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INTERNATIONAL TRADE ALERT

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Food Safety Enhancement Act of 2009

There has been quite a bit of coverage in the press in the last few days about a provision in this bill which would essentially put customs brokers into the same shoes as importers in terms of their obligations to register and validate data. While clearly such an attempt again fails to appreciate the difference between the role of the international trader and his service providers, there are a number of other provisions in the bill equally worthy of note for international traders. It is expected the bill will be marked-up (considered and voted on by the Sub-Committee and, once approved, the bill is sent to the full Committee and then Congress for approval, although amendments could still result) perhaps as early as this week. For a full copy of the bill, see Food Safety Enhancement Act of 2009.

One interesting change is the proposal to now consider food misbranded if it is stored in a facility which is not registered. It appears registration is expanded to include food exported from the U.S. The registration fee for 2010 would be $1,000 and is subject to increase in subsequent years. Of course, this registration fee applies to both U.S. and international facilities which must register with FDA. At the same time, the registration fees are intended to fund food safety activities, and so there is a complex formula provided which arguably allows refunds of the fees paid, but only under what appear to be very limited circumstances.

HACCP (Hazard Analysis and Critical Control Point) is also addressed, but with an interesting twist. Specifically, if an importer does business with an owner, operator, or agent of a facility which does not itself conduct hazard analysis where required, then the goods being stored, manufactured, packed, processed or otherwise transported or handled are considered misbranded. Conducting a hazard analysis means not only identifying any hazards, but also documenting any efforts undertaken, including any corrective action. The proposed record-keeping time frame is two (2) years.

All facilities will now also be required to have food safety plans in place before delivering any food into the U.S. food supply, including preventive controls, how they are monitored, procedures for corrective action, verification activities, record keeping, trace-back and recall procedures, how the supply chain is made secure for ingredients and components and how science-based performance standards will be implemented once guidance is issued or regulations published about these new performance standards. It appears these requirements are intended to expand hazard analysis to all facilities, not just those currently regulated by HACCP, such as seafood, juice and low-acid canned food, which will be a significant change even in the face of the 18-month delay in effective date.

The definition of adulterated food is also expanded, this time to include goods that are manufactured, processed, packed, transported or held under conditions that do not meet the performance standards which are going to be promulgated. These performance standards will be recommended by the Secretary of Health and Human Services (HHS) and are to identify the most significant food-borne contaminants and related hazards, and recommend ways to minimize or eliminate such hazards and contaminants. These performance standards will also apply to fresh produce and other raw agricultural products (plant and fungus), whether they are grown, harvested, packed, sorted, transported or held. In both contexts, the goal is "to prevent the introduction of known or reasonably foreseeable biological, chemical and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism." Specifically mentioned are controls in areas such as manure use, water quality, employee hygiene, temperature, and sanitation and animal controls, although discretion is granted to incorporate other

criteria.

The bill also includes an inspection schedule which is to be dictated based on risk. Enforcement and inspections may occur by federal and state regulators. In the case of facilities in foreign countries, foreign entities may be certified to conduct the inspections. In all cases, the Secretary may limit the inspection schedule based on commodities or food types. The bill then goes on to identify the categories. A Category 1 facility is considered high-risk. It manufactures or processes food, including those that process raw products of animal and fish origin. These facilities are to be inspected every six (6) to 18 months. Category II facilities are low-risk and manufacture, process, pack or label food. They are to be inspected every 18 months to three (3) years. Finally, Category III facilities are warehouses that simply hold food. They are to be inspected every three (3) or four (4) years. FDA is already advising Congress it wants a different inspection schedule as it will need significant time and resources to ramp up for any serious inspection schedule.

There is also additional record-keeping mandated. "Each person who produces, manufactures, processes, packs, transports, distributes, receives, or holds an article of food in the United States or for import into the United States shall" turn over his records upon the officer displaying his credentials within reasonable limits and a reasonable manner. Turning over records is defined to mean making them available for copying. "Records" is intended to include those related to "production, manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location." The record-keeping period is three (3) years.

The term "prohibited act" is being expanded to include food which fails to meet the newly enacted traceability requirements. The traceability system is for all imported and domestic food and must include a full history of the origin and previous distribution and a link to subsequent distribution. The tracking system is to be interoperable (to overcome the recent tracking difficulty which GAO encountered) with other existing systems the person/company already has in place and mandates that each facility owned by a person must have a unique identifier. Any tracking system recommended by HHS is to be evaluated in conjunction with industry which is expected to provide extensive input. There are even references to establishing pilot programs. Direct sales by farms to consumers or restaurants are exempt. Other foods may become exempt if HHS is satisfied they pose no risk to public health. If a facility is found in violation, it may be assessed additional fees, including those related to its being again inspected.

