readily given away to competitors. FDA knows from its own experience that plant configurations tend to be unique to individual processors, or at least have unique features (Ref. 222). While generic plans will have great utility in many circumstances, they serve primarily as starting points for processors to develop their own plans. FDA expects that its Guide will help serve that purpose, but firms will still need to expend time and money to tailor HACCP to their individual circumstances.

Additionally, the agency has come to the conclusion, as a matter of policy, that records and plans should be protected to the extent possible in order to promote the implementation of HACCP across the seafood industry. FDA has concluded that the public will benefit from the protection of records because it will actually strengthen the HACCP system. So long as the legitimate public need to be able to evaluate the system can be met through other means, the confidentiality of HACCP records and plans generally will foster the industry's acceptance of HACCP. Even though HACCP may be mandatory under these regulations, in order for it to succeed, processors must be committed to it because they see value in it for themselves. Fear of public disclosure of matters that have long been regarded as confidential business matters could significantly undermine that commitment. FDA concludes, therefore, that it is in the public interest to foster tailored HACCP plans that demonstrate understanding and thought, rather than promote the use of rote plans and minimally acceptable standards due to fear of public disclosure.

FDA understands that it cannot make promises of confidentiality that exceed the permissible boundaries established under FOIA, nor does the agency wish to do so in this case. The agency still does not expect that it will be in possession of a large volume of plans and records at any given moment. However, given the significant interest in this subject as conveyed by the comments, FDA has concluded that the final regulations should reflect the fact that the HACCP plans and records that do come into FDA's possession will generally meet the definition of either trade secret or commercial confidential materials. A statement to this effect in the final regulations will help to make this fact as widely understood as possible and will clarify the agency's position on this matter. This fact is codified at § 123.9(d)(1), which reads as follows:

(d) *Public disclosure.* (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter, or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

The agency acknowledges that there could be exceptions to this general rule. The nature of information in HACCP plans and records varies. Some of it could be generally available processing methodology or procedures, based on generic or model HACCP plans or guidelines developed by the agency or some other public source, that is sufficiently reflective of an industry standard that it has little if any proprietary value. In such a case, in response to an FOIA request, there may not be a valid reason for protecting this information. The agency has concluded that there should be a provision that makes clear that it will make information available in appropriate circumstances. Consequently, the final regulations in § 123.9(d)(2), state:

(2) However, these records and plans may be subject to disclosure to the extent that they involve materials that are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

There is precedent for describing in regulations the records that have protected status. The low-acid canned food regulations at § 108.35(l) provide that, except under certain limited situations, filed scheduled processes submitted to FDA are not available for public disclosure. Additionally, § 108.35(d) provides that data submitted to the agency to support these processes are to be treated as trade secret. These materials are analogous to HACCP plans, and their treatment is consistent with the agency's views relative to the protected status of HACCP plans. The comments that suggested that the low-acid canned foods regulations grant trade secret status to the monitoring records that are required to be kept by part 113 are incorrect. These records are not provided any special status in those regulations.

4. Agency Access to Records

86. Several comments suggested that the final regulations should require processors to provide access by FDA to HACCP records only after the submission by the agency of a written request for specific records it deems necessary to review. The comments noted that this approach would be similar to § 108.35(h) in the LACF regulations, because processors are familiar and satisfied with such procedures.

FDA remains convinced that access to HACCP documents is essential to the agency's verification of a firm's HACCP system. A key feature of the HACCP verification process is access by government investigators to the HACCP plan, to monitoring records kept according to the plan, and to records of corrective actions that were taken in response to CL deviations. Examination of HACCP records enables an investigator to see how the processing facility or the importer operates over time rather than how it is functioning at one particular moment in time. Additionally, it will enable the regulator to review the adequacy of the processor's or the importer's preventive control system itself.

FDA rejects the idea of being required to request in writing access to HACCP plans and records. The agency is convinced that it has sufficiently limited its access to those records and plans that are minimally necessary to adequately evaluate the adequacy of a firm's HACCP system. Section 123.9(c) has been modified slightly to clarify to which records FDA is required to be granted access.

The comments are correct that the emergency permit regulations for low-acid canned foods at § 108.35 require that FDA issue a written request for access to monitoring records. However, the written request has proven to be merely a mechanical exercise. It has not in any way served to affect the outcome of FDA access to records, nor is it associated with any managerial control over the activities of FDA investigators, with respect to the kind or numbers of records to which they seek access. Moreover, the bottled water regulations at § 129.80(h), promulgated subsequent to the low-acid canned food regulations, do not contain a requirement for the issuance of a written request for records. FDA is not aware of any undue concerns expressed by the bottled water industry relative to agency abuse of its records access authority as a result of the lack of a written request requirement in those regulations. FDA further notes that its investigators are required to present a written notice of inspection to management of the firm at the start of each inspection. The notice explains the authority of the investigator to conduct an inspection of the facility. The agency has concluded that there is no need to further encumber the efficient enforcement of these regulations with a