A small number of comments expressed opposition to the mandatory HACCP approach for seafood, however. One State comment expressed the view that HACCP would not have any significant effect on reducing illnesses from molluscan shellfish. Another comment stated that, overall, seafood-related illness data do not justify mandatory HACCP for seafood. (Several other comments questioned the need for these regulations in light of the NAS' conclusion that commercial seafood is generally safe. These comments either generally opposed the proposed regulations as drafted, or opposed its application to the comments' segments of the seafood industry, but did not express opposition to mandatory HACCP as a concept.) None of these comments supplied any new seafood-related illness data.

2. The Significance of the Illness Data

The preamble to the proposed regulations described broadly what is known and not known about the extent of seafood-related illness in the United States. Foodborne illnesses tend to be significantly underreported to public health authorities. Consequently, precise data on the numbers and causes of foodborne illness in this country do not exist. FDA does know, however, that illness from seafood does occur, and that a wide variety of hazards have been identified that could cause illness from seafood (see Ref. 7, pp. 1–13). The overwhelming majority of these hazards are amenable to preventive controls. FDA's draft Guide addresses controls for over 20 specific types of safety hazards.

The primary purpose of these regulations is to ensure that preventive controls are systematically applied in seafood processing as a matter of routine custom and usage, and in a way that can be verified by company management as well as by regulatory authorities. Thus, while the reported illness data are highly relevant to whether these regulations should be issued, they are not the sole basis for the regulations.

For molluscan shellfish in particular, FDA agrees with the commenters who believe that the principles of the National Shellfish Sanitation Program (NSSP) should continue to form the basis for the molluscan shellfish safety program in this country. There is no clear alternative to proper water classification and patrol by State authorities as the basis for molluscan shellfish safety. HACCP provides processors with an excellent system for ensuring that these preventive-type controls are adhered to in a systematic way.

It may be argued—and some comments made the point—that the best way to reduce the overall number of illnesses from raw molluscan shellfish is to provide additional resources to the States to enhance their water classification and monitoring abilities. Classifying and patrolling shellfish harvesting waters are important means of preventing molluscan shellfish that have been contaminated from sewage from entering the marketplace. However, additional Federal resources will probably not be available for this purpose in the foreseeable future. It is imperative, therefore, that the system that is in place be made as efficient as possible.

It would be incongruous to exempt from a national system of preventive controls the processors of products identified by the NAS as the source of the greatest numbers of seafood-associated illnesses. FDA strongly believes that HACCP controls will help shellfish processors and regulators alike to better focus on potential safety problems and less on tangential matters than historically has been the case. A full discussion of the application of HACCP to raw molluscan shellfish appears later in this preamble.

3. Exempt Specific Industry Segments?

12. Comments stating that HACCP systems should not be mandated for specific industry segments usually referred to either the crab processing or the catfish industries. These comments generally expressed the view that HACCP requirements for these industries were not necessary.

FDA advises that these regulations are flexible enough so that HACCP-type controls are not required where they are not necessary, i.e., where it is reasonably likely that hazards do not exist. It is the agency's experience, however, that there are reasonably likely hazards associated with crabmeat as a cooked, ready-to-eat product, including the growth of pathogens as a result of time-temperature abuse of the product and the potential for pathogen survival from inadequate pasteurization. There are reasonably likely hazards associated with the processing of catfish (e.g., contamination from agricultural chemicals, improperly used aquaculture drugs, and a variety of hazards resulting from the in-plant processing operations). It is incumbent on processors of these products to know and control such hazards.

The agency recognizes that whether reasonably likely hazards exist involves case-by-case determinations. As will be discussed in the ''HACCP plan'' section of this preamble, processors will be given every opportunity to demonstrate why no hazards exist in their operations.

4. Would Voluntary HACCP Be Superior?

13. Some comments believed that a voluntary approach to HACCP for seafood would be preferable to a mandatory approach. One reason given for this view was that, under a mandatory system, the risk of regulatory action by FDA would compel processors to design HACCP controls that were the minimum necessary to comply with the rule. There would be a significant disincentive for processors to design HACCP plans that have the greatest practical impact on food safety out of fear that occasional failure to meet those higher standards would trigger a regulatory response.

If voluntary HACCP systems were already universal, or nearly so in the seafood industry, and they generally applied safety controls that were beyond the minimum needed for safety, FDA would see little reason to establish a mandatory system. However, HACCP is not the norm, and given the current situation in the seafood industry, FDA finds that making HACCP mandatory is necessary to ensure that safe, wholesome, and unadulterated product is produced. Thus, FDA is adopting part 123 (21 CFR part 123).

The agency acknowledges the possibility that, under a mandatory system, firms will perceive that they are on safer ground with FDA if they establish minimum acceptable controls that are more easily met, rather than more stringent controls that are beyond the minimum necessary to ensure safety and, therefore, are harder to meet. For example, in deciding what CCP's to identify in a HACCP plan, a processor might err on the side of inclusion under a voluntary plan but keep the number of CCP's down to the minimum acceptable to FDA if having a plan is mandatory.

It remains to be seen whether processors will really choose to behave this way under a mandatory system. The choices that processors will make may depend, in part, on FDA policy toward HACCP plans that are beyond the minimum. The logic in favor of the agency initiating regulatory action when a processor fails to meet its own CL but succeeds in meeting a minimum level that would have been an acceptable CL to FDA, would be that the firm is out of control vis a vis its own preventive process. The logic against initiating regulatory action would be that the processor is still in control in terms of meeting minimum necessary safety parameters, and that the product is, in