Three years after enactment, a certification of compliance requirement takes effect. Any shipment in violation is deemed misbranded and may be refused admission. There may also be country-specific certifications triggered by the circumstances in a given country and/or the nature of the food or product being imported. These certifications may be made by a foreign government official or a third party recognized by FDA. The third-party certifiers are subject to detailed conflict of interest rules.

There is also a provision which requires anyone who becomes aware of food which could be harmful to report that fact to FDA along with the location of the product. Voluntary recall is authorized as before, but now FDA will also have the ability to issue an order to "cease distribution" which includes giving notice to anyone who has already received the product. In other words, FDA finally gets its long-sought mandatory recall authority. There is a right to appeal within 24 hours and a provision for an informal hearing to be held no more than ten (10) business days later. There are also provisions for an emergency recall as ordered by the FDA with good cause.

Evidencing the ever-growing cooperation between state and federal officials, FDA is allowed to share information with other federal agencies and the state and local governments. FDA is also permitted to share information with foreign governments plus with international organizations for public health reasons, and with regional or global organizations focused on harmonization of standards and

requirements.

The bill also proposes the creation of The Safe and Secure Food Importation Program. To qualify, the importer:

1. verifies that each facility involved in the production, manufacture, processing, packaging, and holding of the food is in compliance with the food safety and security guidelines developed [as per the below criteria] with respect to such food;
2. ensures that appropriate safety and security controls are in place throughout the supply chain for such food; and
3. provides supporting information to the Secretary.

To carry out this program, and sounding a lot like C-TPAT and the produce industry's traceability program, FDA is to develop safety and security guidelines for the importing of food which are to consider:

A. The personnel of the person importing the food;
B. The physical and procedural safety and security of such person's food supply chain;
C. The sufficiency of preventive controls for food and ingredients purchased by such person;
D. Vendor and supplier information; and
E. Such other factors as the Secretary determines necessary.

Criminal penalties and the Sentencing Guidelines are being increased while at the same time HHS is given quarantine authority, meaning if it suspects a food-borne outbreak, HHS is permitted to control the distribution of food and its transportation in that region. Similarly, civil penalties are being increased to a maximum of $100,000 per individual and $500,000 per entity.

What has the customs brokers concerned is the provision which makes it a prohibited act to submit information which is incomplete or inaccurate or to fail to submit information as required. Of course, importers are subject to this same prohibition, but they at least should know what is in the shipment. Brokers only know what is on the documents they are provided as they rarely see the goods, much less inspect them.

There are also specific rules relative to infant formula and carbon monoxide used as a preservative. There is also a new labeling requirement. For processed foods, the goods must now state the last country of processing plus the manufacturer's website, and that website must state the origin of each ingredient in the finished product. With nonprocessed foods, origin and ingredients must be stated but only if the original packer's website does not make the necessary statements. The failure to do so constitutes misbranding.

Misbranding will also apply if both the importer/filer and the customs broker are not registered, another reason the customs brokers are concerned. Importers are expected to exercise good importer practices, which are defined to include verifying good manufacturing practices and preventive controls by foreign suppliers. Customs brokers must be registered and must submit unique facility identifiers. The bill speaks about "other filers" but fails to define that term. However, what is clear is the failure to register by either the importer/filer or the broker constitutes misbranding.

Importers of food, drugs and devices and their customs brokers will all be assessed fees for their registrations, although the exact amount is not specified. The unique identifier is tied to the registrant's primary place of business, not each facility it has. Here again, the fees are intended to support the

food safety efforts of the agency and there is again a complicated formula stated which could result in refunds of the fees paid.

Manufacturers of food, drugs and medical devices are all required to register, whether domestic or foreign. Should any foreign plant or foreign government official delay, limit or refuse an inspection, the resulting product is considered adulterated.

FDA is barred from closing any labs unless it first submits a reorganization plan to Congress. On the other hand, FDA is now given its long-sought subpoena authority to obtain witnesses and records in order to conduct hearings, investigations or other proceedings. If a party fails to comply with a subpoena, the related product is refused admission.

The fact that the underlying goods are considered adulterated, misbranded or prohibited simply allows FDA to get the attention of the importer by forcing the export or destruction of the goods. While the sampling, detention, and refused admission import process remains untouched, violations of the proposed new requirements will likely lead to far fewer options for importers to challenge FDA's determinations.

It is obvious that a lot of effort went into combining hundreds of proposals into this one bill. There are some provisions which seem questionable, but what seems clear is that Congress is intent on passing FDA reform legislation and soon. In other words, the mark-up is likely to go quickly and the only real question is how long will it take before the bill is considered on the floor of Congress. Of course, the other big question is, assuming the House approves the bill, how will the Senate respond? Congressman Waxman, Chair of the Committee on Energy and Commerce, knows how to get bills passed into law. It seems likely this proposal is on a fast track through both Houses, but we will have to wait and see the outcome. In the meantime, traceability is the watchword of the day. Whether it is this proposal or the next one, American food and food product traders should be taking steps to work more closely with their suppliers, and also focus on sustainability, the other major consideration these days.

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