculture drugs, it is unlikely that the intended use will affect the significance of the hazard.

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

For each processing step where "aquaculture drugs" is identified in Column 3 of the Hazard Analysis Worksheet as a significant hazard, determine whether it is necessary to exercise control at that step in order to control the hazard. Figure #A-2 (Appendix 3) is a CCP decision tree that can be used to aid you in your determination.

The following guidance will also assist you in determining whether a processing step is a CCP for "aquaculture drugs":

Is the hazard the result of the use of aquaculture drugs during the raising of fish (i.e. aquaculture) or during the holding of live fish (e.g. lobster pounds)?

1. If it is the result of aquaculture, 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 "aquaculture drugs." The preventive measure for this type of control is on-farm visits to review drug usage, coupled with a supplier's lot-by-lot certificate that any INADs used were used in conformance with the application requirements.

Example:
A processor of aquacultured catfish that regularly purchases from the same growers would visit the grower before the fish are harvested and review the grower's drug usage practices and records. The processor could also receive a guarantee that any INADs used were used in conformance with the application requirements. The processor could then set the critical control point for aquaculture drugs 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 "aquaculture drugs" 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 you have no such relationship with the grower, then you may identify the receiving step as the CCP for "aquaculture drugs." At the receiving step you may exercise one of the following preventive measures:

- Supplier's lot-by-lot certification of proper drug usage, 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 all drugs were used in conformance with applicable regulations and labeled instructions. The processor combines this monitoring procedure with quarterly raw material testing for verification.

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 drug usage records (other than INADs) at receipt of the product, coupled with a supplier's lot-by-lot certificate that any INADs used were used in conformance with the application requirements.

Example:
A processor of aquacultured shrimp that purchases raw material shrimp through various brokers could receive records of drug use (other than INADs) from the growers when the product is delivered. Additionally, the processor could receive a lot-by-lot certificate that would state that any INADs were used in conformance with the application requirements.

Continued

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.

- Drug screening on all lots at receipt. This screening can be performed by rapid analytical methods which may indicate the presence of a family of drugs, rather than any specific drug. If the rapid screening test indicates that a family of drugs is present, further testing and/or follow-up with the supplier would be necessary.

Note: A limited number of drug screening tests for aquaculture are available. Tests are not available to assay for all drugs that might be used in all aquacultured species. Processors should be cautioned that tests that have not been validated may be unreliable. These tests may fail to detect a residue or may give a false positive. FDA has not validated any of the aquaculture screening tests; nor has the Association of Official Analytical Chemists (AOAC). Processors should assure themselves that the tests that they intend to use have otherwise been validated and are appropriate for the species and tissue to be tested.

Example:
A processor of aquacultured shrimp that purchases raw material shrimp through various brokers could screen all incoming lots of shrimp with a bank of validated rapid tests that target the families of drugs likely to be used during grow-out.

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 for aquaculture drug use.

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 which covers aquaculture drug usage.

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 hazard is the result of live fish holding (e.g. lobster pounds), then you may identify the holding step as the CCP for "aquaculture drugs." The preventive measure for this type of control is the controlled application of animal drugs (e.g. oxytetracycline) in a manner consistent with: the established withdrawal times; the labeled instructions for use; extralabel use of an FDA-approved drug, under a veterinarian's supervision in accordance with FDA regulations and guidelines; the conditions specified in the FDA "low regulatory priority aquaculture drug" list; and, the conditions of an INAD application.

Example:
A processor that uses oxytetracycline in the holding of live lobster in a lobster pound would use the drug in accordance with the established withdrawal time and any other labeled instructions.

In this case, you should enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the holding step. This control approach will be referred to as "Control Strategy Example 6" in Steps #14 through 18.

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 "aquaculture drugs" is identified as a significant hazard on the HACCP Plan Form, identify the maximum or minimum value to which a feature of the process must be controlled in order to control the hazard.

