receiving CCP, FDA has modified § 123.6 by including the following sentence in § 123.6(a), ''Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest.''

For consistency, § 123.6(c)(2) needs a space here provides for both types of CCP's, and now reads:

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate: (i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment, and (ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest.

Because most of the environmental hazards to which fish are exposed will be controlled by the first processor to take possession of the fish from the fisherman or aquacultural producer, whether that processor is located in the United States or in another country, subsequent processors need not focus on these hazards in their HACCP plans. For example, pesticide contamination of inland and near shore finfish can be effectively controlled by the first processor by purchasing from fishermen who do not harvest in areas that have been closed by regulatory authorities, and drug residue contamination can be effectively controlled by the first processor by purchasing from aquaculture producers who use animal drugs properly.

4. When Is a Hazard Reasonably Likely To Occur?

In the proposal, FDA identified nine categories of safety hazards that might occur in fishery products. The agency tentatively concluded that a processor must establish HACCP controls when one or more of the listed hazards is reasonably likely to occur.

58. A number of comments, from processors and a trade association, questioned whether certain of these nine hazard categories by themselves justify a HACCP plan. The comments challenged the likelihood that some of these hazards would cause harm and asked for clarification on how a processor is to determine whether a hazard is ''reasonably likely to occur.'' One comment held that, if the term ''reasonably likely to occur'' is linked to actual incidents of illness caused by a given hazard, it would be inappropriate to define some of the listed hazard categories as reasonably likely to occur. This comment also requested that FDA clarify whether the hazards identified in its draft Guide are those that the agency believes are reasonably likely to occur under all conditions for the listed species and processing methods. The comment further noted that residues of industrial or agricultural chemicals present in seafood are usually not present at levels that are reasonably likely to be a safety hazard, even in many of those species that are listed in the Guide as presenting that hazard.

As discussed in the preamble to the proposed regulations, FDA recognizes that HACCP need not be used to control every theoretical hazard, no matter how remote the likelihood of its occurrence. Moreover, as discussed earlier in this preamble, case law interpreting section 402(a)(4) of the act has held that conditions must be such as to create a reasonable possibility that a hazard will occur in order for product to be adulterated under that section of the law. (See *United States* v. *1,200 Cans, Pasteurized Whole Eggs, Etc.,* 339 F. Supp. 140–141.)

Unquestionably, historical occurrence of reported illness is an appropriate starting place for the identification of food safety hazards that are reasonably likely to occur in the absence of controls. For example, illness from scombrotoxin in those species that form the toxin if subjected to time and temperature abuse after harvest is one of the most frequently reported illnesses from seafood. Moreover, the relationship between abuse after harvest and the formation of the toxin is well established. FDA can say with comfort, therefore, that scombrotoxin poisoning is a hazard that is reasonably likely to occur in the absence of appropriate controls for scombrotoxin-forming species of fish.

For some hazards, however, the incidence of reported illness is very low. A good example is illness from the consumption of raw fish species that are prone to parasites. The low number of reported illnesses is probably attributable to underreporting and to the fact that controls for this hazard (e.g., commercial blast freezing that kills parasites) generally exist. However, it is well established that in the absence of controls, infection from parasites is a hazard that is reasonably likely to occur when a species that is prone to parasites is consumed raw.

The incidence of reported illness that is linked to a specific food is virtually nonexistent when the illness is the result of chronic exposure to a chemical contaminant. It is extremely difficult, for example, to link a specific case of cancer to a specific contaminant in food. However, where public health officials have determined that a contaminant represents a chronic health hazard, the standard control strategy to be employed by processors for such contaminants is to ensure that their presence in food remains below specific levels.

Processors are advised of such chronic health hazard determinations through FDA action levels, publications (e.g., Federal Registers at 55 FR 14359, April 17, 1990; 58 FR 11609, February 26, 1993; and 58 FR 48368, September 15, 1993), or other similar guidance documents. If the contaminant is present in food in an amount that is above that level, the food represents a hazard to health that the evidence from the chronic studies shows is reasonably likely to occur. The question, then, is whether the likelihood of finding a fish in which the contaminant is at a higher than acceptable level is an event that is reasonably likely to occur. For open ocean species of fish, for example, a finding of pesticide residues above nationally established tolerances can be a very rare event. For near shore species in certain locations, however, a finding above tolerance can occur often enough so as to warrant controlling for it as a matter of reasonable prudence.

The incidence of reported illness for a particular hazard may also be nonexistent or very low because the hazard may be too new to have generated reported illnesses. The emergence of natural toxins harmful to humans in species or in locales where the toxin has not been found before is a well known phenomenon in seafood. While FDA does not expect that HACCP controls should be in place to control for the possibility of such hazards—the hazard may or may not ever occur—the agency strongly believes that once a hazard does emerge and is identified, HACCP controls are highly appropriate to keep illnesses from occurring. For the duration of the a hazard, it must be treated as one that is reasonably likely to occur.

To provide clarification on the above points, FDA has modified § 123.6 by including the following sentence in new § 123.6(a):

A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information, provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

To reinforce that it was not FDA's intent to suggest that all of the nine hazard categories that it listed in § 123.6(c)(1) are reasonably likely to