

## FDA Clarifications Regarding 2003 Seafood Audit

Representatives of DG SANCO and the U.S. Food and Drug Administration (FDA) met in Brussels, Belgium on February 14 - 16, 2005 to discuss, among other things, remaining issues associated with the 2003 audit by the FVO of the U.S. fishery products control system. The discussions were successful in that the representatives were able to resolve all remaining issues associated with the audit. This letter transmits clarifications to FDA's letter of July 28, 2004, on the matter of the audit findings, in a manner that is intended to be consistent with the discussions held in Brussels.

Following are our final clarifications. For convenience we reference the item numbers listed in a table developed by DG SANCO entitled "Comments provided by the US competent authorities and their assessment by the relevant commission services," dated April 27, 2004.

Item #11, referencing section 2.2.1 of the draft audit report, covering "Establishment Registration/Approval":

The FVO expressed concern that without mandatory registration, some fishery products establishments in the U.S. could operate without FDA oversight. FDA notes that registration is now mandatory for all fishery products establishments, in the U.S. and those abroad that ship to the U.S., that manufacture, process, pack or hold food for consumption in the U.S. This requirement went into effect on December 12, 2003, with the promulgation of an interim final regulation, *Registration of Food Facilities*, which implemented provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Further, FDA has developed draft guidance for the listing of fishery products establishments for shipment to the EU, *Certification of Fish and Fishery Products for Export to the European Union and European Free Trade Association*. A copy of the draft guidance was provided to the DG SANCO representatives during the February 14-16, 2005 meeting in Brussels. The draft guidance was published in the Federal Register on November 22, 2004 and includes a provision that establishments should not be listed for shipment to the EU unless the FDA (or a State authority) has previously inspected them. During the discussions at our February meeting, the DG SANCO representatives requested that FDA consider placing into the guidance a maximum length of time (e.g., one to two years) since the last inspection at the time that an establishment is listed. The guidance is not yet final and FDA will consider such a provision as it moves to a final guidance document in the near future.

Item #14, referencing section 2.2.3 of the draft audit report, covering "Hazard Analysis and HACCP Plan" and Item #31, referencing section 3, "Conclusions":

The FVO expressed concern that the U.S. Seafood HACCP regulation (21 CFR Part 123) does not require documentation that the mandatory reassessment of a HACCP plan was performed. FDA notes that in order to verify that the firm's original hazard analysis and

annual reassessments were properly performed, the FDA investigator evaluates the adequacy of the HACCP plan to ensure that it meets the current conditions of manufacture. Since all hazards determined to be “reasonably likely to occur” by the hazard analysis or reassessment must be identified in the current HACCP plan, the existence of a properly designed HACCP plan is evidence that the hazard analysis and reassessments were effective. Nonetheless, the regulation requires that the performance of the initial hazard analysis and subsequent reassessments be confirmed by the signature of the most responsible individual on-site at the processing facility or by a higher level official of the processor and the date of the signature. The establishment representative is required to sign at the time of each reassessment.

Items #15 and 16, referencing section 2.2.3 of the draft audit report, covering “Hazard Analysis and HACCP Plan” and Item #31, referencing section 3, “Conclusions”:

The FVO expressed concern that review of previous inspection documents associated with one establishment visited during the audit disclosed that FDA had not previously objected to the absence of control of the hazard of histamine formation in a product produced by the firm, when such a hazard was reasonably likely to occur. FDA agrees that this hazard is a significant hazard and notes that during the audit the inspector corrected the condition by citing the violation. FDA has since pursued regulatory action against the processor. Additionally, in an effort to further ensure consistent inspection and regulatory action in this and other matters, FDA is pursuing a certification program for FDA and state inspectors conducting seafood inspections.

Item #21, referencing section 2.2.5 of the draft audit report, covering “Audits of HACCP Implementation”:

The FVO expressed concern that processors and regulators may not be aware that a separate hazard analysis is necessary to identify hazards other than *Clostridium botulinum* that may be reasonably likely to occur in canned fishery products. FDA agrees that a separate hazard analysis must be performed to identify such hazards. The seafood HACCP Regulation requires that processors perform such an analysis and include any such hazards in their HACCP plans [21 CFR 123.6(e)]. Additionally, FDA’s training for federal and state inspectors instructs them to perform their own hazard analysis to identify hazards other than *Clostridium botulinum* that may be reasonably likely to occur and to seek corrective action when the processor fails to properly identify such hazards.

