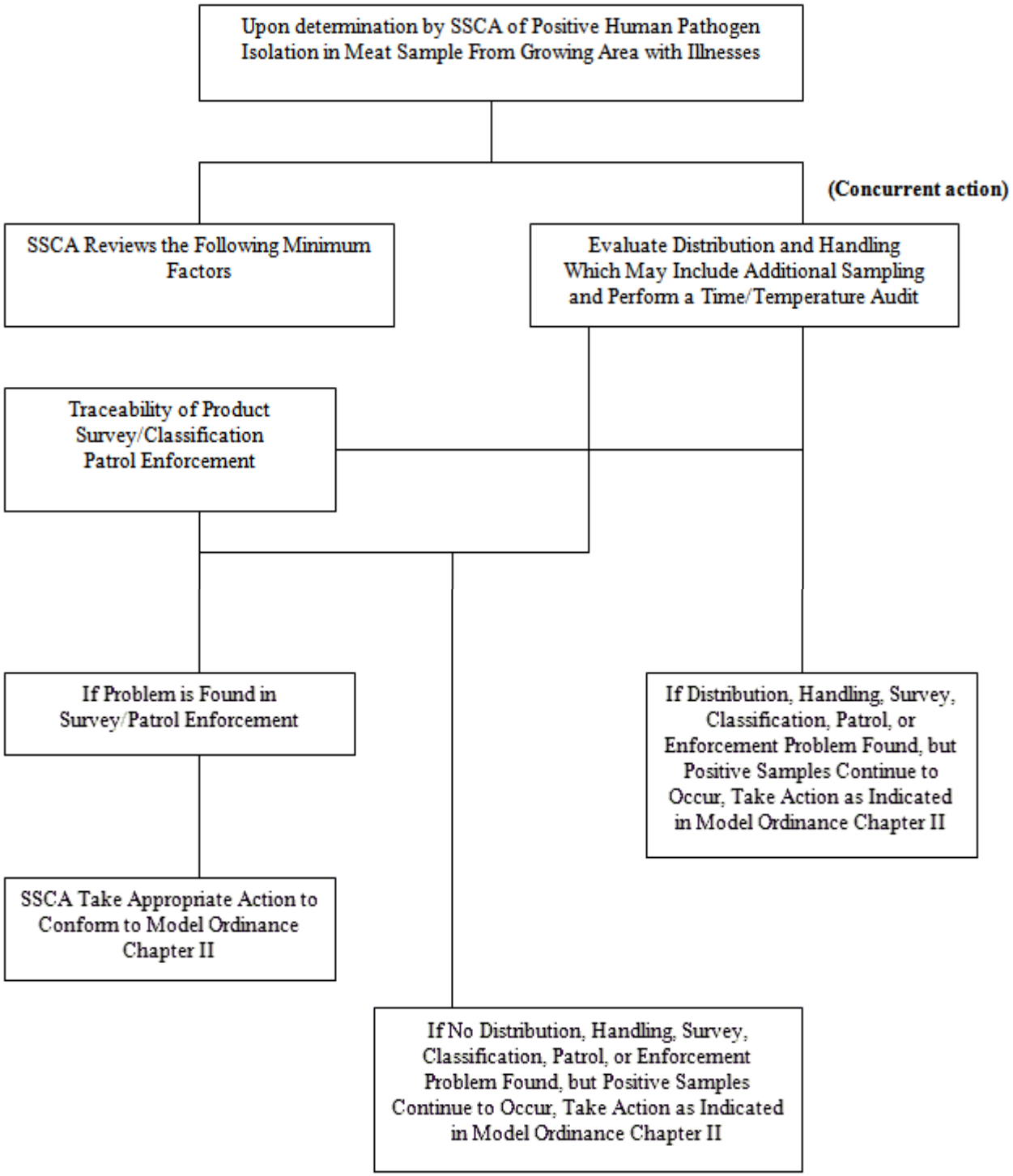
.13 Protocol for Reviewing Classification of Areas Implicated by Pathogens in Shellfish Meat Samples



