''critical control point'' so that the agency's regulations would be consistent with nationally and internationally agreed upon HACCP definitions. One objected to the phrases: ''high probability,'' because of its connotation in statistical applications; ''improper control,'' because of a lack of a standard for proper control; and ''cause, allow, or contribute,'' because it could allow the elevation of trivial concerns to critical control point status.

FDA is persuaded by those comments that urged consistency with the NACMCF definition for ''critical control point.'' The agency has, therefore, modified proposed § 123.3(c) (redesignated as § 123.3(b)) to read, ''*Critical control point* means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.'' The modified language is consistent with the agency's decision to limit the HACCP provisions of part 123 to the avoidance of food safety hazards (see the ''HACCP Plan'' section of this preamble for discussion). It is also compatible with modifications described elsewhere in this preamble aimed at greater consistency with the NACMCF recommendations. The wording change will not have any practical impact on the requirements of the regulations because the definition still reflects the agency's intent to require that seafood be processed in a way that eliminates, to the extent possible, the chance that it will be rendered injurious to health by procedures that are under the control of the processor.

The NACMCF definition does not contain the phrases that were objected to by one of the comments as described above. Thus, the concerns raised by this comment have been resolved.

21. A few comments, however, stated that the definition should also apply to the control of all decomposition because it is a major problem associated with seafood.

FDA acknowledges that, because of the highly perishable nature of fish, decomposition is probably the most common problem associated with seafood. The agency further acknowledges the comments that expressed concern that failure to control this problem will continue to adversely affect consumer confidence. The industry especially should heed this concern and consider the application of HACCP principles to decomposition, if necessary, to help maintain the quality of its products.

Nonetheless, decomposition that is not associated with safety is not appropriately a part of these mandatory HACCP regulations but should remain subject to traditional good manufacturing practices controls (see, e.g., § 110.80(b) (21 CFR 110.80(b))). As discussed earlier, these regulations are being issued, in part, under section 402(a)(4) of the act. That section provides that a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. While decomposition in some species can be injurious to health and is therefore within the scope of section 402(a)(4) of the act, most decomposition affects the quality of seafood but not its safety. Decomposition that affects quality but not safety is subject to section 402(a)(3) of the act. Therefore, FDA is not subjecting decomposition that is not safety related to the requirements of these final regulations but will continue to regulate decomposition under traditional CGMP control.

FDA points out that it has defined ''food safety hazard,'' a term that the agency uses in the definition of ''critical control point,'' in § 123.3(f). The agency discusses this definition, which is consistent with the NACMCF recommended definition, later in this section.

4. Critical Limit (CL)

FDA proposed in § 123.3(d) to define a ''critical limit'' as ''the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk of occurrence of the identified hazard.'' In the preamble to the proposed regulations, the agency explained that the proposed definition was intended to be consistent with the concept of the NACMCF recommended definition, which reads, ''a criterion that must be met for each preventive measure associated with a critical control point.'' However, the proposed definition was also intended to be more explanatory than is the NACMCF definition, especially as it relates to the assignment of a minimum or maximum value and in the relationship of these values to a minimization of the risk, rather than to an absolute elimination of risk.

22. Several comments stated that the proposed definition of a ''critical limit'' should be modified to be the definition recommended by the NACMCF. The comments asserted that the NACMCF definition is the internationally accepted standard, and that its use in the regulations would avoid confusion. A few comments argued that FDA's use of the phrase ''minimize the risk'' implies that the CL must be set to attain the lowest possible risk, unlike the ''reduce to an acceptable level'' standard in the NACMCF definition for CCP.

Although FDA agrees that the definitions in these regulations should closely adhere to the NACMCF's recommended definitions, the agency concludes that, in this instance, FDA's wording is more descriptive for regulatory purposes and more useful to processors. However, FDA has been persuaded that the phrase ''minimize the risk'' may be misinterpreted as requiring outcomes that are not realistically achievable by a processor. To provide clarification and consistency with the revised definition of ''critical control point,'' FDA has replaced the phrase ''minimize the risk'' with the phrase ''prevent, eliminate, or reduce to an acceptable level'' in the final regulation (now codified as § 123.3(c)). As noted previously, this language also appears in the NACMCF definition of ''critical control point.'' The new language correctly provides for the making of scientific judgments about appropriate degrees of hazard reduction, based on the nature of the hazard and the availability of controls, and is more consistent than the proposed language with accepted HACCP convention.

23. One comment stated that the word ''identified'' should be deleted from the proposed definition.

FDA is not persuaded to make any modification to the definition in response to this comment. The ''identified hazard'' refers to the hazard identified in the HACCP plan.

24. One comment stated that the phrase ''in the end product'' should be added following the word ''hazard'' in the proposed definition.

FDA is not persuaded to make any modification to the definition in response to this comment. Food safety hazards are, by definition, those that cause ''a food to be unsafe for human consumption.'' This definition implies a consideration of the end product that will be offered for human consumption.

25. One comment objected to the phrase ''the maximum or minimum value'' in the definition, stating that, as in the case of certain food additives, there are situations where both a maximum and a minimum value exist, and a processor is required to maintain the process between these values.

FDA is not persuaded to make any changes to the proposed language in response to this comment. The word ''or,'' which the agency uses in the definition, is inclusive. Thus, properly read, § 123.3(c) states that a CL is the maximum value, the minimum value, or both the maximum and minimum