Hazard Analysis Worksheet

STEP #10: *UNDERSTAND THE POTENTIAL HAZARD.*

- Pathogens in molluscan shellfish

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses (e.g., hepatitis A virus, Norwalk virus, Norwalk-like viruses).

Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

- Control of pathogens of human/animal origin

Certain pathogens, such as *Vibrio cholerae* 01, *Salmonella* spp., *Shigella* spp., *Campylobacter jejuni,* hepatitis A virus, Norwalk virus, and Norwalk-like viruses, are of sewage or animal origin. To minimize the risk of molluscan shellfish containing these pathogens, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain conditions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been permitted.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; 2) a requirement that molluscan shellfish harvesters be licensed (note that licensing may not be required in all jurisdictions); 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the processor's name, address, and certification number.

Some bacterial pathogens of human sewage or animal waste origin, such as *Vibrio cholerae* 01, and *Salmonella* spp., that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependent upon the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

These controls serve to minimize the risk of molluscan shellfish containing pathogens of sewage or animal origin, but do not fully eliminate the risk. As a result, consumption of raw or undercooked molluscan shellfish may not be safe for individuals with certain health conditions, such as liver disease, chronic alcohol abuse, diabetes, and stomach, blood, and immune disorders. For this reason Shellfish Control Authorities require that shellstock intended for raw consumption bear a tag that instructs retailers to inform their customers that consuming raw or undercooked shellfish may increase the risk of foodborne illness, especially for individuals with certain medical conditions.

Continued

Processors can also eliminate the hazard of "pathogens from the harvest area" by properly cooking or retorting the product. Guidance on cooking controls is provided in Chapter 16. Mandatory retorting controls are described in the low acid canned foods regulation (21 CFR 113). It should be noted that neither cooking nor retorting will eliminate the hazards of "natural toxins" or "chemical contamination" that may be associated with molluscan shellfish that are harvested from closed waters (see Chapters 6 and 9). These hazards must be controlled at receiving. Additionally, the laws and regulations of states that participate in the National Shellfish Sanitation Program require that all molluscan shellfish be harvested from waters authorized for harvesting by the Shellfish Control Authority, regardless of how it will be processed.

- Control of naturally occurring pathogens

Certain pathogens, such as *Vibrio vulnificus, Vibrio parahaemolyticus,* and *Vibrio cholerae* non 01, are naturally occurring. Their presence is not associated with human sewage or animal waste. *V. vulnificus* illness is associated with the consumption of raw oysters harvested from the Gulf of Mexico during the warm weather months. *V. parahaemolyticus* and *V. cholerae* non 01 illness is associated with the consumption of raw oysters harvested during the warm weather months from the Atlantic, Pacific, and Gulf of Mexico regions of the U.S., and similar climates world-wide. To minimize the risk of illness from the consumption of molluscan shellfish containing these pathogens, Shellfish Control Authorities place certain controls on the harvest of molluscan shellfish.

Control for *V. parahaemolyticus* involves monitoring by Shellfish Control Authorities of waters that have been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past three years. Monitoring is performed for both total *V. parahaemolyticus* numbers and for the presence of virulent strains of *V. parahaemolyticus* (i.e. tdh+ strains). As a result of the monitoring, Shellfish Control Authorities may temporarily close some waters to the harvesting of oysters that are intended for raw consumption.

Naturally occurring pathogens may be present in relatively low numbers at the time that molluscan shellfish are harvested, but may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of *Vibrio parahaemolyticus* and *Vibrio cholerae* non 01 pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. As with pathogens of sewage or animal origin, the length of time is dependent upon the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

In most cases, control for *V. vulnificus* similarly involves limits on the time from harvest to refrigeration. The length of time is dependent upon the average monthly maximum water temperature (AMMWT) at the time of harvest, which is also determined by the Shellfish Control Authority.

As with pathogens of sewage origin, the above controls for naturally occurring pathogens minimize the risk of molluscan shellfish containing these pathogens, but do not fully eliminate the risk. For this same reason, Shellfish Control Authorities require that shellstock intended for raw consumption bear a tag containing a warning relative to raw and undercooked consumption (described above).

