

The New Bioterrorism Act

-by Allison Corcoran



The proposed regulation for Title III of The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (usually simply called the Bioterrorism Act) has been published. Title III – Protecting the Safety and Security of the Food and Drug Supply - contains three provisions that are especially relevant to our clients:

Section 305 – Registration of Food Facilities – Owners, operators or agents in charge of facilities, domestic and foreign, that manufacture, process, pack or hold food intended for consumption in the U.S. are required to register the facility with the FDA.

Section 307 – Prior Notice of Imported Food – The FDA must receive advance notice of each food shipment into the US. Currently, the proposed regulation requires the prior notice to be given electronically by noon of the day before the food is expected to enter the country. The

proposal allows for an amendment (for example, to the exact amount) to be filed up to two hours before the shipment is expected to arrive.

Section 306 – Establishment and Maintenance of Records – Businesses that manufacture, process, pack, transport, distribute, receive, hold or import food are required to create and maintain records that the FDA had determined are necessary to identify the immediate source – where it came from – and the immediate recipient.

The proposed legislation is still in the 60 day comment period. The legislation goes into effect December 12, 2003 even if the final regulations have not been issued. The FDA website contains a link to the new act, or go directly to <http://www.fda.gov/oc/bioterrorism/bioact.html>

Surefish is watching this issue carefully, and we will keep you updated as the regulation is finalized.

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