You should set the critical limit at the point that if not met the safety of the product may be 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 VISITS

Critical Limit: Animal drugs are used on fish only if the drugs have been:

- Approved by FDA and used in accordance with proper withdrawal times and other labeled conditions;

OR

- Approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guide lines. The regulations and guidelines are available from the FDA Center for Veterinary Medicine, HFV-230, 7500 Standish Place, Rockville, MD 20855;

OR

- Listed on the FDA "low regulatory priority aquaculture drug" list;

OR

- Permitted by FDA for use in food fish under the conditions of an INAD (as evidenced by a lot-by-lot written certificate from the grower).

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Critical Limit: Certificate indicating proper drug usage accompanying each lot of incoming aquacultured fish.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Critical Limit: Animal drugs used on fish only if the drugs have been:

- Approved by FDA and used in accordance with proper withdrawal times and other labeled conditions;

OR

- Approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guide lines. The regulations and guidelines are available from the FDA Center for Veterinary Medicine, HFV-230, 7500 Standish Place, Rockville, MD 20855;

OR

- Listed on the "low regulatory priority aquaculture drug" list;

OR

- Permitted by FDA for use in food fish under the conditions of an INAD (as evidenced by a lot-by-lot written certificate from the grower).

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

Critical Limit: No fish will be accepted that contains unapproved drug residues (other than those used within the provisions of an INAD application or used in accordance with the criteria specified in the "low regulatory priority aquaculture drug" list).

Continued

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Critical Limit: Third party certificate indicating that the producer operates under a third party-audited Quality Assurance program for aquaculture drug use, either for each lot of incoming aquacultured fish or for each producer of incoming aquacultured fish.

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

Critical Limit: Animal drugs are used on fish only if the drugs have been:

- Approved by FDA and used in accordance with proper withdrawal times and other labeled conditions;

OR

- Approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guidelines. The regulations and guidelines are available from the FDA Center for Veterinary Medicine, HFV-230, 7500 Standish Place, Rockville, MD 20855;

OR

- Listed on the FDA "low regulatory priority aquaculture drug" list;

OR

- Permitted by FDA for use in food fish under the conditions of an INAD.

- FDA-approved aquaculture drugs

FDA approved aquaculture drugs with their approved sources, species and withdrawal times are listed below. Additional details on conditions of use (e.g. disease conditions and dosage levels) can be obtained from: the Code of Federal Regulations as cited below; the labeling for the drug; the FDA Center for Veterinary Medicine (www.fda.gov/cvm/index/aquaculture); or "Guide to Drug, Vaccine, and Pesticide Use in Aquaculture," Texas Agricultural Extension Service, Publication B-5085.

- **Chorionic Gonadotropin**
  Supplied by Intervet, Inc., Millsboro, DE, may be used as an aid in improving spawning function in male and female brood finfish, (21 CFR 522.1081);
- **Formalin solution**
  Supplied by Natchez Animal Supply Co., Natchez, MS or Argent Laboratories, Redmond, WA, may only be used in salmon, trout, catfish, largemouth bass, and bluegill for the control of protozoa and monogenetic tremetodes, and on the eggs of salmon, trout and pike (esocids) for control of fungi of the family *Saprolegniacea*, (21 CFR 529.1030);
- **Formalin solution**
  Supplied by Western Chemical, Inc., Ferndale, WA, may be used to control: external protozoa and monogenetic tremetodes on all fin fish species; external protozoan parasites on shrimp; and fungi of the family *Saprolegniaceae* on the eggs of all fin fish species, (21 CFR 529.1030);
- **Tricaine methanesulfonate** (MS-222)
  Supplied by Argent Laboratories, Redmond, WA, and Western Chemical, Inc., Ferndale, WA, may only be used in the families *Ictaluridae* (catfish), *Salmonidae* (salmon and trout), *Esocidae* (pike), and *Percidae* (perch) when the fish is intended to be used for food. It may not be used within 21 days of harvesting fish for food. In other fish and in cold-blooded animals, the drug should be limited to hatchery or laboratory use, (21 CFR 529.2503);
- **Oxytetracycline**
  For feed use, supplied by Pfizer, Inc., may only be used in salmonids, catfish, and lobster. Withdrawal times are: marking in pacific salmon, 7 days; disease control in salmonids, 21 days; catfish, 21 days; lobster, 30 days (21 CFR 558.450). Oxytetracycline tolerance in the flesh is 2.0 ppm, (21 CFR 556.500).
- **Sulfamerazine**
  Supplied by Roche Vitamins, Inc., may only be used in trout. It may not be used within 21 days of harvest (21 CFR 558.582). Sulfamerazine tolerance in the flesh is zero, (21 CFR 556.660). Note: this product is currently not marketed.
- **Sulfadimethoxine/ormetoprim combination**
  Supplied by Roche Vitamins, Inc., may only be used in salmonids and catfish. Withdrawal times are: salmonids, 42 days; catfish, 3 days (21 CFR 558.575). Sulfadimethoxine/ormetoprim combination tolerance in the flesh is 0.1 ppm for both drugs, (21 CFR 556.640).