The controls for *V. vulnificus* and *V. parahaemolyticus* discussed in this chapter only apply to molluscan shellfish if they are intended for raw consumption. For example, they would not be applied to oyster shellstock from the Gulf of Mexico if tags on the containers of shellstock indicate that they must be shucked and cooked before consumption.

V. vulnificus, V. parahaemolyticus, and *V. cholerae* non 01 can be eliminated or reduced to nondetectable levels by cooking, pasteurizing, and retorting. Guidance for these control mechanisms can be found in Chapters 16 (cooking) and 17 (pasteurization) and the low acid canned foods regulation (21 CFR 113). Other mechanisms, such as freezing and hydrostatic pressure, are being studied.

Appropriate controls to prevent further growth of these pathogens during processing, storage, and transportation between processors is discussed in Chapter 12.

- Pathogens in fish other than molluscan shellfish

It is possible that, in performing your hazard analysis, you may have identified pathogens from the harvest area as a potential hazard for fish types other than molluscan shellfish. In some cases, this would be an appropriate decision, as pathogens, may be found on raw fish as a result of near-shore harvest water contamination, contamination on the harvest vessel and poor aquacultural practices.

This hazard can be controlled by the processor by proper cooking, pasteurizing, or retorting. Guidance for these control mechanisms can be found in Chapters 16 (cooking) and 17 (pasteurizing), and the low acid canned foods regulation, 21 CFR 113 (retorting).

For many products (e.g. raw fish fillets) there is no cooking, pasteurizing, or retorting step performed by the processor. For most of these products, cooking is performed by the consumer or end user before consumption. FDA is not aware of any HACCP controls that may exist internationally for the control of pathogens in fish and fishery products that are intended to be fully cooked by the consumer or end user before consumption, other than a rigorous sanitation regime as part of either a prerequisite program or as part of HACCP itself. The Seafood HACCP Regulation requires such a regime. The proper application of sanitation controls is essential because of the likelihood that any pathogens that may be present in seafood products are introduced through poor handling practices (e.g. by the aquacultural producer, the fisherman, or the processor).

FDA is interested in information regarding any HACCP controls beyond sanitation that may be both necessary and practical for the control of pathogens in fish and fishery products that are intended to be fully cooked by the consumer or end user before consumption. However, the agency makes no recommendations in this Guide and has no specific expectations with regard to such controls in processors' HACCP plans. The agency plans to develop guidance for harvest vessels and for aquaculture, in an effort to minimize the likelihood that these operations will contribute pathogens to fish and fishery product.

The guidance contained in the remainder of this chapter applies to molluscan shellfish, only.

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

At each processing step, determine whether "pathogens from the harvest area" is a significant hazard. The criteria are:

1. Is it reasonably likely that unsafe levels of pathogens from the harvest area will be introduced at the receiving step (e.g. are pathogens present in the raw material at unsafe levels)?

Under ordinary circumstances, it would be reasonably likely that pathogens from the harvest area could enter the process at unsafe levels at the receiving step from the following types of fish:
- Raw oysters;
- Raw clams;
- Raw mussels;
- Raw scallops

(See information provided under "Intended use").

Under ordinary circumstances, it would be reasonably likely that *V. vulnificus* could enter the process from oysters harvested from the Gulf of Mexico (i.e., States which have been confirmed as the original source of oysters associated with two or more *V. vulnificus* illnesses).

Under ordinary circumstances, it would be reasonably likely that *V. parahaemolyticus* could enter the process from oysters harvested in an area which has been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past three years.

Continued

2. Can unsafe levels of pathogens from the harvest area, which were introduced at the receiving step, be eliminated or reduced to an acceptable level at this processing step? (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.)

