foods. One comment felt that the specific grant of records access for drugs and devices in section 704 of the act precluded expansion of access to records not specifically mentioned in the act. Other comments felt that FDA was barred from access simply because the act does not expressly grant it.

FDA does not agree, as the agency's authority under sections 402 and 701(a) of the act to issue these regulations provides ample authority for records access. The line of cases cited above stands for the proposition that a lack of explicit delegated authority does not invalidate agency regulations so long as the regulations are consistent with the act's overriding purpose. In *Confectioners*, the court upheld FDA's authority to adopt recordkeeping requirements in the absence of an explicit delegation of authority. In that case, moreover, the court found no evidence that Congress intended to immunize food processors from limited recordkeeping (569 F.2d at 695). Similarly, the court in *Nova Scotia* concluded, in the absence of such evidence, that there was no impediment to a broad reading of the statute based on the general purpose of the Congress in protecting public health (568 F.2d at 248).

FDA has concluded, therefore, that these regulations are consistent with section 704 of the act and with the act as a whole. Because the preventive controls required by HACCP are essential to the production of safe food as a matter of design, the statutory scheme is benefited by agency access to records that demonstrate that these controls are being systematically applied. The case law supports FDA's authority to require such recordkeeping and to have access to such records.

Other countries, including Canada, the European Union (EU) Norway, Australia, and New Zealand, which have already implemented HACCP-type systems, have deemed it necessary to the success of their systems to provide for recordkeeping and record access along the lines of this regulation (for either their entire seafood industries or seafood export industries). Thus, it is widely accepted that recordkeeping and inspectional access are essential components of a HACCP-type seafood system. In addition, in order to maintain other countries' faith in the safety standards of U.S. seafood exports, FDA needs similar access to records showing HACCP implementation.

7. One comment expressed the view that the copying of records by FDA, as authorized by these regulations, is beyond the scope of section 704 of the act.

FDA points out that it is not acting under section 704 of the act. To effectuate the broad purposes of the act, there may be some circumstances in which access to the records would be meaningless without the opportunity to copy them. While the agency does not anticipate that copying will be necessary in most instances, perhaps the most readily predictable circumstance in which copying would be necessary is when an investigator needs assistance from relevant experts in headquarters to evaluate the record. Without copying, it would be necessary for the agency to rely solely on the notations and report of the investigator.

This reliance may not be adequate in many circumstances. For example, there may be a deviation from a critical limit (CL) that poses no health risks. Without the ability to show a copy of the records to someone within the agency with the necessary expertise in the area, an investigator would have to cite the company for a violation. If, however, an agency expert determined that the deviation posed no safety risks, the agency could use its enforcement discretion not to pursue a violation.

8. One comment expressed the view that the act does not support a mandatory HACCP program that includes access to records for the entire seafood industry. According to the comment, the act permits FDA access to records only under extreme conditions where there is a potential for injury, but, the comment noted, hazards are only associated with a small percentage of fish.

FDA cannot agree. While it is true that those seafood-related illnesses that are reported to public health authorities tend to be associated with a limited number of species, potential hazards are much broader. As indicated above, the 1991 NAS report on seafood safety provides an extensive inventory of hazards.

For the benefit of the commentor it is worth noting that if a processor is involved with species and processes for which there are no food safety hazards that are reasonably likely to occur, a HACCP plan will not be necessary under these regulations. As will be discussed later in this preamble, the agency anticipates a post-implementation dialog with firms on whether they have hazards that must be controlled in accordance with these regulations and, if so, how many.

9. One comment expressed the view that the authority to inspect ordinary food records has not been asserted before. This statement was made in support of the contention that there is no statutory basis for FDA access to ordinary food records.

The legal basis for FDA's access to records has already been fully addressed in this preamble. It is important to note that the agency is not claiming a right of access to food records coextensive with that for drugs and devices under section 704 of the act. Rather, FDA is asserting a right to access to records that is narrowly tailored to advance the purposes of the sections of the act that it is implementing here, i.e., records relating to the CCP's in a firm's process.

While the agency is not sure what the comment meant by ''ordinary'' food records, it is worth pointing out that the position in this regulation on agency access to records is a longstanding interpretation for regulations of this type. Agency access to processing and production records has been required since the early 1970's in FDA's regulations for thermally processed low-acid foods packaged in hermetically sealed containers (part 113) and for acidified foods part 114 (21 CFR 114). As discussed in the new section, these regulations were issued primarily under the authority of both sections 402(a)(4) and 404 of the act (21 U.S.C. 344), neither of which specifically mention access to records.

5. Relevance of Section 404 of the Act

10. Several comments expressed the view that FDA should base HACCP regulations on section 404 of the act rather than on section 402(a)(4) of the act. Some of these comments were referring to these seafood HACCP regulations, while others were primarily concerned with any HACCP regulations that FDA might issue for other foods. Other comments expressed the view that FDA's existing low-acid canned food regulations should serve as a model for new HACCP programs. Because some of the low-acid canned food regulations have been issued under section 404 of the act, all of these comments may have been making the same general point.

Most of those that advocated use of section 404 of the act as the legal basis expressed concerns about the appropriateness of relying on section 402(a)(4) of the act and the narrow grants of access to records in the act, especially in section 704 of the act, and concluded that the act only grants the agency access to records under extreme situations. One comment urged that FDA issue the seafood HACCP regulations under the authority of section 404 of the act in order to enhance the agency's ability to achieve compliance through the permit system.