Item #22, referencing section 2.2.6 of the draft audit report, covering “Certification Procedures”:

The FVO expressed concern that there may be no U.S. regulatory requirement that frozen fishery products be stored at a temperature and in a manner to prevent adulteration. FDA notes that all frozen storage warehouses that store fishery products are subject to FDA oversight and to the requirements of the Seafood HACCP Regulation (21 CFR Part 123) and the Current Good Manufacturing Practices Regulation (GMP, 21 CFR Part 110). The GMP regulations require that frozen foods be processed and stored under conditions

that prevent the food from becoming adulterated within the meaning of the Federal Food, Drug and Cosmetic Act (21 CFR 110.80(a)(6), and (b)(3), and 110.93). FDA and state inspectors evaluate compliance with these requirements during inspections of fishery product establishments.

Item #23, referencing section 2.2.6 of the draft audit report, covering "Certification Procedures" and Item #28, referencing section 3, "Conclusions":

The FVO expressed concern that FDA could not ensure that imported raw materials used in the production of fishery products destined for the EU were sourced from EU-approved countries and establishments. FDA agrees that the U.S. system is not designed to ensure compliance with EU-specific requirements, such as this one. During the February meeting, FDA provided an overview of the U.S. system for ensuring the safety of fishery products imported into the U.S. The system includes: sampling, analysis, and examination of products at time of entry into the U.S.; import alerts to FDA's import inspection staff that target products with a history of noncompliance with U.S. requirements; and inspections of foreign processing facilities. This system does provide an assurance of safety that is at least equivalent to that provided by the EU system of approved sources.

Nonetheless, FDA agreed to consider further modification to its draft guidance on listing for shipment to the EU to address this issue. FDA anticipates reissuance of this guidance in the near future. The following modifications are under consideration:

- a. Providing that firms should not be listed unless they had been inspected by FDA or by a State operating under FDA contract and should be removed from the list upon FDA determination of the firm's non-compliance with applicable *FDA* regulations.
- b. Having firms self-certify that all raw materials would be sourced from the EU-approved list of countries/firms
- c. Firms committing to providing FDA access to records necessary for the agency to verify sourcing of raw materials
- d. Firms acknowledging that providing FDA with false information intended to demonstrate satisfaction of the certification criteria in the guidance would subject them to penalties under Title 18 and to immediate removal from the US list of "export eligible" firms and that failure to satisfy the certification criteria in the guidance could also result in removal from the list.
- e. FDA periodically verifying the accuracy of the statements in the self-certifications.

Items #24, 25 and 26, referencing section 2.3.1 of the draft audit report, covering "Audit of the FDA Inspection Control" and Items #29 and 30, referencing section 3, "Conclusions":

The FVO expressed concern with apparent inconsistencies in the nature of sanitation deficiencies cited by FDA and state inspectors and the manner in which corrective action was pursued. FDA provided extensive comment relative to this concern in its letter of July 28, 2004. Included in that discussion was mention of an "Ad hoc Sanitation Committee." The committee was charged with evaluating the findings of the FVO audit and making any necessary recommendations for improvement to the Agency. The activities of the committee have identified a number of areas for improvement, generally related to a re-emphasis on those elements of the inspection that are most likely to identify significant sanitation deficiencies (e.g., beginning the inspection before the start of the day's production operations in order to assess clean-up operations), and regulatory follow-up to such deficiencies when they pose a significant potential for product contamination. FDA is committed to share the findings of the "Ad hoc Sanitation Committee" with management of its field operations so that improvements in this area can be realized.

Additionally, the FVO expressed concern with the observed use of chlorine hypochlorite in water with direct product contact in one establishment during the audit. FDA does not permit the use of chlorine hypochlorite in water with direct product contact at levels greater than 10 ppm. When advised of that fact, the firm in which the finding was made discontinued the practice.