later, but the results will have no formal status with the agency and would not warrant an extension of the effective date.

The agency has heard considerable concern that it will automatically seek to seize or otherwise remove from commerce all products being produced under a HACCP system that is determined to be deficient in any respect. That concern is unfounded. The consequence of being out of compliance with HACCP requirements, on the first inspection after implementation or otherwise, is addressed throughout this section. In summary, FDA's reaction will depend, as it does today, on the overall public health significance of the deficiency.

2. Public Meetings

158. One comment suggested that FDA conduct public meetings to explain the requirements of these regulations to the seafood processing industry between the publication date and effective date of these regulations. The comment also encouraged a coordination of research, training, and educational efforts between industry and FDA in order to facilitate the implementation of this HACCP program.

FDA fully agrees with the comment. It is the intent of the agency to engage in a dialog with industry, through a combination of public meetings and discussions at trade association meetings, to facilitate a thorough understanding of the regulations. FDA's affiliation with the Alliance reflects the agency's commitment to a cooperative relationship among industry, government (Federal and State), and academia in the areas of research, training, and technical assistance.

3. Penalties for Noncompliance

159. A significant number of comments, from processors and trade associations, requested that FDA address how noncompliance with the mandatory sanitation control procedures will be handled. Several of these comments also requested that FDA describe the penalties that can be imposed upon a processor and its officers for: Failure of a processor to have and implement a HACCP plan; noncompliance with sanitation control procedures; and failure to meet minor requirements of the regulations, such as the lack of a signature on a document. One comment stated that FDA's legal authorities and enforcement procedures do not provide a means for the agency to respond in a manner that is related to the severity of deficiencies—that is, a less severe response to a less significant deficiency.

FDA has a longstanding practice of tailoring its regulatory response to the facts. A deviation from any of the provisions of these regulations, including those involving the control of sanitation, carries the potential for regulatory action pursuant to section 402(a)(4) of the act. However, FDA intends to enforce these regulations in a manner that focuses on those deviations that have the greatest potential for causing harm. It is not FDA's intent to pursue regulatory action against a product or a processor exclusively for clerical errors or minor errors of omission. To do so would certainly not be an efficient use of agency resources, nor would it be in the best interests of the consuming public.

The penalty provisions for food found to be adulterated are described at ''Prohibited Acts and Penalties,'' in chapter III of the act. The statutory sanctions that FDA may seek include seizure and condemnation of a food and injunction and criminal penalties against a person (i.e., a firm and its responsible management).

FDA may also use existing administrative procedures, such as warning letters and conferences with a processor, to bring instances of noncompliance to the processor's attention as it frequently does under its current inspection programs.

The agency cannot state precisely what type of action it will take when it detects a deficiency because FDA evaluates each deficiency on a case-by-case basis to determine the public health significance of the violation and the appropriate response.

4. Preapproval of HACCP Plans

In the preamble to the proposed regulations, FDA tentatively concluded that HACCP plans would not have to be submitted to the agency or otherwise preapproved before their implementation by processors. The reasons for the agency's tentative conclusion included: (1) HACCP plans should be judged in the context of the processing plant, a process best accomplished during routine FDA inspections of processing facilities; and (2) the agency does not have sufficient resources to review HACCP plans from all domestic and foreign seafood processors in advance of either HACCP implementation by the processor or the conduct of HACCP-based inspections by FDA.

160. Approximately 20 comments addressed this issue. About two-thirds of these comments, from consumer advocacy groups, processors, trade associations, and State government agencies, contended that a processor should be required to file a HACCP plan and obtain approval from FDA before implementing the plan. The remaining comments, from processors, trade associations, and a foreign government, agreed with FDA's tentative conclusion that HACCP plans need not be submitted to the agency or preapproved before they are implemented.

Some of the comments favoring preapproval argued that FDA should have control over the design of each plan before it is implemented to ensure that all of the CCP's are identified, and that appropriate records will be kept. Other comments contended that, in the absence of a preapproved plan, a processor may implement a plan that FDA would later judge to be inadequate, possibly raising concerns about the product already produced under the plan.

Several comments in opposition to preapproval argued that it would be too expensive and difficult for both FDA and the processors (the latter because implementation would be delayed while processors waited for FDA to preapprove the plan and every subsequent change to the plan). One comment expressed concern that, in formally approving a HACCP plan, regulatory authorities would assume some responsibility for the HACCP system of an individual processor.

A few comments stated that HACCP plans will evolve as operations are adjusted, based on the processor's verification activities. These comments argued that a requirement for the preapproval of HACCP plans would encumber a processor's ability to update its HACCP plan.

The resource situation since the proposal was issued in January, 1994, has not changed in any way that would make the preapproval of HACCP plans by FDA practicable. Thus, FDA's analysis of the comments has focused on whether a lack of preapproval raises significant implementation problems that the agency must address. The comments have not convinced the agency that it does. FDA finds that a preapproval system would unduly burden the agency's resources, without providing significant advantages to the public health. The effectiveness of a HACCP plan, including monitoring, recordkeeping, and verification, can best be evaluated under actual operating conditions.

The preapproval of HACCP plans is distinguishable from the situation for low acid canned foods, where FDA reviews submissions of scheduled processes and revisions to these processes without hinging that review on a visual inspection of the facility. For