"Pathogens from the harvest area" should also be considered a significant hazard at any processing step where a preventive measure is or can be used to eliminate unsafe levels of pathogens that are reasonably likely to come in with the raw materials, or where a preventive measure is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. Preventive measures for pathogens from the harvest area could include:

- Checking incoming molluscan shellfish to ensure that they are properly tagged or labeled;
- Making sure that incoming molluscan shellfish are supplied by a licensed harvester (where licensing is required by law) or by a certified dealer;
- Killing the pathogens by cooking (covered in Chapter #16), pasteurizing (covered in Chapter #17), or retorting (covered by the low acid canned foods regulation, 21 CFR 113). It should be noted that neither cooking nor retorting will eliminate the hazards of "natural toxins" or "chemical contamination" that may be associated with molluscan shellfish that are harvested from closed waters;
- Minimizing the growth of *V. cholerae*, *V. parahaemolyticus*, *V. vulnificus*, and *L. monocytogenes* by limiting the time from harvest to refrigeration.
- Including a warning on tags on containers of molluscan shellfish intended for raw consumption that instructs retailers to inform their customers that consuming raw or undercooked shellfish may increase the risk of foodborne illness, especially for individuals with certain medical conditions.

List such preventive measures in Column 5 of the Hazard Analysis Worksheet at the appropriate processing step(s).

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

It is important to note that identifying this hazard as significant at a processing step does not mean that it must be controlled at that processing step. The next step will help you determine where in the process the critical control point is located.

- Intended use

In determining whether a hazard is significant you should also consider the intended use of the product, which you developed in Step #4. For most raw molluscan shellfish products you should assume that the product will be consumed raw. You should, therefore, identify the hazard as significant if it meets the above criteria.

However, where the product consists of scallop adductor muscle only, it is reasonable to assume that the product will be cooked before consumption. In this case you would not need to identify "pathogens from the harvest area" as a significant hazard. You should then enter "No" in Column 3 of the Hazard Analysis Worksheet for each of the processing steps. For each "No" entry briefly explain in Column 4 that the product is not ordinarily consumed raw. In this case, you need not complete Steps #12 through 18 for this hazard.

Additionally, the controls for *V. vulnificus* and *V. parahaemolyticus* that are discussed in this chapter only need be applied to molluscan shellfish if they are intended for raw consumption. For example, they need not be applied to oyster shellstock from the Gulf of Mexico if tags on the containers of shellstock indicate that they must be shucked and cooked before consumption.

Similarly, the raw consumption warning need not be applied to containers of shucked shellfish, because these products are generally cooked before consumption.

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

For each processing step where "pathogens from the harvest area" 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 "pathogens from the harvest area":

1. Will the product be cooked or retorted sufficiently to kill pathogens during processing in your facility?

    a. If it will be, you may identify the cook step or retorting step as the CCP. In this case you would not need to identify the receiving step as a CCP for the hazard of "pathogens from the harvest area." However, it should be noted that neither cooking nor retorting will eliminate the hazards of "natural toxins" or "environmental chemical contaminants and pesticides" that may be associated with molluscan shellfish that are harvested from closed waters (see Chapters 6 and 9). These hazards must be controlled at receiving. Additionally, the laws and regulations of states that participate in the National Shellfish Sanitation Program require that all molluscan shellfish be harvested from waters authorized for harvesting by the Shellfish Control Authority.

    Example:

    A canned clam chowder processor sets the critical control point for pathogens from the harvest area at the retorting step, and does not identify the receiving step as a critical control point for this hazard.

    In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the cooking or retorting step, and enter "No" for the receiving step. In addition, note in Column 5 that the hazard is controlled by the cooking or retorting step. (Note: if you have not previously identified "pathogens from the harvest area" as a significant hazard at the cooking or retorting step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes.") If you chose to follow this approach you should refer to Chapter 16 (cooking) or to the low acid canned foods regulation (retorting) for further guidance.

    b. If the product will not be cooked or retorted sufficiently to kill pathogens during processing in your facility, you should identify the receiving step as a CCP, where you can exercise control over the source of the molluscan shellfish and the time from harvest to refrigeration to control pathogens from the harvest area. If the finished product is shellstock intended for raw consumption, you should also identify the labeling step as a CCP, where you can ensure that the raw consumption warning is on the tag.

    Example:

    A processor that shucks raw oysters and ships a raw product checks the tags of incoming shellstock (in-shell oysters), the license of the harvesters that supply the shellstock, and the length of time between harvesting and refrigeration. The processor identifies receiving as the CCP for this hazard.