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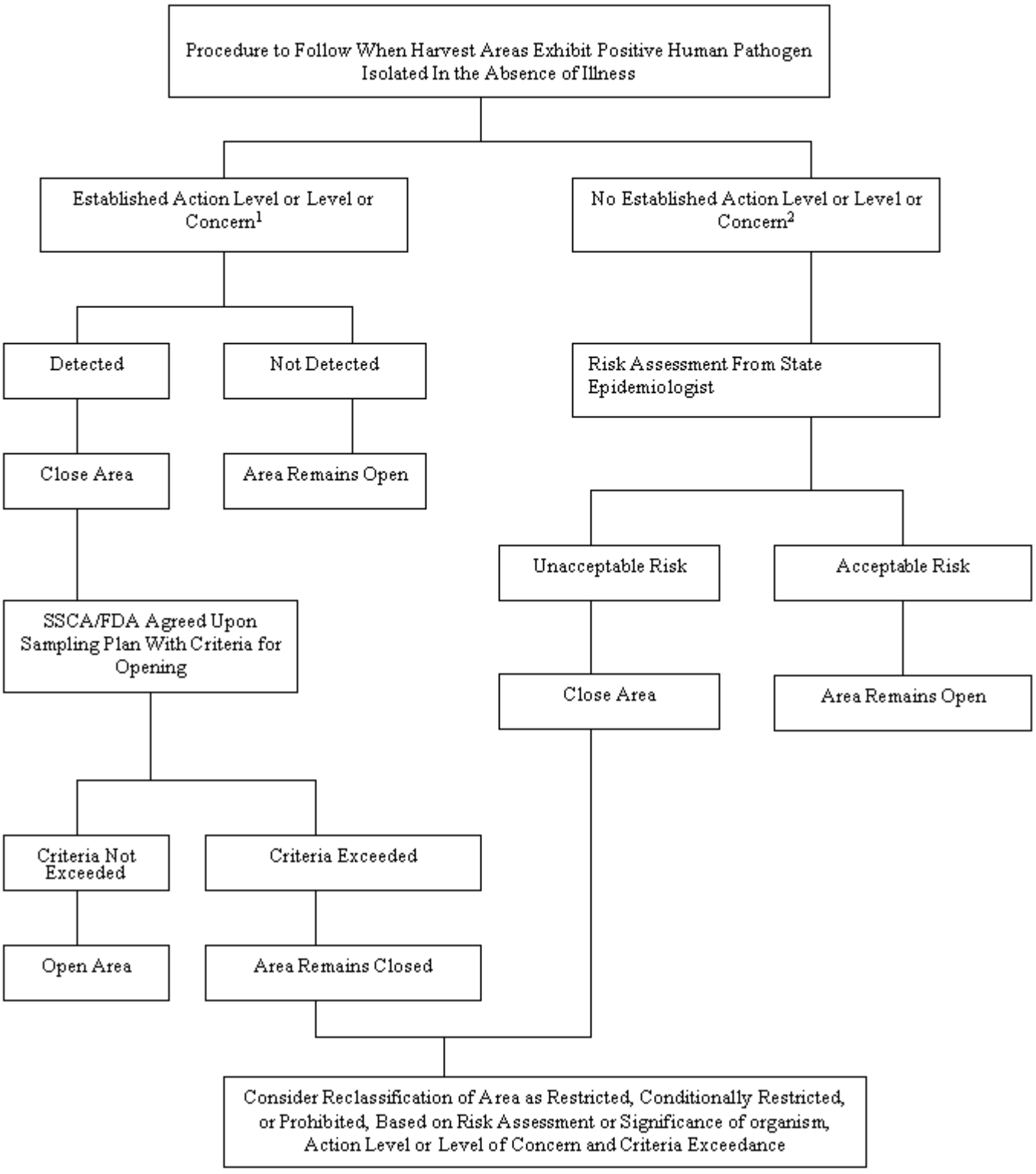

Footnotes

[1] FDA has established action levels or levels of concern for certain microbial pathogens in molluscan shellfish. The Agency will consider enforcement action against the shipment of molluscan shellfish if the following levels of pathogens are detected:

- ***Salmonella*** - positive for the presence of the organism;
- Enterotoxigenic ***Escherichia coli*** (ETEC) - 1,000 per gram, heat-labile toxin (LT) or heat-stable enterotoxin (ST) positive (may be determined by MPN method);
- ***Vibrio cholerae*** - presence of toxin-producing 01 or non-01 organisms;
- ***Vibrio parahaemolyticus*** - levels equal to or greater than a MPN count of 10,000 per gram and Kanagawa positive or negative; and
- ***Staphylococcus aureus*** - positive for staphylococcal enterotoxin or when the viable MPN count is 10,000 per gram.

[2]Other pathogens under review include: ***Listeria monocytogenes***, non-toxin producing non-01 ***Vibrio cholerae***, and ***Vibrio vulnificus***. In the absence of an established action level or level of concern for these pathogens, enforcement action is considered on a case-by-case basis taking into account all the factors associated with the specific situation.

Description: Two flow charts showing the process for reviewing the classification of growing areas implicated by pathogens in shellfish meat samples.

The first flow chart describes the procedure to follow when positive human pathogens are isolated from shellfish meat samples and there have been associated illnesses. The second chart describes the process when positive human pathogens are isolated from shellfish meat samples from a growing area in the absence of illness.

Upon determination by the State Shellfish Control Authority (SSCA) of positive human pathogen isolation in meat samples from a growing area with associated illnesses, the SSCA shall review the following minimum factors: (1) Traceability of product, (2) Sanitary survey/classification of the growing area, and (3) Patrol and enforcement. If a problem is found in one of these three factors, the SSCA shall take action as indicated in Model Ordinance Chapter II.

Concurrent with review of the three factors described above the SSCA shall evaluate distribution and handling of the shellfish. This may include additional sampling and performance of a time/temperature audit of the product.

If a distribution, handling, sanitary survey, classification of the growing area, patrol or enforcement problem is found, but positive sample results continue to occur, the SSCA shall take action as indicated in Model Ordinance Chapter II.

If no distribution, handling, sanitary survey, classification or the growing area, patrol or enforcement problem is found, but positive sample results continue to occur, the SSCA shall take action as indicated in Model Ordinance Chapter II.

The second flow chart describes the procedure to follow when positive human pathogens are isolated from shellfish meat samples in the absence of illness.

If there is an established action level or level of concern for the pathogen detected and that level is exceeded then the area shall be closed[1]. In such cases the SSCA and Food and Drug Administration (FDA) will develop an agreed upon sampling plan with criteria for opening the area that is closed. If the reopening criteria are not exceeded, the area can be reopened. If the reopening criteria are exceeded, the area shall remain closed and be considered for reclassification as restricted, conditionally restricted, or prohibited, based on a risk assessment or the significance of the organism, action level or level of concern and criteria exceedance.

If the established action level or level of concern is not exceeded, then the area can remain open.

If there is not an established action level or level of concern for the pathogen detected, the state epidemiologist shall conduct a risk assessment[2]. If the risk is determined acceptable, the area can remain open. If the risk is determined unacceptable, the area shall be closed and considered for reclassification as restricted, conditionally restricted, or prohibited, based on a risk assessment or the significance of the organism, action level or level of concern and criteria exceedance.