procedures than that the regulations exempt the low risk end of the industry.

FDA has considered these points of view and has concluded that, at least for now, there is no reasonable way to divide seafood products into high risk and low risk for purposes of these regulations. The comments that suggested defining ''high risk'' in terms of the most frequently reported illnesses are correct that the volume of reporting tends to concentrate substantially in the three hazard areas mentioned above. Because illnesses that are confirmed and reported tend to be those that are the most easily traced or diagnosed, however, the relative significance of the high level of reporting in these three areas—as well as the drop-off in reporting in other areas—is not fully known. Moreover, illnesses associated with chronic hazards are virtually unreported because of the difficulties in associating such illnesses to specific food sources.

The comments did not include any new data that would reveal whether the risks associated with the most reported illnesses are actually the highest risks or only the most apparent. No new information was provided to allow FDA to determine whether distinguishing high risk from low risk on the basis of reported illnesses would constitute a rational division for purposes of these regulations. Nor has FDA been supplied with information that would allow it to conclude whether other valid criteria exist.

FDA agrees with the comments that pointed out that the requirements of HACCP are less when risks are low. Moreover, as will be discussed later in this preamble, FDA has revised the final regulations to provide that HACCP plans are not required when there are no reasonably likely safety hazards to control. Thus, HACCP inherently tends to distinguish between high- and low-risk products without the need for explicit exemptions.

FDA also agrees that broad exemptions would put at risk some of the principal objectives of these regulations. Explicit exemptions make the system less flexible and might not cover emerging situations for which preventive controls are necessary to keep illnesses from occurring in the first place. A system that includes such exemptions would likely not provide as much consumer confidence as would a complete HACCP system. In addition, FDA notes that the benefits to the industry in international trade from adopting a HACCP system might be minimized if such exemptions were adopted because the United States' international trading partners are opting for complete systems.

2. Exempt Small Processors?

18. Over 60 comments addressed the question of whether the regulations should exempt small businesses. About five out of six of these comments opposed an exemption.

Those that supported an exemption for small businesses expressed concern about the effect of the general costs of implementation, particularly the costs of training and recordkeeping. One comment observed that many small businesses are economically-strapped, old, family enterprises that support an often fragile local economy. Another comment expressed the view that small businesses should be exempt because they are not involved in international trade. One comment noted that the highest volume producers (i.e., large businesses) are where a mistake affects the most consumers.

One comment recommended that FDA develop exemption procedures to relieve small companies of paperwork and training requirements, especially if they produce low-risk products. A few comments suggested that small businesses, or at least small businesses with good records, be exempt from ''positive'' recordkeeping, i.e., recording the results of each monitoring. Under this kind of exemption, small businesses would only record unusual occurrences and corrective actions.

The majority of comments that argued against exempting small businesses provided a number of reasons. One comment pointed out that as much as half of seafood consumed in the United States is from small firms. Several comments stated that size is not related to risk. Small firms are the major producers of many high-risk products (e.g. cooked, ready-to-eat and raw molluscan shellfish). Thus, according to the comment, the final regulations would represent a futile exercise if small firms were not included. One comment observed that small companies sometimes represent more of a risk potential than large companies due to lack of enough trained quality control personnel. Other comments pointed out that small businesses with simple operations would have simple plans and a minimum of recordkeeping.

One comment pointed to difficulties that FDA would have in administering exemptions to the regulations, particularly in distinguishing between firms that were and were not entitled to an exemption. Another concern expressed by comments was the potential unfairness of exempting some companies while requiring HACCP of others.

One State that has implemented mandatory HACCP for seafood processors observed that HACCP requirements had not proven to be an excessive burden to small businesses in that State.

Some comments that supported including small businesses in the coverage of the HACCP requirement recommended, nonetheless, that FDA should provide assistance to small businesses through guidelines, model plans, and technical and financial assistance. Some comments acknowledged that small firms can work through trade groups on common plans and training.

Other comments felt that dropping small firms from the final regulations would adversely affect consumer confidence. One comment expressed fear that the international standing of FDA's seafood safety program would be in jeopardy if the regulations were to exempt some firms.

FDA does not know how to exempt small business without jeopardizing the public health objectives of the regulations. An exemption for small processors of ''low-risk'' products would run into the difficulties explained above in the discussion of whether these regulations should only apply to ''high-risk'' products. FDA agrees with the comments that, in the seafood industry, the size of the operation often does not coincide with the number or type of hazards that must be controlled in order to ensure a safe product (i.e., small size does not automatically mean minimal hazards). For example, cooked, ready-to-eat seafood processing, a relatively complex manufacturing operation, typically requiring a larger than average number of CCP's, is concentrated in the small business portion of the seafood industry. Additionally, the processing of raw molluscan shellfish, a product identified by NAS as being associated with a disproportionately large percentage of the seafood-borne illnesses, is most commonly performed by small firms. FDA also agrees that, because seafood businesses tend to be small, an exemption for small businesses could make HACCP the exception, rather than the rule, in this industry.

The concerns expressed in the comments about the possible adverse consequences of these regulations on small business, however, should not be taken lightly, and the agency has not done so. FDA has no desire to establish a mandatory regime that cannot be met by otherwise responsible companies,