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MEMORANDUM

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FROM: Olsson Frank Weeda Terman Bode Matz PC

RE: Rep. Dingell Circulates Draft of Major Food Safety Legislation

Rep. John Dingell (D-MI), chair of the House Energy and Commerce Committee, this week circulated a discussion draft of major food safety legislation, the *Food and Drug Administration Globalization Act of 2008*. In a memorandum accompanying the draft bill, Dingell declared his intention to hold hearings on the draft over the next few weeks and to markup the bill shortly thereafter.

The draft bill has titles addressing the safety of drugs, medical devices, and cosmetics, as well as food. Some of the provisions in the bill have delayed effective dates.

This memorandum very briefly summarizes the main provisions of the bill regarding food:

1. Registration of Food Facilities and Importers

- Food facilities would be required to re-register with FDA annually.¹
- FDA would be required to charge an annual registration fee of \$2,000 per facility, subject to an inflation adjustment after 2009. Failure to pay the fee would be a prohibited act, subject to injunction and criminal prosecution.
- FDA would be authorized to suspend a facility's registration for any violation that could result in serious adverse health consequences or death to humans or animals or if the facility delays, limits, or denies an FDA inspection.²

¹ Under existing section 415(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a "facility" is defined as "any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food." The definition includes both domestic and foreign facilities. It does not include farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared or served directly to consumers, or fishing vessels (except for vessels that engage in processing).

² Although it appears to be the intent of the bill to prohibit a suspended facility from distributing food in interstate commerce, the bill as currently drafted does not do this.

- FDA would be required to issue regulations requiring that food importers not registered with FDA under FD&C Act section 415(b) would be required to register with FDA under section 801(s). An annual fee of \$10,000 would be assessed for each importer registration. It would be a prohibited act, subject to injunction and criminal prosecution, for an importer to import any food (other than for personal use only) unless the importer is registered with FDA under either section 415(b) or section 801(s).

2. Food Safety Plans

- Before introducing, or delivering for introduction, into interstate commerce any shipment of food, all facilities would be required to develop and implement a written food safety plan.³ The plan must be based on an analysis of all hazards that are reasonably likely to be present, or that have been present, in any food manufactured, processed, packaged, or held by the facility. The plan must include the following elements: preventive controls to address identified hazards, validation, monitoring, recordkeeping, and recall procedures.
- FDA may require that a facility's food safety plan include specific hazard controls if needed to protect public health.
- FDA may, by regulation, establish performance standards for specific foods and specific food safety hazards.
- FDA may, by regulation, require food safety plans for particular types of fresh produce.⁴

3. Inspections

- FDA shall develop "an inspection system for the conduct of unannounced inspections of facilities."
- During inspection of a facility, FDA would be authorized to inspect "all things therein that bear on whether food products are in compliance." This sweeping expansion of FDA records access authority would give inspectors access to all company records, including electronic records. Any records obtained by FDA during an inspection, except for trade secrets, would then be subject to public disclosure under the Freedom of Information Act. FDA would also be authorized to take photographs during an inspection.
- If a facility delays, limits, or denies inspection, FDA may suspend the facility's registration.
- If the inspector has reason to believe a food is adulterated or misbranded, FDA may detain the food and, if objection is not made within 48 hours, condemn the food.

³ The scope of this requirement is very broad, since it applies to all "facilities" as defined in section 415(b) of the FD&C Act, including, for example, warehouses and foreign food facilities.

⁴ It appears this requirement could extend to farms, which otherwise would not be required to have a food safety plan because they are excluded from the definition of "facility."

- If FDA must re-inspect a facility because of a violation of any requirement, FDA shall assess a re-inspection fee, the amount of which would be determined by FDA.

4. Certification Program

- FDA would be required to establish a voluntary certification program for facilities. Under the program, either FDA or an accredited certifying agent would certify that the facility is in compliance with the FD&C Act. Certification would have to be renewed every two years.
- FDA would be required to post the list of all certified facilities on its website.
- FDA would be required to establish a system for accrediting foreign governments, State or regional food authorities, foreign or domestic cooperatives that aggregate food, or other third parties as certifying agents.
- For food imports (other than those for personal use), unless each facility that manufactures, processes, packs, or holds the food is certified, the food would be required to enter the United States through a port of entry located in a metropolitan area with a federal laboratory.

