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November 16, 2010

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Available Online: [dpc.senate.gov](http://dpc.senate.gov)

## **S. 510, the *Food Safety Modernization Act***

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# Summary

During the November work period the Senate may consider **S. 510**, the *FDA Food Safety Modernization Act*. The Senate's consideration of this legislation has been preceded by over a year of bipartisan work from, among others, Senators **Durbin, Harkin, Dodd**, Alexander, Burr, Gregg, and the late Senator **Kennedy**.

This bipartisan legislation would overhaul our current food safety system, which has failed to protect far too many Americans and will continue to fail them unless Congress improves the nation's food safety laws. The legislation would address a number of the weaknesses of the current system by, among other provisions:

- Giving the Food and Drug Administration (FDA) the authority to recall foods when firms fail to voluntarily recall products on their own, when a food is adulterated or contains undeclared allergens and will cause serious adverse health consequences or death to humans or animals;
- Requiring the Secretary of Health and Human Services (HHS), within three years of enactment, to publish a notice of proposed rulemaking that would establish a national trace-back system;
- Requiring food importers to perform food safety supplier verification activities and prohibit the importation of food by an importer if they do not undertake food safety supplier verification activities;
- Expands the nation's current food facility registration laws requiring all food facilities (excluding farms) to register with the FDA biennially and gives the FDA the authority and the assurance that it will be permitted to inspect registered facilities as permitted; and
- Requires all registered domestic facilities (excluding farms) to identify known or reasonably foreseeable hazards and implement preventive controls to significantly minimize or prevent those identified hazards.

## Major Provisions

### ***Title I—Improving Capacity to Prevent Food Safety Problems***

**Section 101—inspection of records.** The *FDA Food Safety Modernization Act* would give the FDA expanded access to food facility records (excluding farms and restaurants) if:

- The Secretary of HHS has a reasonable probability that a food or a related article of food will cause serious adverse health consequences or death to humans or animals.

**Section 102—registration of food facilities.** The *FDA Food Safety Modernization Act* would expand current registration requirements for food facilities by:

- Requiring all food facilities to register and renew their registration biennially;

- Granting FDA the authority to adjust food registration categories; and
- Giving the Secretary of HHS the authority to suspend facility registration if there is a reasonable probability that food from the facility will cause serious adverse health consequences or death to humans or animals.

**Section 103—hazard analysis and risk-based preventive controls.** The *FDA Food Safety Modernization Act* would require:

- All registered domestic facilities to identify known or reasonably foreseeable hazards and implement preventive controls to significantly minimize or prevent those identified hazards; and
- Each owner or operator to have a written plan describing their hazard analysis and preventative controls, which shall be made available to FDA upon request. Failure to comply with this section is a prohibited act under the Federal Food, Drug, and Cosmetic Act.

**Section 104—performance standards.** The *FDA Food Safety Modernization Act* would require the FDA, not less than every two years, to:

- Determine the most significant food-borne contaminants; and
- When appropriate, issue science-based guidance documents, action levels, and/or regulations in order to prevent and reduce the risk of serious illness or death, adulteration, or the spread of communicable disease.

**Section 105—standards for produce safety.** The *FDA Food Safety Modernization Act* would give the FDA authority to:

- Set commodity-specific standards for the safety of fresh produce. The states may apply for variances from the standards due to local growing conditions.

**Section 106—intentional adulteration.** The *FDA Food Safety Modernization Act* would require the FDA, working with the Department of Homeland Security (DHS) and the Department of Agriculture (USDA), to:

- Conduct vulnerability assessments and issue regulations to protect against the intentional adulteration of food.

**Section 107—authority to collect fees.** The *FDA Food Safety Modernization Act* would:

- Allow the FDA to assess fees for compliance failures (recalls and re-inspections) and participate in a voluntary qualified importer program.

The legislation would also require appropriated funding to keep pace in order for fees to be collected.

**Section 108—national agriculture and food defense strategy.** The *FDA Food Safety Modernization Act* would require HHS and USDA, in consultations with DHS, to:

- Develop a National Agriculture and Food Defense Strategy and research agenda, including specific emergency preparedness, detection, response, and recovery goals.

**Section 109—food and agriculture coordinating councils.** The *FDA Food Safety Modernization Act* would require DHS, in consultation with HHS and USDA, to:

- Report to Congress on the activities of the government and private sector coordinating councils for agriculture and food defense, which are designed to improve information sharing between government and private sector partners in protecting the food system.

**Section 110—building domestic food safety capacity.** The *FDA Food Safety Modernization Act* requires a series of reports and actions intended to focus FDA's attention on several challenges, including:

- Information technology;
- Data sharing;
- Research; and
- Government capacity.

**Section 111—sanitary transportation of food.** The *FDA Food Safety Modernization Act* would require the FDA to:

- Promulgate regulations on the sanitary transportation of food pursuant to section 416(b) of the Federal Food, Drug, and Cosmetic Act.