    Example:

    A processor that ships oyster shellstock checks the tags of incoming shellstock, the license of the harvesters that supply the shellstock, and the length of time between harvesting and refrigeration. The processor identifies receiving as a CCP for this hazard. The processor also identifies the labeling step as a CCP for this hazard, and checks for the presence of the raw consumption warning.

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 1" in Steps #14 through 18. Note that this control strategy is identical to Control Strategy Example 6 for "environmental chemical contaminants and pesticides" (Chapter 9) and Control Strategy Example 1 for "natural toxins" (Chapter 6). If you choose an identical control strategy for two or more of these hazards, you may combine the hazards in the HACCP Plan Form.

You only need to answer Questions 2 and 3 if you answered "no" to Question 1.

2. If the finished product is raw oyster shellstock intended for raw consumption and is from the Gulf of Mexico (i.e., States which have ever been confirmed as the original source of oysters associated with two or more *V. Vulnificus* illnesses), will it be pasteurized sufficiently to kill *V. vulnificus* during processing in your facility (i.e. reduced to a nondetectable level; less than 3 MPN/gram, as defined by the NSSP)? Other mechanisms, such as freezing and hydrostatic pressure, are being studied and may also be suitable for control of these pathogens.

   a. If it will be, you may identify the pasteurization step as the CCP for control of *V. vulnificus*. In this case you will not need to identify the receiving step as a CCP for the control of *V. vulnificus*.

   Example:
   An oyster processor on the Gulf of Mexico sets the critical control point for V. vulnificus at the pasteurizing step, and does not identify the receiving step as a critical control point for that pathogen.

   In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the pasteurizing step. (Note: if you have not previously identified pathogens from the harvest area as a significant hazard at the pasteurizing step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) If you chose to follow this approach you should refer to Chapter 17 (pasteurizing) for further guidance.

   b. If the product will not be pasteurized sufficiently to kill *V. vulnificus* during processing in your facility, you should identify the receiving step as a CCP, where you can exercise control over the time from harvest to refrigeration to control *V. vulnificus*. You should also identify the labeling step as a CCP for this hazard, where you can ensure that the raw consumption warning is on the tag.

   Example:
   Another oyster processor on the Gulf of Mexico sets the critical controls point for V. vulnificus at the receiving step and the tagging step.

   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 #14-18.

   Note that the controls listed under "2," above, should be considered in addition to those listed under "1," above and "3," below. In some cases, two or more types of controls will be necessary.

3. If the finished product is raw oyster shellstock intended for raw consumption and is from an area which has been confirmed as the original source of oysters associated with two or more *V. parahaemolyticus* illnesses in the past three years, will it be pasteurized sufficiently to kill *V. parahaemolyticus* during processing in your facility? Other mechanisms, such as freezing and hydrostatic pressure, are being studied and may also be suitable for control of these pathogens.

a. If it will be, you may identify the pasteurization step as the CCP for control of *V. parahaemolyticus*. In this case you will not need to identify the receiving step as a CCP for the control of *V. parahaemolyticus*.

Example:

An oyster processor sets the critical control point for V. parahaemolyticus at the pasteurizing step, and does not identify the receiving step as a critical control point for that pathogen.

In this case enter "Yes" in Column 6 of the Hazard Analysis Worksheet for the pasteurizing step. (Note: if you have not previously identified pathogens from the harvest area as a significant hazard at the pasteurizing step in Column 3 of the Hazard Analysis Worksheet, you should change the entry in Column 3 to "Yes".) If you chose to follow this approach you should refer to Chapter 17 (pasteurizing) for further guidance.

b. If the product will not be pasteurized sufficiently to kill *V. parahaemolyticus* during processing in your facility, you should identify the receiving step as a CCP, where you can exercise control over the time from harvest to refrigeration to control *V. parahaemolyticus*. You should also identify the labeling step as a CCP for this hazard, where you can ensure that the raw consumption warning is on the tag.

Example:

Another oyster processor sets the critical control point for V. parahaemolyticus at the receiving step and the tagging step.

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 14-18.