• FDA low regulatory priority aquaculture drugs

FDA's Center for Veterinary Medicine has identified a number of "low regulatory priority aquaculture drugs." The following list identifies these compounds and provides their indicated use and usage levels. These compounds have undergone review by the Food and Drug Administration and have been determined to be new animal drugs of low regulatory priority. Additional information on this subject can be obtained from: the FDA Center for Veterinary Medicine (www.fda.gov/cvm/index/aquaculture); or "Guide to Drug, Vaccine, and Pesticide Use in Aquaculture," Texas Agricultural Extension Service, Publication B-5085.

- **Acetic Acid**
  Used in a 1000 to 2000 ppm dip for 1 to 10 minutes as a parasitide for fish.
- **Calcium Chloride**
  Used to increase water calcium concentration to insure proper egg hardening. Dosages used would be those necessary to raise calcium concentration to 1-20 ppm $CaCO_3$. Used up to 150 ppm indefinitely to increase the hardness of water for holding and transporting fish in order to enable fish to maintain osmotic balance.
- **Calcium Oxide**
  Used as an external protozoacide for fingerlings to adult fish at a concentration of 2000 mg/L for 5 seconds.
- **Carbon Dioxide Gas**
  Used for anesthetic purposes in cold, cool, and warm water fish.
- **Fuller's Earth**
  Used to reduce the adhesiveness of fish eggs to improve hatchability.
- **Garlic** (whole form)
  Used for control of helminth and sea lice infestations of marine salmonids at all life stages.
- **Hydrogen Peroxide**
  Used at 250-500 mg/L to control fungi on all species and life states of fish, including eggs.
- **Ice**
  Used to reduce metabolic rate of fish during transport.
- **Magnesium Sulfate**
  Used to treat external monogenic trematode infestations and external crustacean infestations in fish at all life stages. Used in all freshwater species. Fish are immersed in a 30,000 mg $MgSO_4$/L and 7000 mg NaCl/L solutions for 5 to 10 minutes.
- **Onion** (whole form)
  Used to treat external crustacean parasites, and to deter sea lice from infesting external surface of salmonids at all life stages.
- **Papain**
  Used in a 0.2% solution to remove the gelatinous matrix of fish egg masses in order to improve hatchability and decrease the incidence of disease.
- **Potassium Chloride**
  Used as an aid in osmoregulation; relieves stress and prevents shock. Dosages used would be those necessary to increase chloride ion concentration to 10-2000 mg/L.
- **Povidone Iodine**
  Used in a 100 ppm solution for 10 minutes as an egg surface disinfectant during and after water hardening.
- **Sodium Bicarbonate**
  Used at 142 to 642 ppm for 5 minutes as a means of introducing carbon dioxide into the water to anesthetize fish.
- **Sodium Chloride**
  Used in a 0.5% to 1.0% solution for an indefinite period as an osmoregulatory aid for the relief of stress and prevention of shock; and 3% solution for 10 to 30 minutes as a parasitide.
- **Sodium Sulfite**
  Used in a 15% solution for 5 to 8 minutes to treat eggs in order to improve their hatchability.
- **Thiamine Hydrochloride**
  Used to prevent or treat thiamine deficiency in salmonids. Eggs are immersed in an aqueous solution of up to 100 ppm for up to four hours during water hardening. Sac fry are immersed in an aqueous solution of up to 1,000 ppm for up to one hour.
- **Urea & Tannic Acid**
  Used to denature the adhesive component of fish eggs at concentrations of 15g urea and 20g NaCl/5 liters of water for approximately 6 minutes, followed by a separate solution of 0.75 g tannic acid/5 liters of water for an additional 6 minutes. These amounts will treat approximately 400,000 eggs.

