tagging provisions of subpart C of part 123 and § 1240.60(b).

The comments stated that limiting these provisions to raw products would allow foreign firms to continue to heat-treat or can molluscan shellfish that are harvested from foreign waters that do not meet NSSP standards and to export them to the United States. The comments stated that this situation was not in the best interest of the public health because of the potential for the presence of heat-stable natural toxins, such as paralytic shellfish poison or amnesiac shellfish poison, as well as chemical contaminants. The comments also complained that, because State laws and regulations require that all molluscan shellfish harvested in the United States come from waters approved by a shellfish control authority regardless of whether they are to be consumed raw or cooked, continuing to allow foreign processors who export cooked shellfish to the United States to use molluscan shellfish from unapproved growing waters places the domestic shellfish industry at a competitive disadvantage. Other comments requested that FDA clarify whether canned shellfish were included in subpart C of part 123 but did not suggest that canned and other heat-processed shellfish be included.

FDA has responded to these comments generally in response to comment 34, *supra.* The agency adds the following points:

It is important to recognize that foreign processors who export cooked molluscan shellfish to the United States now will have to have HACCP systems through which they identify and control hazards that are reasonably likely to occur. These hazards include heat stable toxins and chemical contaminants that would cause these products to be adulterated under U.S. law.

To further clarify that the requirements of subpart C of part 123 apply only to the processing of molluscan shellfish that are not heat treated or treated in some other manner by the processor to eliminate microorganisms of public health concern, FDA has modified the language at § 123.20 to read, ''This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.''

4. Shellfish Control Authorities

FDA proposed to require that processors only process molluscan shellfish that originate from waters approved for harvesting by a shellfish control authority. The term ''shellfish control authority'' is defined at § 123.3(o) to include foreign government health authorities that are legally responsible for the administration of a program that includes classification of molluscan shellfish growing areas.

145. Two trade associations questioned how a processor could evaluate the competency of a foreign shellfish control authority. They stated that FDA should require that a foreign country that exports shellfish to the United States have an agreement with the agency that establishes that a competent shellfish control authority exists in that country, and that the foreign shellfish program meets NSSP standards. One comment from a seafood processor argued that it would be unreasonable to require processors to verify that molluscan shellfish from all over the world are caught or cultivated in waters that meet NSSP standards. The comment stated, moreover, that a processor could not keep abreast of which countries have current shellfish agreements with FDA and which countries do not.

FDA acknowledges the merits of requiring that a foreign country that exports shellfish to the United States have an agreement with the agency but has concluded that, given the significance of such a requirement and the agency's failure to raise the possibility of imposing it in the proposal, it is beyond the scope of this rulemaking. Even though FDA is not imposing such a requirement, it is the case that the only means by which a processor can ensure that the molluscan shellfish of foreign origin that it receives are in compliance with the requirements of subpart C of part 123 of these regulations is by determining whether the foreign shellfish control authority is formally recognized by FDA. It is not likely that the processor could employ any other process that would give it assurance that molluscan shellfish harvesting waters that are approved by the shellfish control authority are properly classified. Such a determination is appropriately performed through government to government audit.

5. Shellfish From Federal Waters

146. Comments from a significant number of trade associations and seafood processors stated that a requirement that shellfish originate only in waters ''approved for harvesting by a shellfish control authority'' would preclude harvesting in Federal waters unless the Federal government introduced a formal approval process for waters under its purview through a Federal shellfish control authority.

Under the current system, State agencies are responsible for approving molluscan shellfish growing waters. However, State jurisdiction extends only to waters that are within three miles of the shore. Waters beyond that point but up to 200 miles offshore are under the jurisdiction of the Federal government. The comments pointed out that the harvesting of molluscan shellfish is permitted in all of the oceanic waters under Federal control unless there is a specific Federal action to declare an area unsafe under the provisions of the Magnuson Fishery Conservation and Management Act. The comments further noted that large volumes of molluscan shellfish are harvested in Federal waters.

How Federal waters will be classified, and by whom, has not been fully resolved. The comments are correct that the proposed requirement, if incorporated into the final rule, would pose significant problems for molluscan shellfish processors who receive product harvested from Federal waters. Therefore, FDA has modified § 123.28(b) to allow for the receipt of molluscan shellfish that are harvested in U.S. Federal waters except where such waters are specifically closed to harvesting by an agency of the Federal government. This provision is consistent with the provisions of the Magnuson Act.

It is worth noting that, by allowing Federal waters to be open unless they are specifically closed, this system is the opposite of the State system, under which waters are closed unless they are affirmatively classified so as to be open. This difference is reasonable from a public health standpoint because there is less likelihood that Federal waters will be affected by pollution than will near shore State waters.

Furthermore, because there is no Federal authority to license shellfish harvesters who fish in Federal waters, FDA has modified § 123.28(c) to require only that a harvester be in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish, rather than specifically requiring licensure.

6. Tagging and Recordkeeping Requirements

147. FDA proposed recordkeeping requirements for processors to follow with respect to shellstock and shucked molluscan shellfish in § 123.28 and requirements for the information to be included on the shellstock tag in § 1240.60. A few comments stated that