Note that the controls listed under "3," above, should be considered in addition to those listed under "1," and "2" above. In many cases, two or more types of controls will be necessary.

The time to refrigeration controls for *V. vulnificus* that are discussed in this chapter need only be applied by the primary processor (the processor who takes possession of the molluscan shellfish from the harvester), since this is the processor that is in the best position to control the time from harvest to refrigeration.

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 "pathogens from the harvest area" 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 CL at the point that if not met the safety of the product may be questionable. If you set a more restrictive CL 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 CL 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 CL. In this way you can adjust the process when the operating limit is triggered, but before a triggering of the CL 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 CL.

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

Continued

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Critical Limit: All shellstock (in-shell molluscan shellfish) containers must bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the Shellfish Control Authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). For bulk shipments of shellstock, where the shellstock is not containerized, accept shellstock only if it is accompanied by a bill of lading or other similar shipping document that contains the same information;

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 containers of shucked molluscan shellfish must bear a label that identifies the name, address, and certification number of the packer or repacker of the product;

AND

All molluscan shellfish must be from a harvester that is licensed as required (note that licensing may not be required in all jurisdictions) or from a processor that is certified by a Shellfish Control Authority.

AND

The following criteria is met for the maximum time from harvest to refrigeration:

- For AMMAT of less than 66˚F (less than 19˚C): 36 hours;
- For AMMAT of 66 to 80˚F (19 to 27˚C): 24 hours;
- For AMMAT of greater than 80˚F (greater than 27˚C): 20 hours.

AND

All finished product shellstock intended for raw consumption must bear a tag that instructs retailers to inform their customers that consuming raw or undercooked shellfish may increase the risk of foodborne illness, especially for individuals with certain medical conditions.

(Note: Average Monthly Maximum Air Temperature (AMMAT) is determined by the Shellfish Control Authority)

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls relative to the identification of the harvester, the harvester's license, the approval status of the harvest waters, or the time-of-harvest to time-of-refrigeration.)

- CONTROL STRATEGY EXAMPLE 2 - *V. VULNIFICUS* CONTROL

Critical Limit: Maximum time from harvest to refrigeration (Note: these apply only to certain products, as described in Steps #11 and 12):

- For AMMWT of less than 65˚F (less than18˚C): 36 hours
- For AMMWT of 65 to 74˚F (18 to 23˚C): 14 hours;
- For AMMWT of greater than 74 to 84˚F (greater than 23 to 28˚C): 12 hours;
- For AMMWT of greater than 84˚F (greater than 28˚C): 10 hours

AND

All finished product shellstock intended for raw consumption must bear a tag that instructs retailers to inform their customers that consuming raw or undercooked shellfish may increase the risk of foodborne illness, especially for individuals with certain medical conditions.

(Note: Average Monthly Maximum Water Temperature (AMMWT) is determined by the Shellfish Control Authority.)

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls for time-of-harvest to time-of-refrigeration.)

- CONTROL STRATEGY EXAMPLE 3 – *V. PARAHAEMOLYTICUS* CONTROL

Critical Limit: Maximum time from harvest to refrigeration (Note: these apply only to certain products, as described in Steps #11 and 12):

- For AMMAT of less than 66˚F (less than 19˚C): 36 hours
- For AMMAT of 66˚F to 80˚F (19˚C to 27˚C): 12 hours
- For AMMAT of greater than 80˚F (greater than 27˚C): 10 hours

AND

All finished product shellstock intended for raw consumption must bear a tag that instructs retailers to inform their customers that consuming raw or undercooked shellfish may increase the risk of foodborne illness, especially for individuals with certain medical conditions.

(Note: Average Monthly Maximum Air Temperature (AMMAT) is determined by the Shellfish Control Authority.)

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls for time-of harvest to time of refrigeration.).

Much of Control Strategy Example 1 is specifically mandated by 21 CFR 123.28. However, for those provisions that are not specifically included in the regulation, you may select a different control strategy, provided that it assures an equivalent degree of safety of the product.

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

STEP #15: *ESTABLISH MONITORING PROCEDURES.*

For each processing step where "pathogens from the harvest area" 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 CL is being met. That is, the monitoring process should directly measure the feature for which you have established a CL.

