regulatory, because once the effective date has been reached, compliance with the regulations should be enforced.

FDA agrees with the comments that suggested that a smooth transition to a mandatory HACCP system of preventive controls is more likely the result of dialogue than regulatory action. For HACCP to succeed, processors must be committed to it because they perceive benefits to themselves from its use other than simply the avoidance of regulatory sanctions.

FDA has concluded that a 2-year effective date, rather than the 1-year date that was proposed, will provide substantial opportunity for dialogue. Moreover, the proportional response to problems that FDA intends to employ, taking into account the newness of the system, should obviate many of the comments' concerns about excessive regulatory sanctions early in the process. Consequently, FDA concludes that an officially designated, nonregulatory first inspection is not necessary.

FDA has concluded that 2 years is sufficient time for a processor to train employees or secure properly trained consultants, perform a hazard analysis, develop a HACCP plan, and implement and evaluate HACCP control procedures that will comply with these regulations. The additional year will enable the agency's field investigative force and the industry to begin sorting out many of the issues that are likely to develop during implementation.

As stated earlier, the agency intends to perform informal HACCP evaluations of willing processors during routine inspections conducted during the 2-year implementation period. These evaluations should serve to aid the development of both the industry's HACCP programs and the agency's HACCP inspectional skills. They will also largely take the place of the proposed type of nonregulatory inspections.

FDA agrees with the comment that pointed out that the initiation of this program will generate many questions and issues that will have to be worked out between processors and the agency. Moreover, FDA accepts that, despite the years of groundwork and the pilot programs that have been the basis for agency policy decisions to date, there will be details that will have to evolve over time as the program is implemented. It is highly likely that this evolution will continue well after the effective date of these regulations. FDA will take this factor into account in its initial interactions with processors after the effective date. The agency may find it appropriate to use its regulatory discretion when it finds a basis for concern about a processor's HACCP plan or procedures that relate to a matter about which policy is still being formulated.

However, the agency is concerned that there could be significant problems if it officially designated its HACCP review during the first inspection as being nonregulatory. First, such a step could create unfair situations. For example, FDA could find itself in the position of pursuing regulatory action against one processor for failure to adequately control a particular hazard while, at the same time, treating a similar deficiency by another processor as ''nonregulatory.'' Second, it could foster actions by firms to avoid application of the regulations, such as name changes or reorganizations to create the argument that the ''new firm'' is entitled to a nonregulatory inspection. Third, it is not clear how long such a policy should last. Arguably, the reasons in support of a nonregulatory first inspection become much weaker in the case of a firm that goes into business for the first time a number of years after the effective date of the program.

For all of the foregoing reasons, FDA has concluded that it can accomplish the things that led it to inquire about the possibility of, and the comments to support, designating the first HACCP inspection as a nonregulatory inspection without making such a designation and creating the problems that such a designation could cause.

8. Role of the FDA Investigator

164. In the preamble to the proposal, FDA stated its tentative conclusion that its investigators would, among other things, evaluate the adequacy of processors' HACCP plans during routine inspections. A few comments objected to this role for the investigators. These comments stated that investigators should be responsible for verifying that the processor has performed a hazard analysis; developed a HACCP plan where warranted; implemented the HACCP plan; and recognized, corrected, and recorded deviations from the HACCP plan. The comments further stated that investigators should not be in a position to challenge the adequacy or design of a HACCP plan.

The comments pointed out that HACCP plans are tailored for each operation, designed by either a company team or a knowledgeable individual thoroughly familiar with the operation. They questioned whether an FDA investigator would have the expertise to determine the acceptability of the plan.

Many FDA investigators already have considerable training in HACCP and food science, and most have an academic background in the sciences. They will also receive training during the implementation period that focuses on compliance with these regulations. The investigators will be exposed to the Guide, among other sources, for information about potential hazards to be considered for particular products and processes. This exposure, coupled with investigators' experience with the industries with which they work, will give them a sound basis for making screening determinations about the adequacy of processors' HACCP plans. There is little doubt that the caliber of investigator screening decisions will improve with experience with these regulations and with exposure to more and varied processor HACCP programs. FDA is confident that its field investigative staff will quickly adjust to the task of fostering compliance with these regulations, as they have to past initiatives.

Where investigators are unsure about the adequacy of a processor's HACCP plan, they will have ready access to, and will be encouraged to consult with, district, regional, and headquarters experts. Investigators will also be instructed to discuss with plant management the reasons and scientific support for hazard analysis and HACCP plan decisions that are in question. Where, because of the complexity of a particular situation, the investigator cannot reach a decision about the adequacy of a particular aspect of a processor's HACCP plan, the investigator will be instructed to collect as much information, including supporting data, as is necessary in order to facilitate further agency review.

Therefore, FDA concludes that the existing system adequately addresses the concerns of the comments.

9. Disagreements and Appeals

165. A significant number of comments, primarily from processors and trade associations, stated that FDA should have a mechanism to resolve differences between an FDA investigator and a processor regarding the adequacy of the processor's HACCP plan, especially given the subjective nature of the determination as to what the hazards are that are reasonably likely to occur and that therefore must be controlled through HACCP. The comments contended that a cooperative discussion between FDA and the processor's HACCP experts would be preferable to an enforcement confrontation, and that this discussion would allow a processor to explain its decisions and procedures. Other comments urged FDA to formalize an