Continued

The Agency is unlikely to object to the use of low regulatory priority substances if the following conditions are met: 1) the substances are used for the stated indications; 2) the substances are used at the prescribed levels; 3) the substances are used according to good management practices; 4) the product is of an appropriate grade for use in food animals; and, 5) there is not likely to be an adverse effect on the environment.

The Agency's enforcement position on the use of these substances should not be considered an approval, nor an affirmation of their safety and effectiveness. The Agency reserves the right to take a different position on the use of any or all of these substances at some time in the future.

Classification of these substances as new animal drugs of low regulatory priority does not exempt facilities from complying with other Federal, State, and local environmental requirements. For, example, facilities using these substances would still be required to comply with National Pollutant Discharge Elimination System (NPDES) requirements.

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

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "aquaculture drugs" 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 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 VISITS

What: On-farm drug usage procedures;
AND
Producer certificate indicating proper INAD usage.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

What: Producer certificate indicating proper drug usage.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

What: On farm drug usage procedures;
AND
Producer certificate indicating proper INAD usage.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

What: Fish flesh for drug residues.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

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

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

What: Type of aquaculture drug used;
AND
Date and quantity of drug use;
AND
Any other conditions of drug use that are relevant to: the established withdrawal times; the labeled instructions for use; the extralabel use of an FDA-approved drug used under a veterinarians's supervision in accordance with FDA regulations and guidelines; the conditions specified in the FDA "low regulatory priority aquaculture drug" list; or, the conditions of the INAD application;
AND
Date of distribution of the finished product.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

How: Survey farm husbandry procedures, ask questions, and review drug usage records;
AND
Visual for presence of INAD certificate.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

How: Visual for presence of lot-by-lot certificate.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

How: Review drug records;
AND
Visual for presence of INAD certificate.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

How: Obtain samples and analyze for drugs, using rapid screening methods.

Note: A limited number of drug screening tests for aquaculture are available, and these have not been validated by FDA or AOAC. This topic is further discussed in Step #12.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

How: Visual for presence of third party certificate.

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

How: Visually observe drug use and distribution.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

Frequency: At least once per year for each aquaculture site.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Frequency: Each lot received.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Frequency: Each lot received.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

Frequency: Each lot received.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

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

Continued

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

Frequency: Every time aquaculture drugs are used during holding;
AND
Every time the product is distributed.

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

Who: Field agent (employee or contractor) or any other person who has an understanding of animal drug usage and limits.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

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

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Who: Production supervisor, member of the quality control staff, or any other personnel who has an understanding of animal drug usage and limits.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG 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 - CONTROL DURING HOLDING

Who: Production employee or supervisor, member of the quality control staff, or any other personnel who has an understanding of drug usage and limits.

