technical bulletins, workshops, and meetings.

Several of the comments that suggested that the proposed guidelines remain as guidelines argued that FDA has not demonstrated that present practices in the smoked fish industry are causing risks that would justify regulations, and that there have been no recent incidents of botulism attributable to smoked fish. Several comments stated that most of the problems with smoked fish in the past have resulted from abuse of the product at retail or by the consumer.

A few comments objected to FDA's contention that large portions of the industry do not conduct final product testing and to the inference that all smoked fish processors do not monitor the composition of their products. The comments stated that responsible companies do conduct product testing on a regular and routine schedule, have scheduled processes, and are aware of what they are doing.

Other comments recommended that FDA enforcement of the current CGMP's, coupled with State and local enforcement of the Food Code for smoked products that are produced in restaurants, retail, and food service establishments, would make it unnecessary to treat smoked fish products any differently than other products under these HACCP regulations. One comment suggested that guidelines would have the same impact as regulations because HACCP plans would be rejected by FDA if they do not contain the recommended controls, and because States would adopt the guidelines as regulations.

One comment argued that the issuance of prescriptive regulations would eliminate the diversity in the types of smoked fish products available and result in a ''homogeneous'' market. Another comment counseled that the issuance of a regulation would cause Alaskan native salmon processors to abandon their traditional trade.

The agency remains convinced that smoked and smoke-flavored fish is a potentially hazardous food. While cases of botulism have not been attributed to commercially prepared smoked or smoke-flavored fish in over 30 years, the outbreaks of the 1960's clearly demonstrate the potential for such occurrence. Virtually all the research that has been conducted establish that processors need to control time, temperature, and salinity (T-T-S) parameters and other matters for these products in order to provide adequate barriers to toxin production (Ref. 214).

As the preamble to the proposed regulations pointed out, FDA and a number of States have longstanding concerns that the actions of a significant portion of the smoked fish industry do not demonstrate a full appreciation for the nature of the risks. FDA and New York State surveys of the smoked fish industry in the late 1980's, for example, showed that many processors did not routinely control their T-T-S parameters.

The comments have not persuaded FDA that, even without regulations, processors will employ preventive controls to ensure the safety of these products as a matter of design and not of chance. Botulism derives from one of the most dangerous toxins known to exist. Controls to prevent the formation of this toxin cannot be left to chance. HACCP controls for this hazard are highly appropriate because HACCP requires that the processor analyze its operation to determine how hazards affecting its product can arise, and that it institute specific controls to prevent those hazards. The majority of comments that addressed smoked and smoke flavored fish products either supported the concept of HACCP controls or did not argue against them.

140. The question, therefore, is whether, in addition to requiring HACCP plans for these products, FDA should mandate specific CCP's, minimum CL's, monitoring frequencies, and other matters that processors would have to include in their HACCP plans. If the agency were to codify draft guidelines as regulations, the agency would be answering that question in the affirmative. The preamble to the proposed regulations identified the T-T-S parameters in the draft guidelines as being scientifically established minimums for ensuring that toxin produced by *C. botulinum* will not be produced over the shelf life of the product under refrigerated conditions and under conditions of moderate temperature abuse. FDA has been urged for years to mandate such T-T-S parameters for these products. In 1988 and 1989, for example, AFDO passed resolutions asking FDA to expedite the development of regulations for the safe processing of smoked fish. The comments to this rulemaking that supported regulations over guidelines support the mandating of specific T-T-S parameters.

However, a significant number of other comments challenged whether some of the parameters in the guidelines were actually minimums, as FDA had contended. They specifically objected to the minimum water-phase salt levels in the draft guidelines for air packaged smoked and smoke-flavored fish. Generally, these comments stated that there is little safety concern with air-packaged smoked or smoke-flavored fish (hot or cold smoked) containing as little as 2.5 percent water phase salt (less than the minimum stated in the guidelines), and requested that FDA reexamine the existing scientific data. A few comments stated that air-packaged smoked fish has a limited shelf life in the refrigerated state and that NMFS research has shown that spoilage occurs before toxin production. One comment stated that NMFS, New York State Department of Agriculture and Markets, and AFDO all consider a minimum water-phase salt content of 2.5 percent to be acceptable for air-packaged products.

A few comments suggested that an alternative to specifying T-T-S parameters would be to require that all processors have a scheduled process for air-packaged products. The comment stated that this requirement has been successful in the State of New York and has enabled industry to produce products with water-phase salt concentrations that are lower than those proposed by FDA. A few comments suggested that the high salt levels proposed by FDA for smoked and smoke-flavored products would be counterproductive to those government programs aimed at reducing salt in the human diet and would be unacceptable, or only marginally acceptable, to consumers. Other comments suggested that the necessary minimum salt levels for smoked and smoke-flavored fish might be reduced by shortening the shelf life of the product or by storing and distributing the product frozen.

The comments have persuaded FDA that it may be possible for processors to use parameters other than those in FDA's draft guidelines and still produce a safe product. Moreover, the NACMCF has recently endorsed AFDO's recommended parameters for smoked and smoke-flavored fish. Most notably, these recommendations differ from those in FDA's draft guidelines in that they provide for a minimum finished product water phase salt content in air-packed product of 2.5 percent, whereas the FDA proposal provided for a range of minimum values of from 2.5 percent to 3.5 percent, depending upon other processing parameters.

The agency acknowledges, therefore, that some recommended T-T-S parameters differ from those in FDA's draft guidelines. FDA acknowledges the possibility that other safe T-T-S parameters exist as well. It is reasonable to suppose that there is more to be learned about how the development of *C. botulinum* toxin is controlled in these products, given the lack of reported illnesses in recent years. Thus, while