Christine M. Humphrey, Esq.
(786) 245-0439
chumphrey@fuerstlaw.com

FDA Food Protection Plan

FHI Briefing on Import Prototype Proposal:

Accreditation of Global Compliance Verification Services

By Third Parties

I. Background

The prototype proposed by FHI in June 2005 consists of a voluntary Third Party Verification and/or Self Certification the United States. The purpose of this pilot program is similar to that used in the medical device industry to: (1) provide exporters of food into the U.S. a proactive review process that could yield more rapid admissibility decisions at the time of entry; and (2) enable FDA to use its scientific and regulatory review resources for high-risk food products, while maintaining confidence in the review by third parties of low-to-medium risk foods as well as certain high risk foods. The prototype contemplated a program for all food manufacturers. The initial prototype was formulated as a proposal for implementation as to bottled water.

II. Overview

1. Elimination of the "snapshot" approach to determine admissibility at the border and replacement using a life cycle approach;

2. Use of risk-relevant data to assess and manage safety and security risks associated with a product's full life cycle starting with its raw materials, proceeding through the manufacturing and distribution process; and

3. Enhancement of FDA's ability to make risk assessments through availability of verified and certified product life cycle information.

III. Prototype

This voluntary prototype is modeled after the FDA's existing Hazard Analysis and Critical Control Point (HACCP) requirements under 21 Code of Federal Regulations Part 123- Fish & Fishery Products. However, the hazard analysis will address safety and security hazards associated with the manufacturing, storage and distribution of food products subject to the Bioterrorism Act.

1. Collection, verification and certification of full product life cycle and submission upon FDA request;

2. The HACCP plan identifies the entire life cycle of the product beginning at receipt of raw materials, storage, processing, finished product storage, and distribution. The plan will include:

a. Identification of safety hazards, critical control points for each identified hazard and the critical limits that must be met to adequately control the hazard. (See 21 C.F.R. § 123.6)

b. Corrective action plan for purposes of controlling and responding deviations from established critical limits (See 21 C.F.R. § 123.7)

c. Verification procedures to ensure periodic review of the HACCP plan (See 21 C.F.R. § 123.8)

d. Record management of raw material receipt, manufacturing, storage and distribution processes covered by the HACCP plan (See 21 C.F.R. § 123.9)

e. Sanitation Control Procedures identifying how the manufacture, storage facility and shipper will monitor and control sanitation conditions. (See 21 C.F.R. § 123.11)

Importer verification may also be satisfied through voluntary submission of the following types of information, similar to those requirements identified in 21 C.F.R. § 123.12. The following information embodies the concepts of harmonization acknowledged by the FDA through participation as a member in the Codex Alimentarius, WTO and GATT agreements. The types of information include:

a. Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the FDA and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system; or

b. Implement written verification procedures for ensuring that the food products that they offer for import into the U.S. were processed in accordance with requirements similar to 21 C.F.R. Part 123. The procedures should list at a minimum: Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,

c. Affirmative steps that may include any of the following:

(1.) Obtaining from the foreign processor the HACCP and sanitation

(2.) Monitoring records required by this part that relate to the specific lot of food products being offered for import;

(3.) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third-party certifying that the imported food product is or was processed in accordance with requirements, similar to 21 C.F.R. Part 123;

(4.) Regularly inspecting the foreign processor's facilities to ensure that the imported food product is being processed in accordance with requirements, similar to 21 C.F.R. Part 123;

(5.) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported food product is processed in accordance with the specified requirements;

(6.) Periodically testing the imported food product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported food product is processed in accordance with the requirements or,

(7.) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements part.

IV. Competent Third Party

1. An importer may hire a competent third party to assist with or;

2. Perform any or all of the verification activities including writing the importer's verification procedures on the importer's behalf.

V. Section 304 authority under the Bioterrorism Act

FDA may require importers of food products to:

1. Maintain records, in English, that document the performance and results of the affirmative steps taken by the foreign supplier.

2. The records would be subject to the applicable provisions, similar to those identified in Sec. 123.9 of the HACCP regulations.

VI. Expedited Admissibility Decisions

Food products having an established HACCP plan from sources known to be in compliance with the Federal Food Drug & Cosmetic Act would be given expedited admissibility.

1. Similar to prescription drug products that have approved applications and provide the FDA assurance that the facility, raw materials, manufacturing processes, storage and distribution operations are in compliance with CGMPs.

2. Similar to Customs CTPAT security initiative.

VII. Accountability

The prototype embodies Congress' mandate, under Section 302(b)(2) of the Bioterrorism Act, that FDA give high priority to facilitate the importation of food that is in compliance with the Food Drug & Cosmetic Act. FDA's initial implementation of the Accredited Third Party Verification Program will include a number of features designed to maintain a high level of quality of the verifications by Accredited Persons and to minimize risks to the public:

1. FDA oversight of Accredited Person reviews/recommendations and FDA's continued responsibility for the assessment of admissibility decisions;

2. Provisions for FDA to make onsite visits on a periodic basis to each Third Party to

audit performance and to inspect records, correspondence, and other materials relating to Third Party review;

3. FDA retains its authority to manage risk based on information the FDA deems to be risk-relevant. This means that having a certified HACCP plan does not preclude FDA sampling, detention or refusal at the time of entry.

Very truly yours,

Christine M. Humphrey, Esq.