5. Laboratories

- FDA would be required to accredit laboratories for the sampling and testing of food, using accreditation standards published in the *Federal Register*. FDA would be required to collect an annual fee for such accreditation and to conduct an annual onsite audit of each accredited lab.
- If a facility is not certified (see above), it would be a prohibited act, subject to injunction and criminal prosecution, for such facility to introduce, or deliver for introduction, into interstate commerce any shipment of food without first having such food sampled and tested for compliance with applicable food safety standards and submitting the results to FDA.
- Even if a facility is certified, it would be required to have its food shipments sampled and tested on a periodic basis specified by FDA.

6. Mandatory Notification and Recall

- If any person (other than a household consumer or other individual who is the intended consumer of the food) has reason to believe that an article of food is adulterated or misbranded in a manner that may result in injury or illness would be required to notify FDA of the identity and location of the food as soon as practicable. It would be a prohibited act, subject to injunction and criminal prosecution, to fail to notify FDA.
- If FDA determines that an article of food is adulterated or misbranded in a manner that may result in injury or illness, FDA would be required to give all appropriate persons an opportunity to cease distribution, recall the food, and notify other parties.

- If the appropriate person does not take action within the time period and in the manner prescribed by FDA, FDA would be required to issue an order requiring the person to cease distribution and notify other parties; FDA may also seize the food. It would be a prohibited act, subject to injunction and criminal prosecution, to fail to comply with the order.
- After an opportunity for a hearing, FDA may amend the order to mandate a recall or other appropriate action. It would be a prohibited act, subject to injunction and criminal prosecution, to fail to comply with the amended order.

7. Civil Fines

- For any prohibited act, FDA may assess a civil penalty of \$100,000 for individuals or \$500,000 for any other person. Each prohibited act and each day during which the act continues would be considered a separate offense.

8. Imports and Exports

- FDA would be required to establish, by regulation, a program to expedite movement of food through the import process if each facility involved in the production, manufacture, processing, packaging, and holding of the food is a certified facility and agrees to comply with FDA food safety and security guidelines to be developed by FDA.
- All food imports, other than those for personal use, would be required to enter the United States through a port of entry located in a metropolitan area with a federal laboratory, unless each facility that manufactured, processed, packed, or held the food has been certified (see above).
- FDA may refuse admission into the United States of any food offered for import (except food imported for personal use only) if the government of the foreign country from which the food is imported, or any facility at which the food is manufactured, processed, packed, or held, does not provide timely consent to an FDA investigation when food from that country or facility is linked to a foodborne illness outbreak or is otherwise found to be adulterated or misbranded.
- FDA would be authorized to charge a fee for issuance of export certificates for food and animal feed.

9. Country of Origin Labeling

- A processed food would be deemed to be misbranded if its labeling fails to identify the country in which final processing of the food occurs, or if the manufacturer's website does not identify the countries of origin for each ingredient used in the food.
- A non-processed food would be deemed to be misbranded if its labeling fails to identify the country of origin of the food, or if the original packer's website fails to identify the country of origin of the food.

- FDA would be required to issue regulations implementing these new country of origin labeling requirements.⁵

10. Carbon Monoxide

- Meat and poultry products and seafood products treated with carbon monoxide would be required to bear a label notice reading as follows:
“CONSUMER NOTICE: Carbon monoxide has been used to preserve the color of this product. Do not rely on color or the ‘use or freeze by’ date alone to judge the freshness of the product.”

11. GRAS Substances

- Upon receiving a request to determine that a food substance is generally recognized as safe (GRAS), FDA would be required to publish a notice in the Federal Register within 60 days after receipt and to determine whether the substance is GRAS within 90 days after publishing the notice.⁶

⁵ It is not clear how these country of origin labeling requirements would interact with existing country of origin labeling requirements of the Bureau of Customs and Border Protection (CBP) and the U.S. Department of Agriculture’s Agricultural Marketing Service (AMS).

⁶ By reviving FDA’s GRAS affirmation process and shortening the time limit for GRAS determinations, this provision might effectively eliminate FDA’s current GRAS notification process for substances used in food.