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 "aquaculture drugs" 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 VISITS

Corrective Action: Reject product, if the CL is not met;
AND
Discontinue use of supplier until evidence is obtained that drug treatment practices have changed.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Corrective Action: Reject lot, if the CL is not met;
AND
Discontinue use of supplier until a commitment is obtained that a certificate will accompany each lot.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Corrective Action: Reject lot, if the CL is not met;
AND
Discontinue use of supplier until evidence is obtained that drug treatment practices have changed.

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

Corrective Action: Reject lot, if the CL is not met;
AND
Discontinue use of supplier until evidence is obtained that drug treatment practices have changed.

- CONTROL STRATEGY EXAMPLE 5 - QA PROGRAM

Corrective Action: Reject lot, if the CL is not met;
AND
Discontinue use of supplier until a certificate is provided.

- CONTROL STRATEGY EXAMPLE 6 - CONTROL DURING HOLDING

Corrective Action: Hold the product until the drug residue is at or below tolerance. This may be accomplished by collecting and analyzing a representative sample of the product, using an approved method;
OR
Destroy the product;
OR
Divert the product to non-food use.
AND
Modify drug use practices

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

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

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "aquaculture drugs" 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.

- CONTROL STRATEGY EXAMPLE 1 - ON-FARM VISITS

Records: On-site audit report;
AND
INAD certificate.

- CONTROL STRATEGY EXAMPLE 2 - SUPPLIER'S CERTIFICATION

Records: Certificate;
AND
Receiving record showing lots received and presence/absence of certificate.

- CONTROL STRATEGY EXAMPLE 3 - RECORDS OF DRUG USE

Records: Grower's drug records;
AND
INAD certificate;
AND
Receiving record showing lots received and presence/absence of certificate.

Continued

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG TESTING

Records: Analytical 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 - CONTROL DURING HOLDING

Records: Drug use records;
AND
Records indicating date of distribution of drug-treated product.

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 "aquaculture drugs" 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 of "aquaculture drugs"; 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 VISITS

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 to review the grower's drug usage procedures;
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 DRUG USE

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

- CONTROL STRATEGY EXAMPLE 4 - RESIDUE DRUG 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 - CONTROL DURING HOLDING

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 #11-1

Control Strategy Example 1 - On-farm visits

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs in farm-raised catfish, using Control Strategy Example 1 - On-farm visits. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards in this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Pre-harvest	Aquaculture drugs	Animal drugs used on fish only if the drugs have been: a) approved by FDA and used in accordance with proper withdrawal times and other labeled conditions; b) approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guidelines; c) listed on the "low regulatory priority aquaculture drug" list; or, d) permitted by FDA for use in food fish under the conditions of an INAD (as evidenced by a lot-by-lot written certificate from the grower)	• On farm drug usage procedures	• Survey farm husbandry procedures, ask questions, and review drug records	• Once per year for each aquaculture site	• Field agent	• Reject AND • Discontinue use of supplier until evidence is obtained that drug treatment practices have changed	• On-site audit report	• Review monitoring and corrective action records within one week of preparation
			• Certificate indicating proper INAD usage	• Visual	• Same	• Same	• Reject	• Certificate of INAD usage	

TABLE #11-2

Control Strategy Example 2 - Supplier's certification

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs in pond-raised shrimp, using Control Strategy Example 2 - Supplier's certification. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards in this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Receiving	Aquaculture Drugs	Certificate indicating proper drug usage accompanying all lots of incoming pond-raised shrimp	Presence of a certificate indicating proper drug usage	Visual	Each lot received	Receiving dock employee	• Reject lot AND • Discontinue use until supplier agrees to provide certificate for each lot	• Grower's drug usage certificate • Receiving record	• Visit all new pond-raised shrimp suppliers within the year and all existing suppliers at 25% per year on a rotating basis to review the grower's drug usage procedures • Review monitoring, corrective action, and verification records within one week of preparation

