5. Other Issues

16. One comment supported the concept of HACCP but expressed the view that the regulation drafting process should be started over by forming a committee consisting of representatives from various segments of the seafood industry, and appropriate government and university personnel. A few other comments expressed the view that FDA had acted too quickly in issuing the proposed regulations and also requested that FDA start over by engaging in discussions with industry, foreign regulatory agencies, academia, and consumers. These latter comments, which were mostly from companies not primarily involved in the processing of seafood, preferred a voluntary approach to HACCP, with mandatory applications only in exceptional situations. FDA did not act too quickly, or without appropriate consultation, in issuing the proposal in this proceeding. As the preamble to the proposed rule documented at some length, the proposal was the culmination of an extensive process by FDA and others, including the seafood industry itself, that led major representatives of that industry to request the issuance of the proposal. Before that, industry trade associations testified repeatedly before Congress in the late 1980's through the early 1990's in support of legislation that would have required a mandatory inspection system for seafood based on HACCP principles.

FDA participated in pilot programs in the past such as the seafood HACCP pilot conducted jointly by FDA and the National Marine Fisheries Service (NMFS) of the Department of Commerce (DOC) in 1990 to 1991. In addition, FDA ran programs with seven other countries. In developing these regulations, the agency also took advantage of information from the Model Seafood Surveillance Project (MSSP). The MSSP was conducted by the DOC at the request of Congress in 1986 to design an inspection system for seafood consistent with HACCP principles. As part of the MSSP project, 49 workshops were conducted involving 1,200 industry, State, and university participants. Canada currently has a HACCP system, and the EU has issued directives that move in that direction. The agency has concluded that sufficient field trials have already taken place to conclude that HACCP is a viable method of hazard control for the seafood industry.

Public input into the development of the HACCP approach contained in these regulations has been substantial. As described earlier in this preamble, FDA engaged in a series of ''town meetings'' in nine cities across the country shortly after the proposal was published in order to answer questions about the proposed regulations and encourage comments. The public response to FDA's proposal contributed substantially to the contents of the final regulations.

C. *Should Some Types of Processors Be Exempt?*

In the preamble to the proposed regulations FDA asked for comment on whether either processors of ''low-risk'' products or small processors, or both, should be exempted from the requirements of the final regulations. The agency asked for information on whether the regulatory burden could be reduced without compromising the public health protection goals of the regulations, and whether there exists a rational way to distinguish ''high risk'' from ''low risk,'' and big processors from little processors, for purposes of HACCP.

1. Exempt Low Risk?

The most obvious way of distinguishing high-risk products from low-risk products would be on the basis of reported, confirmed, seafood-related illnesses. The preamble to the proposed regulations pointed out some problems with this approach. First, the agency pointed out that the underreporting and skewed reporting that occurs with respect to foodborne illness creates significant concern as to whether reported illnesses represent a reliable enough factor to serve as the basis for an exemption to these regulations. Second, FDA stated that it was concerned that there could be a significant potential for harm that could be controlled by HACCP but that would not have shown up in the data that is relied on to establish risk. For example, while there may be no reported cases of botulism associated with some products that have the potential for *Clostridium botulinum* toxin, the severity of the consequences of the hazard warrant preventive controls. Likewise, while there may be no reported cases of domoic acid intoxication associated with shellfish from a particular area, preventive controls are warranted as soon as a such a case is made public. Thus, the preamble asked whether potential for harm might be a reasonable way to distinguish high-risk from low-risk products for purposes of an exemption. FDA was interested in whether comments could provide usable criteria for such an exemption.

About 45 comments addressed the question of whether the regulations should apply to high-risk products only. Roughly two-thirds of these comments preferred a high-risk approach. For the most part, they either did not define ''high risk,'' or defined it as including essentially the top three reported seafood- related illnesses (virus-related from raw molluscan shellfish, scombrotoxin, and ciguatoxin). For the most part, other hazards were assumed to represent a low risk.

17. One comment recommended that the regulations initially cover the hazards reported at the highest levels of to the Centers for Disease Control and Prevention (CDC) because these hazards are at least known to be causing illness, and that the agency should phase in other hazards as appropriate if the foodborne-illness reporting system were to reveal a need to do so.

Few comments were received on whether there could be a basis for distinguishing high risk from low risk other than reported illnesses. Some comments suggested that the agency should consider severity of illness as a criterion. Some of these comments specifically cited smoked and smoke-flavored fish as products that should be covered on this basis because of the devastating effects of botulism. A few comments expressed the view that mandatory HACCP should be limited to hazards that can cause loss of life or irreversible injury.

Several comments objected to a ''low risk'' exemption in any form. Some pointed out that, given the underreporting and skewed reporting that exists, the CDC foodborne-illness reporting system does not provide a suitable basis for making determinations of comparative risk (i.e., high risk versus low risk). These comments expressed concern that linking the requirements of these regulations to illness reporting that has already occurred would have the effect of exempting emerging hazards, at least until they caused reported illness.

Other comments stated that there is no significant advantage to exempting low-risk products because processors of these products will have simpler HACCP plans than those who process products with more potential safety hazards. One comment stated that a high risk-only approach made some sense but, as a practical matter, would negate the added assurance to consumers from HACCP that seafood is safe and processed under some form of regulation. According to this comment, from a large seafood trade association, it is more important that the entire food category be recognized as having been subjected to modern safety assurance