S. 510 – The FDA Food Safety Modernization Act

Summary of Key Provisions*

• **Inspections of Records** – If there is a reasonable probability that a food, or a related article of food, will cause serious adverse health consequences or death to humans or animals, the Food and Drug Administration (FDA) will be authorized to access relevant records for that food and any related article of food that may be similarly contaminated.

• **Registration of Food Facilities** – Food facilities as defined in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) must register with FDA and renew registration biennially. Most, if not all, facilities in the cold chain are already registered with FDA. The big change is the requirement to renew registration every two years. In addition, facility registration may be suspended if there is a reasonable probability that food from the responsible facility will cause serious adverse health consequences or death to humans or animals.

• **Hazard Analysis and Risk-Based Preventive Controls** – All registered facilities must identify known or reasonably foreseeable hazards and implement preventive controls to significantly minimize or prevent those identified hazards. Those subject to these requirements must have a written plan describing their hazard analysis and preventive controls, which shall be made available to FDA upon request. The provision provides flexible compliance timeframes for small and very small businesses, and deems facilities in compliance with existing seafood, juice, and low-acid canned foods regulations to be exempt from this section. Standards must be science-based, and the regulations are required to be flexible and minimize the burden for small businesses. FDA is also required to publish a small entity compliance guide on the new standards.

• **Authority to Collect Fees** – Allows FDA to assess fees for compliance failures (recalls and re-inspections) and for participation in a voluntary qualified importer program.

• **Sanitary Transportation of Food** – Requires FDA to promulgate regulations on the sanitary transportation of food. FDA has already initiated the rulemaking process for these regulations. GCCA is closely monitoring the progress of this rulemaking activity and working with others in the food industry as the process moves forward.
• **Targeting Inspection Resources** – Requires FDA to allocate food inspection resources according to the risk profile of the facility and other important criteria. Facilities deemed “high risk” would be inspected no less that once every two years. “Low risk” facilities would be inspected no less than once every four years. The legislation gives FDA general direction on risk characteristics, but the agency will have some discretion as it defines the risk categories.

• **Enhancing Tracking and Tracing of Food and Recordkeeping** – Requires FDA, in coordination with the food industry, to establish pilot projects to test and evaluate new methods for rapidly and effectively tracking and tracing food products to prevent and mitigate foodborne illness outbreaks. FDA shall, in consultation with USDA, establish a product tracing system within the FDA based on these pilots, and shall develop additional recordkeeping requirements for foods determined to be “high risk.” Ensures methods and requirements are appropriate for small businesses, and exempts or limits requirements for farms, restaurants, raw agricultural commodities, and fishing vessels. Requires GAO to conduct an examination and provide recommendations regarding the effectiveness of these new requirements.

• **Mandatory Recall Authority** – Gives FDA the authority to order food recalls when firms fail to voluntarily recall products that are either adulterated or contain undeclared allergens and which will cause serious adverse health consequences or death to humans or animals.

• **Administrative Detention** – Allows FDA to use administrative detention to hold food for a short period of time when FDA has reason to believe that a food is adulterated or misbranded.

• **Foreign Supplier Verification Program** – Requires importers to perform food safety supplier verification activities to mitigate risks in imported foods and ensure that imported foods are as safe as those manufactured and sold in the United States. Importation of a food by an importer who does not have such a program in place is prohibited. Importers already in compliance with existing seafood, juice, and low-acid canned foods regulations are exempted from this requirement.

• **Voluntary Qualified Importer Program** – Allows importers to qualify for expedited review and importation of food if they go above and beyond the minimum standards to ensure the safety of imported food.

• **Authority to Require Import Certifications for Food** – Allows FDA to require certification or other assurance of safety for high-risk food imports. Requires the Secretary of Health and Human Services to consider public health factors when requiring certifications for high risk
foods, including (1) known safety risks of the food, (2) known safety risks of the country of origin, (3) inadequate government controls in country of origin, and (4) information submitted by the country of origin related to the quality of its government controls. FDA may refuse admission of a food import lacking required certification.

- **Inspection of Foreign Food Facilities** – Allows FDA to enter into agreements and arrangements with foreign governments to facilitate the inspection of foreign facilities. Prohibits entry of food from a foreign facility or country that fails to permit inspection by the United States. Also authorizes the Department of Commerce, in coordination with HHS, to assess foreign facilities that import seafood into the United States and provide technical assistance.

- **Employee protections** – Prohibits retaliation by manufacturers, processors, packagers, transporters, distributors, receivers, holders, or importers against their employees who have, in relation to potential or real food safety violations, provided information to officials, assisted or testified in violation proceedings, or refused to participate in any work-related activity that they believe may be a food safety violation.

*NOTE: This document is intended to provide a summary of key provisions impacting the cold chain industry; it does not represent an exhaustive list of all provisions contained in the legislation.*