small or otherwise, that are producing safe food. Indeed, these regulations are based on the premises that: (1) Preventive controls for safety should be within the reach of anyone who is producing seafood for commerce (i.e., preventive controls should not be prohibitively burdensome, either financially or conceptually); and (2) it is in the public interest that everyone who is producing seafood for commerce should practice preventive control for human food safety. The fundamental question that the issue of whether to exempt small business raises is whether these premises are valid.

Having fully considered the comments on this issue, FDA is not persuaded that awareness of likely food safety hazards would cause financial hardship to small businesses, or that having reasonable, practical controls for those hazards will cause undue harm. As will be discussed in the ''Records'' section of this preamble, the costs associated with the recordkeeping requirements of HACCP are really incidental to the cost of monitoring and need not place a significant burden on small businesses. For example, after checking the temperature of a refrigerator, the observer need only take an additional moment to document the result of the observation. The agency cannot emphasize too strongly that, in most instances, only very simple recordkeeping is needed to adequately serve the purposes of the system. The question from the agency's standpoint, therefore, is whether the actual monitoring of critical operations, at reasonable frequencies, would be prohibitively expensive to the small operator. FDA has not been provided with a basis for such a conclusion.

This leaves plan development and training as costs. The guidelines that FDA is making available on plan development should help substantially to keep development costs down. FDA is also aware that trade associations and others are interested in developing model plans that, when used in concert with the guidelines, should further reduce the resources that a firm will need for plan development. The creation of a HACCP plan does require some thought and effort by the processor to ensure that hazards and controls are understood and identified. Nonetheless, the guidelines and model plans will enable small processors to be able to apply the thought and effort necessary to create a HACCP plan with maximum efficiency and minimum cost.

FDA is requiring that all processors either employ at least one trained individual or contract for services from at least one trained individual, as needed. There are unavoidable costs associated with this requirement. It is imperative that these costs be affordable to small business and be no greater than necessary. As discussed at length in the ''Training'' section of this preamble, FDA has been extensively involved with a consortium called the ''Seafood HACCP Alliance'' (the Alliance) consisting of representatives from Federal and State agencies, industry, and academia, to create a uniform, core training program that will meet the requirements of these regulations and will cost very little. The agency is also aware of HACCP training that has been provided for years for members of industry by NMFS and others. As an additional matter, FDA is allowing job experience to serve as a form of training in order to avoid the unnecessary expense to a processor of having to pay for a HACCP course when at least one employee already has knowledge that is equivalent to that provided by the course.

These efforts should alleviate the concerns of those who believe that the training requirement will be too burdensome on small business. The agency will monitor the situation closely once this training gets underway. If costs turn out to be significantly higher than FDA anticipates, the agency will consider some modification to the requirement.

While the agency regrets that grant monies are not available to small businesses from FDA, the effort that the agency is investing in guidelines and training development is a form of subsidy that should keep costs down generally.

D. Definitions

1. General

In addition to relying on the definitions contained in the act and those in the umbrella good manufacturing practice regulations at part 110 (21 CFR 110), FDA proposed at § 123.3 (a) through (t) to define 20 terms that are essential to the interpretation of part 123. Approximately 100 comments addressed various aspects of the proposed definitions at § 123.3.

The majority of the comments on definitions were concerned with the meanings that FDA proposed for ''processor'' (§ 123.3(n)) and ''processing'' (§ 123.3(m)). These comments generally asked for clarification about the applicability of the definitions to a given commercial activity, or contended that the definitions should be amended to either include or exclude certain activities. Most of the other comments that addressed the definitions were primarily concerned with the meanings proposed for ''fish,'' fishery product,'' ''critical control point,'' ''cooked ready-to-eat,'' and ''importer.'' As a result of the comments as well as agency decisions to modify other provisions in part 123, FDA has deleted, revised, and added definitions to those proposed at § 123.3.

2. Cooked, Ready-To-Eat Fishery Product

19. The proposed regulations contained a definition for ''cooked, ready-to-eat fishery product'' at § 123.3(b). The term was used at proposed § 123.10(a) and in the appendices to the proposed regulations. The final regulations no longer contain this term, and the appendices are not being codified. For these reasons, FDA has eliminated the definition of ''cooked, ready-to-eat fishery product'' from the final regulations.

Nonetheless, a large number of comments expressed concerns about the definition as it was proposed. In general, the comments urged that certain products be excluded from the definition of ''cooked, ready-to-eat fishery products;'' those that are not fully cooked by the processor or that will be recooked by the consumer, and low-acid canned foods subject to the provisions of part 113.

FDA recognizes the significance of the use of the term. Because the agency has excluded use of the term in these final regulations, it will defer consideration of the comments until drafting of the Guide.

3. Critical Control Point (CCP)

FDA proposed at § 123.3(c) to define a critical control point as ''a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard in the final food.'' The word ''hazard'' in this definition was intended to refer primarily to food safety hazards. It could also have applied to quality and economic hazards, however, because the agency was proposing at § 123.6(c) to encourage processors to apply HACCP to these hazards as well.

20. A significant number of comments urged the agency to modify the definition so that it clearly addresses only food safety. These comments recommended that the word ''hazard'' should be prefaced with either ''food safety'' or ''health,'' or that FDA should codify the definition for ''hazard'' that has been recommended by the NACMCF.

Several of the comments urged FDA to adopt the NACMCF definition for