toxin forming species to make specific reference to only tuna, bluefish, and mahi mahi, since the overwhelming majority of scombroid poisonings are associated with these types of fish. Processors should assess the potential of other species to product histamine. The key to the definition is whether significant levels of histamine may be produced in the flesh of the fish.

17. Shellfish Control Authority

FDA proposed to define ''shellfish control authority'' as ''a Federal or State health authority, or foreign government health authority, legally responsible for the administration of a program that includes classification of molluscan shellfish growing areas, enforcement of harvesting controls, and certification of molluscan shellfish processors.''

49. A few comments pointed out that the definition should not require that a shellfish control authority be a State ''health'' authority because in some States the responsibility is vested in other than a health agency, such as a resource management agency.

FDA recognizes that these comments are correct. For this reason, the agency has modified the language in § 123.3(o) to read, in part, ''State agency.'' FDA believes that this term is sufficiently broad to encompass any of the present State arrangements. FDA has made a parallel change with respect to foreign government authorities, in order to accommodate the same kind of variations in regulatory arrangements. These final regulations similarly refer to a ''foreign agency.''

50. One comment, from a State regulatory agency, stated that within the United States, FDA should be the responsible shellfish control authority and should mandate that processors register with FDA, much as it has done with low-acid canned foods and medical devices. The comment further stated that a requirement in Federal regulations that State agencies perform this function may be unconstitutional.

The comment misconstrued the provision. The provision is intended to define the term ''shellfish control authority'' rather than to provide substantive requirements. Furthermore, these regulations at no point mandate that States perform certain functions.

51. Some comments expressed concern that the proposed definition of ''shellfish control authority'' was too narrow in that it did not include any entities that could serve the function of a shellfish control authority for Federal waters. The effect of the proposal, the comments pointed out, would be to close unnecessarily all molluscan shellfish harvesting in Federal waters.

It was never FDA's intent to close Federal waters to molluscan shellfish harvesting. These waters are beyond the jurisdiction of State shellfish control authorities, and no Federal agency classifies them in the same way that States classify their own waters. FDA is seeking a means to classify Federal waters. An agreement with NMFS relating to the classification of Federal waters is one possible solution. For this reason, FDA has modified proposed § 123.3(o) to state that a shellfish control authority may be ''a Federal agency.'' This subject is also discussed in the ''Molluscan Shellfish'' section of this preamble.

52. One comment urged that FDA provide for the possibility of sovereign tribal governments serving as shellfish control authorities.

FDA recognizes that the proposed definition was deficient because it failed to include tribal governments in the list of possible shellfish control authorities. The agency, the State of Washington, and 19 Indian tribes have recently entered into a settlement that will likely result in such an arrangement in the State of Washington (Ref. 202). When such governments meet the necessary criteria, it is the intent of the agency to formally recognize them for purposes of classifying shellfish growing waters and certifying shellfish processing plants for inclusion on the Interstate Certified Shellfish Shippers List. To provide for this situation, FDA has modified the definition of ''shellfish control authority'' to include ''sovereign tribal governments.''

FDA has also recognized that in many cases the functions of ''classification of molluscan shellfish growing areas, enforcement of harvesting controls, and certification of molluscan shellfish,'' as listed in the proposed regulations, are not carried out by a single agency. To provide for such a situation, FDA has modified the proposed language at § 123.3(o) to read, ''program that includes activities such as,'' rather than simply ''program that includes.''

18. Smoked and Smoke-Flavored Fishery Products

The terms such as ''smoked fishery products,'' ''smoked fish,'' ''smoked and smoke-flavored fishery products'' were used in the proposed regulations and throughout appendix 1 to the proposal. As a result of decisions discussed elsewhere in this preamble, reference to ''smoked and smoke-flavored fishery products'' has been eliminated in these regulations except in part 123, subpart B.

While no definition of ''smoked and smoke-flavored fishery products'' was included in the definitions section of the proposed regulations, the terms ''smoke-flavored fish'' and ''smoked fish'' were separately defined in appendix 1 to the proposal as: ''*Smoked-flavored fish* means fish that is prepared by treating it with salt (sodium chloride) and then imparting to it the flavor of smoke by other than the direct action of smoke, such as immersing it in a solution of liquid smoke,'' and ''*Smoked fish* means fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust, or similar material.'' FDA solicited comment on the materials in appendix 1. Because the term is used in these final regulations and FDA is concerned that there may be confusion about its application, the agency has determined that a definition of ''smoked and smoke-flavored fishery products'' is needed in the codified portion of these regulations. FDA has included one at § 123.3(s) that is consistent with those proposed in the appendix 1 to the proposal. Section § 123.3(s) reads:

> *Smoked or smoke-flavored fishery products* means the finished food prepared by: (1) Treating fish with salt (sodium chloride), and (2) subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

FDA received numerous comments on the regulatory treatment of smoked and smoke-flavored fishery products, but none that would affect this definition.

E. The HACCP Plan

Approximately 100 comments addressed one or more of the provisions of proposed § 123.6. This section of the proposed regulations set out who must write and implement a HACCP plan, and what the HACCP plan must include.

1. Preliminary Steps

FDA proposed in § 123.6 to require that all processors of fish and fishery products prepare and implement a HACCP plan that identifies the hazards that are reasonably likely to occur and thus that must be controlled for that product. In the proposal, FDA acknowledged the process recommended by the NACMCF for developing a HACCP plan but did not propose to require that processors follow it. The process recommended by the NACMCF includes: Assembling a HACCP team, describing the food and its distribution, identifying the intended use and consumers of the food, developing a flow diagram, verifying the