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 CL. Additionally, the greater the time span between measurements the more product you are putting at risk should a measurement show that a CL 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.

Continued

What Will Be Monitored?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

What: The tags on containers of incoming shellstock. The Bill of Lading or other similar shipping document accompanying bulk shipments of shellstock;
AND
The harvest site listed on the tag or on the Bill of Lading or other similar shipping document;
AND
The labels on containers of incoming shucked molluscan shellfish;
AND
The license of fishermen, where applicable;
AND
The certification number of suppliers (other than fishermen) of shellstock or shucked molluscan shellfish;
AND
Time harvesting began;
AND
Time shellstock was placed under refrigeration;
AND
The raw consumption advisory on tags on containers of finished product shellstock intended for raw consumption.

- CONTROL STRATEGY EXAMPLES 2 & 3

What: Time harvesting began;
AND
Time shellstock was placed under refrigeration;
AND
The raw consumption advisory on tags on containers of finished product shellstock intended for raw consumption.

How Will Monitoring Be Done?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

How: Visual checks;
AND
For time of harvest:
- Obtain information from Shellfish Control Authority;

OR
- Check harvester's log;

OR
- Note time of departure from dock;

OR
- Ask harvester.

- CONTROL STRATEGY EXAMPLES 2 & 3

How: Visual checks;
AND
For time of harvest:
- Obtain information from Shellfish Control Authority;

OR
- Check harvester's log;

OR
- Note time of departure from dock;

OR
- Ask harvester.

How Often Will Monitoring Be Done (Frequency)?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Frequency: For checking incoming tags: every container;
AND
For checking harvest site: every lot;
AND
For checking incoming labels: at least three containers randomly selected from throughout every lot;
AND
For checking licenses: every delivery;

AND
For checking certification numbers: every delivery;
AND
For checking time-of-harvest and time-of-refrigeration: every delivery;
AND
For checking raw consumption advisory on finished product tags: each lot of finished product or each lot of tags (at receipt of tags).

- CONTROL STRATEGY EXAMPLES 2 & 3

Frequency: Every delivery;
AND
For checking raw consumption advisory on finished product tags: each lot of finished product or each lot of tags (at receipt of tags).

Who Will Perform the Monitoring?

- CONTROL STRATEGY EXAMPLE 1 - SOURCE CONTROL

Who: Monitoring may be performed by the receiving employee, a supervisor, a member of the quality control staff, or any other person who has an understanding of the nature of the controls.

- CONTROL STRATEGY EXAMPLES 2 & 3

Who: Monitoring may be performed by the receiving employee, a supervisor, a member of the quality control staff, or any other person who has an understanding of the nature of the controls.

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls relative to the identification of the harvester, the harvester's license, the approval status of the harvest waters, or the time-of-harvest to time-of-refrigeration.)

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 "pathogens from the harvest area" is identified as a significant hazard on the HACCP Plan Form, describe the procedures that you will use when your monitoring indicates that the CL 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 CL 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 - SOURCE CONTROL

Corrective Action: Reject incoming shellstock that is not properly tagged or is not accompanied by a proper shipping document;
AND
Reject incoming shucked molluscan shellfish that is not properly labeled;
AND
Reject incoming molluscan shellfish that has been harvested from unapproved waters;
AND
Reject incoming molluscan shellfish that is not from a licensed harvester or certified processor;
AND
Reject incoming shellstock that does not meet the time-of-harvest to time-of-refrigeration critical limits;
AND
Relabel finished product shellstock intended for raw consumption that does not bear a tag that contains the raw consumption warning;
OR
Reject any incoming tags to be used on finished product shellstock intended for raw consumption that do not contain the raw consumption warning;
AND
Discontinue use of supplier until evidence is obtained that harvesting, tagging, and/or labeling practices have changed.