TABLE #11-3

Control Strategy Example 3 - Records of drug use

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs in pond-raised shrimp, using Control Strategy Example 3 - Records of drug use. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards in this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants, food and color additives, and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Receiving	Aquaculture Drugs	Animal drugs used on fish only if the drugs have been: a) approved by FDA and used in accordance with proper withdrawal times and other labeled conditions; b) approved by FDA and used in an extra-label manner under a veterinarian's supervision in accordance with FDA regulations and guidelines; c) listed on the "low regulatory priority aquaculture drug" list; or d) permitted by FDA for use in food fish under the conditions of an INAD (as evidence by a lot-by-lot written certificate)	• On-farm drug usage procedures • Certificate indicating proper INAD usage	• Review drug records at receipt • Visual	• Each lot received • Same	• Production supervisor • Same	• Reject lot AND • Discontinue use of supplier until evidence is obtained that drug treatment practices have changed • Same	• Grower's drug usage records • Receiving record • Certificate of INAD usage	• Review monitoring and corrective action records within one week of preparation

TABLE #11-4

Control Strategy Example 4 - Residue drug testing

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs in farm-raised catfish, using Control Strategy Example 4 - Residue drug testing. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards in this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Receiving	Aquaculture Drugs	No fish will be accepted that contains unapproved drug residues (other than those used under an INAD application or included on the "low regulatory priority aquaculture drug" list)	Fish flesh for drug residues	Obtain samples and analyze for drugs using rapid screening methods Note: A limited number of drug screening tests for aquaculture are available, and these have not been validated by FDA or AOAC. This topic is further discussed in Step #12.	Each lot received	Quality assurance personnel	• Reject lot AND • Discontinue use of supplier until evidence is obtained that drug treatment practices have changed	• Analytical results	Review monitoring and corrective action records within one week of preparation

TABLE #11-5

Control Strategy Example 5 - QA program

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs for an aquacultured trout processor, using Control Strategy Example 5 - QA program. It is provided for illustrative purposes only. Aquaculture drugs may be only one of several significant hazards for this product. Refer to Tables 3-1, 3-2, and 3-3 (Chapter 3) for other potential hazards (e.g. chemical contaminants and metal fragments).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			Monitoring						
			What	How	Frequency	Who			
Receiving	Aquaculture Drugs	Third party certificate indicating that the producer operates under a third party audited Quality Assurance Program that covers aquaculture drug usage	Presence of third party certificate	Visual, for presence of certificate	Each lot checked to see if covered by certificate, which is renewed annually	Receiving dock employee	• Reject lot AND • Discontinue use until a certificate is obtained	• Third party certificate of operation • Receiving record	Review monitoring and corrective action records within one week of preparation

TABLE #11-6

Control Strategy Example 6 - Control during holding

This table is an example of a portion of a HACCP plan relating to the control of aquaculture drugs for a processor that holds live lobster in a lobster pound, using Control Strategy Example 6 - Control during holding. It is provided for illustrative purposes only. Aquaculture drugs 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. natural toxins and food and color additives).

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits for each Preventive Measure	(4) Monitoring	(5) Monitoring	(6) Monitoring	(7) Monitoring	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			
Holding	Aquaculture Drugs	• Lobster will be withheld from distribution for 30 days after treatment with oxytetracycline in accordance with the labeled directions for use • No other aquaculture drugs will be used	• Type of aquaculture drug used • Date and quantity of drug use • Date of finished product distribution	• Visual observation of drug use • Visual observation of drug use • Visual observation of drug use	• Every time aquaculture drugs are used • Every time aquaculture drugs are used • Every time aquaculture drugs are used	• Production employee • Production employee • Shipping supervisor	• Hold the product AND • Collect a sample of the finished product and have analyzed for oxytetracycline residue by contact laboratory. If 2.0 ppm or less, release. If higher than 2.0 ppm, hold product an additional 5 days and then retest AND • Destroy the lot when unapproved drugs are used AND • modify drug use practices	• Drug use record • Drug use record • Shipping record	Review monitoring and corrective action records within one week of preparation