APPENDIX

Major Changes to Waxman Food Safety Legislation: Comparison of May 5 and May 26 Drafts

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Name of Bill

- The new version includes a name for the bill, the "Food Safety Enhancement Act of 2009."

Registration of Food Facilities

- New version provides that owner, operator, or agent in charge of facility whose registration has been suspended may request that the suspension be vacated once the violation that is the basis for suspension has been corrected. FDA shall vacate the suspension if FDA determines that adequate reasons do not exist to continue the suspension.

- New version sets the annual registration fee at $1,000 for FY 2010, to be adjusted for each of FYs 2011-2014.

Inspection

- New version requires that the minimum frequency of inspection be based on a food facility's risk category, as follows:

  - Category 1: High-risk facilities, including any facility that manufactures or processes raw products of animal origin (including fish and fisheries products) or other foods designated by FDA, must be randomly inspected at least every 6 to 18 months;
  - Category 2: Low-risk facilities that manufacture or process food and facilities that pack or label food must be randomly inspected at least every 18 months to 3 years; and
  - Category 3: Facilities that hold food must be randomly inspected at least every 3 to 4 years.

- New version requires that inspection must be by an FDA-recognized inspector. For domestic facilities, inspection must be by a Federal, State, or local official recognized by FDA. For foreign facilities, it must be by "an agency or a representative of a country that is recognized" by FDA.

- New version omits the requirement that FDA inspect foreign facilities at least as frequently as domestic facilities.

Recordkeeping and Records Access

- New version provides that FDA shall have access to a food facility's food safety plan as well as "all records collected or developed to comply with section 418 [hazard analysis and risk-based preventive controls] or 418A [food safety plan]."

- New version would extend the maximum retention period for records of immediate previous sources and immediate subsequent recipients of food from 2 to 3 years. It would also require FDA to issue regulations amending 21 C.F.R. Part 1, Subpart J.

- New version would exempt the following foods from the requirement to have a "tracing system for food that is located in the United States or is for import into the United States": (a) food produced on a farm and sold directly to consumers or restaurants; and (b) food exempted by FDA in a *Federal Register* notice determining that tracing of such food is not needed to protect public health. In the case of foods so exempted by FDA, however, each person who produces, manufactures, processes, packs, transports, or holds the exempted food would be required to maintain records of the immediate previous sources of the food and its ingredients and the immediate subsequent recipients of the food.

- New version requires that FDA identify technologies that could be used for the "tracing system" and assess their feasibility and costs and benefits before publishing a proposed rule. It also requires FDA to hold public meetings and conduct one or more pilot projects.

Fees

- New version sets annual fee for registration of food facilities at $1,000 in FY 2010, to be adjusted for FY 2011 and each subsequent fiscal year. It would still sunset after FY 2014.

- New version provides that annual registration fee for importers and customs brokers and filers will be determined by FDA.

- New version provides that a fee would be charged if FDA needs to re-inspect a facility because of a recall.

Imports

- New version provides that FDA may require, by regulation or guidance, submission of documentation or other information for articles of food imported or offered for import, and FDA may specify the format for submission.

- New version provides that FDA may inspect the facilities of food importers and customs brokers and filers.

- New version provides that FDA shall set the annual registration fee for importers and customs brokers and filers (The fee for importers in the May 5 version had been $10,000).

- New version adds provisions on suspension and cancellation of registration for importers and customs brokers and filers. It also provides that FDA shall (not "may") condition maintenance of registration on compliance with good importer practices. Such practices include verification of good manufacturing practices (GMPs) and preventive controls by the importer's foreign suppliers.

- New version changes the conditions in which FDA may require third-party certification as a condition of admitting imported food. FDA may require certification by a "qualified certifying entity" if: (a) certification would assist FDA in making an admissibility determination with respect to food from a particular country or region due to the adequacy of government controls in that country or region or other information; (b) the food is a type of food that could pose a significant risk to health, and certification would assist FDA in determining whether the food poses such a risk; or (c) there is an agreement between FDA and the government of the exporting country providing for such certification. New version would require a qualified certifying entity to notify FDA whenever it suspends or cancels a facility's certification.

- New version makes it a prohibited act to fail to submit information, or to submit inaccurate or incomplete information, as required by the Federal Food, Drug, and Cosmetic Act (FD&C) section 801 [imports and exports] or section 802 [exports of unapproved products].

- New version would make it a prohibited act to produce, manufacture, process, prepare, pack, hold, or distribute an adulterated or misbranded food with the knowledge or intent that such food will be imported into the United States. It also provides "extraterritorial Federal jurisdiction over any violation of the FD&C Act" relating to an article of food if such food is intended for import into the United States or if any act in furtherance of the violation was committed in the United States.

Laboratory Accreditation

- New version provides that FDA may observe an accreditation body's onsite audit of a lab, and may conduct its own onsite audits of labs accredited by a recognized accreditation body. Such FDA audits may include inspection and copying of "any related records."

Fresh Produce and Other Raw Agricultural Commodities

- New version would require FDA to issue updated Good Agricultural Practices (GAPs) guidance within one year after the date of enactment.

- New version provides that FDA "shall" (not "may") establish, by regulation, science-based standards for the growing, harvesting, packing, sorting, transporting, and holding of fresh produce for which FDA determines such standards will minimize the risk of serious adverse health consequences or death to humans or animals. In addition, it extends this provision to also cover other raw agricultural commodities that are "from a plant or a fungus," not just raw fruits and vegetables.

Miscellaneous Changes

- New version deletes the provision on requiring FDA to deny approval of "critical antimicrobial animal drugs" and drugs of the same class unless the applicant can show a reasonable certainty of no harm.

- New version revises the provision on carbon monoxide (CO) used to treat meat, poultry, and seafood products. This provision now would require FDA to make an up-or-down decision to allow use of CO as a "color additive" in meat, poultry, and seafood products, or decline to do so. This amendment would apply to any use of CO beginning on the date that FDA promulgates a color additive regulation allowing its use or publishes a decision declining to do so.

- New version provides for expedited procedures in seizure actions against food. Specifically, it states that "exigent circumstances shall be deemed to exist for all seizures brought under this section, and the summons and arrest warrant shall be issued by the clerk of the court without court review in any such case."

- New version would require FDA to respond within 60 days (by posting a notice on its website and sending an acknowledgement to the requester) after receiving a request for a GRAS determination, but it would not require FDA to make an actual GRAS determination or set any deadline for doing so.

- New version provides that it does not prohibit or limit any cause of action under State law or the introduction of evidence of compliance or noncompliance with the FD&C Act.

- New version would increase the criminal penalties only for "knowing" commission of certain prohibited acts.