Continued

- CONTROL STRATEGY EXAMPLES 2 & 3

Corrective Action: Reject lots that do not meet the CL;
OR
Relabel the shellstock with tags that identify its use for shucking and cooking only;
OR
Subject the shellstock to a pasteurization process that reduces *V. vulnificus* or *Vibrio parahaemolyticus*, as appropriate, in the shellstock to a non-detectable level (i.e. less than 3 MPN/gram, as defined in the NSSP). See Chapter 17 for further guidance on pasteurization.
AND
Relabel finished product shellstock that does not bear a tag that contains the raw consumption warning;
OR
Reject any incoming tags to be used on finished product shellstock that do not contain the raw consumption warning;
AND
Discontinue use of supplier until evidence is obtained that harvesting, tagging, and/or labeling practices have changed.

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.

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls relative to the identification of the harvester, the harvester's license, the approval status of the harvest waters, or the time-of-harvest to time-of-refrigeration.)

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

STEP #17: *ESTABLISH A RECORDKEEPING SYSTEM.*

For each processing step where "pathogens from the harvest area" 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 - SOURCE CONTROL

For shellstock:

Records: Receiving record that documents:
- Date of harvest;

AND
- Location of harvest by State and site;

AND
- Quantity and type of shellfish;

AND
- Name of the harvester, name or registration number of the harvester's vessel, or an identification number issued to the harvester by the Shellfish Control Authority;

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

AND
- Certification number of the shipper, where applicable;

AND
- Time harvesting began;

AND
- Time shellstock was placed under refrigeration;

AND
- AMMAT, where applicable;

AND
- For shellstock intended for raw consumption, labeling record that documents the presence of the raw consumption warning.

For shucked molluscan shellfish:

Records: Receiving record that documents:

- Date of receipt;

AND

- Quantity and type of shellfish;

AND

- Name and certification number of the packer or repacker.

- CONTROL STRATEGY EXAMPLES 2 & 3

Records: Receiving record that documents:

- Time harvesting began;

AND

- Time shellstock was placed under refrigeration;

AND

- AMMWT;

AND

- For shellstock intended for raw consumption, labeling record that documents the presence of the raw consumption warning.

(Note: only the primary processor (the processor that takes possession of the molluscan shellfish from the harvester) need apply controls relative to the identification of the harvester, the harvester's license, the approval status of the harvest waters, or the time-of-harvest to time-of-refrigeration.)

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 "pathogens from the harvest area" 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 "pathogens from the harvest area"; 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 - SOURCE CONTROL

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

- CONTROL STRATEGY EXAMPLES 2 & 3

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 #4-1

Control Strategy Example 1 - Source control

This table is an example of a portion of a HACCP plan relating to the control of pathogens from the harvest area for a primary processor (processor that takes possession of the oysters from the harvester) of shellstock oysters (shellstock shipper), using Control Strategy Example 1 - Source controls. It is provided for illustrative purposes only. Pathogens from the harvest area 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, chemical contaminants, pathogens during processing, 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 - shellstock	Pathogens from harvest area	• All incoming shellstock must be tagged	• Incoming shellstock tags	• Visual	• Every sack	• Receiving employee	• Reject untagged sacks	• Receiving record	• Review monitoring and corrective action records within one week of preparation
		• All shellstock must be from open waters	• Harvest site on tags	• Visual	• Every lot	• Receiving employee	• Reject lots from unapproved waters	• Receiving record	
		• All shellstock must be from licensed fishermen.	• License of fisherman	• Visual	• Every delivery	• Receiving employee	• Reject lots from unlicensed fishermen	• Receiving record	
		• Maximum time from harvest to refrigeration: AMMAT <66°F: 36 hours; AMMAT 66-80°F: 24 hours; AMMAT >80°F: 20 hours.	• Time of harvest	• Harvester's log	• Every delivery	• Receiving employee	• Reject lot	• Receiving record	
			• Time placed in refrigeration	• Visual	• Every delivery	• Receiving employee	• Discontinue use of supplier until evidence is obtained that harvesting, tagging, and/or labeling practices have changed	• Receiving record	
Receiving - labels	Pathogens from harvest area	• All shellstock labels must contain the raw consumption warning	• Tags for finished product shellstock	• Visual	• Three tags from each lot of tags	• Receiving employee	• Reject tags	• Receiving record	• Review monitoring and corrective action records within one week of preparation