



PBB GLOBAL LOGISTICS – WHITE PAPER

FDA's New Anti-Bioterrorism Powers Target Imports

Importing food into the U.S. becomes increasingly complex

With the creation of the Department of Homeland Security (DHS), tougher customs enforcement at the country's ports of entry and a multitude of new import and export regulations, shipping into the United States is growing in complexity.

But conspicuously left out of the massive DHS merger, the Food and Drug Administration (FDA) still has the primary responsibility for public safety concerning the nation's food supply. As a result, agri-food traders face additional – even overlapping – responsibilities when shipping to the U.S.

Concurrent with ongoing security measures driven by Customs & Border Protection (formerly U.S. Customs), the FDA has undertaken some far-reaching changes of its own. Registration of food facilities and new recordkeeping requirements are major components of the FDA's new framework, but neither should be overly onerous to the business community. However, "prior notice" regulations are weighing heavily on companies that import product into the U.S. Understanding the scope of these changes is critical to anyone involved in supply chain management in the agri-food industry.

The FDA's regulatory authority emanates from the Public Health Security and Bioterrorism Response Act of 2002 ("Bioterrorism Act"). In February 2003, the FDA set forth a series of proposals to implement the Bioterrorism Act. Interim final regulations were published October 10, 2003 and implementation came into effect on December 12, 2003.



From apples to zucchini, the FDA's comprehensive anti-bioterrorism regulations affects most foreign and domestic food businesses.

Registration of food facilities – is your business affected?

The FDA wants to maintain a complete listing of all facilities involved in the nation's food supply to improve its efficiency in regulating the industry and to help it respond more quickly to potential emergencies.

With few exceptions, domestic and foreign companies need to register with the FDA all facilities that manufacture, process, pack or hold food for consumption in the U.S. Estimates suggest that over 400,000 facilities are affected by this requirement. The registration process is designed to be fairly simple through an on-line system, and may be done by the facility itself or by an individual authorized by the owner, operator or agent in charge of the facility.

The FDA also requires that all foreign food facilities have a U.S. resident agent. Normally, the FDA will communicate directly with that agent who, in effect, will proffer a U.S. presence for the foreign food facility. Many service providers, including PBB Global Logistics, are in a position to serve as agent, a practical solution where they are already privy to shipment and trade details.

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Businesses need to familiarize themselves with the regulations since there are a number of exemptions. Farms, retailers and restaurants are conditionally exempt, but there are some exceptions. Meat and poultry processors, when they fall under the exclusive regulatory ambit of the U.S. Department of Agriculture (USDA), are likewise exempt.

Companies that only pack or hold food may find themselves required to register, although truck terminals and freight forwarders that are part of the transportation network and only have possession, custody or control of food for the sole purpose of facilitating its transport are not required to register.

Prior notice – adjusting your supply chain

Much more onerous to the agri-food industry is the requirement to provide prior notice before importing food products. Few exemptions exist beyond food that is exclusively USDA-regulated. Even shipments from farms are subject to prior notice.

Prior notice is deemed necessary to give the FDA sufficient information and time to determine whether a potential threat exists and whether shipment inspection might be warranted. In the past couple years, the FDA has added several hundred new inspectors along the border to help handle the typical 20,000 prior notices received daily and the resulting increased inspection workload.

Under the final rules, the FDA must be notified between 2 and 8 hours prior to the arrival of a shipment, depending on the mode of transport.

Under the original proposals, the process was to be separate from Customs' Automated Commercial System (ACS). Fortunately, both agencies have since announced streamlined measures enabling ACS to serve as the single system including FDA prior notice requirements. This integrated approach is expected to

continue when Customs launches its new Automated Commercial Environment system, targeted for 2005. Shippers, however, still have the option of transmitting their prior notices themselves, using the FDA's Prior Notice Systems Interface (PNSI).

Depending on the mode of transport, the prior notice requirement minimally ranges from 2 (truck) to 8 (vessel) hours. In practical terms this means that the filer of the prior notice, generally the broker, needs that information well in advance of the time by which the prior notice must be filed. This is because the

broker must, in effect, prepare the entry as part of the prior notice, a process which previously extended 10 working days from date of release to accomplish.

If adequate prior notice is not provided, the FDA will refuse admission into the United States and shipments will be held at the port of entry or in a nearby secure facility, with transportation and storage costs at the expense of the purchaser, owner, importer or consignee. Food will be held until proper prior notice is submitted and accepted by the FDA. Only then, barring FDA inspection or outstanding Customs entry issues, would the shipment be released. Failure to comply with these regulations may be regarded as a prohibited act which could result in both civil and criminal penalties.

New recordkeeping requirements

Finally, the Bioterrorism Act also authorizes the FDA to mandate the type of records that businesses need to create and maintain for up to two years. This affects manufacturers, processors, packers, carriers, distributors, receivers, storage facilities and importers alike, while exempting some farms and restaurants.

The intention is to improve the FDA's ability to follow up on credible threats and investigate any food-related disease outbreaks. The final regulations were published on December 9, 2004.

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How to prepare for food exports to the U.S.

In light of the breadth of the FDA's regulatory requirements, any business operating directly or indirectly in the agri-food industry is wise to familiarize itself with the new rules. The devil is in the details: depending on the type of operation, it may or may not be subject to the registration, prior notice and/or recordkeeping requirements.

While registration of facilities and recordkeeping requirements place additional administrative burdens upon food companies, prior notice requirements have the most profound impact on their operations. Depending on the nature of the supply chain, adjustments may be necessary to comply.

Inevitably, these new administrative and logistics burdens will force agri-food businesses to incur additional costs. Companies should analyze the overall financial impact before or shortly

after implementation to determine whether increased costs warrant any revisions in pricing.

It is also important to ensure that trading partners – vendors, carriers, third party logistics providers – are up-to-date. Foreign food companies should appoint a U.S. agent and register with FDA as soon as possible. All parties should come to agreement about financial and logistical responsibilities in the event a shipment is refused entry.

As with the numerous security initiatives underway with Customs & Border Protection – C-TPAT (Customs-Trade Partnership Against Terrorism), Container Security Initiative, FAST (Free And Secure Trade) and advance notification – the new FDA framework is the

reality of supply chain management today. As any shipper experienced in the new framework can attest, advance preparation is the key to avoiding unpleasant and costly surprises.

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