**Section 112—food allergy and anaphylaxis management in children.** The *FDA Food Safety Modernization Act* directs HHS, in consultation with the Department of Education, to develop voluntary food allergy management guidelines to manage the risk of food allergy and anaphylaxis in schools or early childhood education programs. The legislation would also provide for non-renewable food allergy management incentive grants for up to two years to assist local educational agencies (LEAs) with adoption and implementation of the voluntary food allergy management guidelines.

**Section 113—new dietary ingredients.** The *FDA Food Safety Modernization Act* would require the FDA to:

- Submit information to DEA if it denies a New Dietary Ingredient notification on the grounds that the dietary ingredient may contain an illegal steroid, and FDA must publish a guidance that clarifies regulation of new dietary ingredients in 180 days.

**Section 114—post harvest processing of raw oysters.** The *FDA Food Safety Modernization Act* would require the FDA to:

- Conduct public health and cost assessments before issuing any guidance or rulemaking related to post harvest processing of raw oysters.

**Section 115—port shopping.** The *FDA Food Safety Modernization Act* would require that until FDA publishes its final rule on the marking of food imports that are refused entry into the United States (as required by the Bioterrorism Act) that the FDA:

- Notify DHS of all instances in which it refuses to admit a food into the United States so that DHS, acting through Customs and Border Protection, can notify all ports in the United States and thereby prevent food that is refused in one port from being admitted into the country by another.

**Section 116—alcohol-related facilities.** The *FDA Food Safety Modernization Act* would require the FDA to:

- Exempt facilities that manufacture alcoholic beverages from several sections of the bill, including the preventive control requirements in section 418.

## ***Title II: Improving Capacity to Prevent Food Safety Problems***

**Section 201—targeting inspection resources.** The *FDA Food Safety Modernization Act* would require the FDA to:

- Allocate food inspection resources according to the risk profile of the facility and other important criteria;
- Increase the frequency of inspections at all facilities, with high-risk facilities inspected annually and other facilities inspected at least once every four years; and
- Submit an annual report to Congress regarding the frequency of, and costs associated with, inspections.

**Section 202—laboratory accreditation.** The *FDA Food Safety and Modernization Act* would direct the FDA to:

- Recognize laboratory accreditation bodies that accredit food testing laboratories and to establish a publicly available registry of those bodies;
- Require all laboratory testing done for FDA regulatory purposes to be conducted by either an FDA lab or a lab accredited by an FDA-recognized accreditation body; and
- Require a report to Congress on the implementation of the national laboratory Food Emergency Response Network to support early detection, rapid response, and management of food-related emergencies.

**Section 203—integrated consortium of laboratory networks.** The *FDA Food Safety and Modernization Act* would require DHS to work with HHS, Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) to effectively integrate laboratory networks and other relevant data sources to optimize national preparedness by:

- Quickly sharing information;

- Conducting analyses; and
- Alerting responders.

**Section 204—enhancing traceback and recordkeeping.** The *FDA Food Safety and Modernization Act* would require the FDA, in coordination with the produce industry, to:

- Establish pilot projects to test and evaluate new methods for rapidly and effectively tracking and tracing fruits and vegetables;
- Ensure that methods are appropriate for small businesses; and
- After completion of the pilot project, to establish standards for the types of information, information format, and timeframes for submission of food records to aid the Secretary in rapidly performing traceback activities in the event of a food-borne illness outbreak.

**Section 205—pilot project to enhance traceback and recordkeeping with respect to processed food.** The *FDA Food Safety and Modernization Act* would require the Secretary of HHS to establish a pilot project to:

- Explore and evaluate methods for rapidly and effectively tracking and tracing processed food, so that, if an outbreak which involves processed food occurs, the source of the outbreak and recipients of the contaminated food may be quickly identified.

**Section 206—surveillance.** The *FDA Food Safety and Modernization Act* would:

- Require the Secretary to enhance food-borne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on food-borne illnesses;
- Establish a diverse working group of experts and stakeholders from federal, state, and local food safety and health agencies, the food industry, consumer organizations, and academia to provide recommendations on an ongoing basis regarding the improvement of food-borne illness surveillance; and
- Require the Secretary to develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies.

**Section 207—mandatory recall authority.** The *FDA Food Safety and Modernization Act* would give the FDA Commissioner the authority to:

- Order food recalls when firms fail to voluntarily recall products on their own, or when a food is adulterated or contains undeclared allergens and will cause serious adverse health consequences or death to humans or animals.

**Section 208—administrative detention.** The *FDA Food Safety and Modernization Act* would allow the FDA to:

- Use administrative detention when the FDA has reason to believe that a food is adulterated or misbranded.

**Section 209—decontamination and disposal standards and plans.** The *FDA Food Safety and Modernization Act* would require the EPA, in coordination with HHS, DHS, and USDA, to:

- Develop decontamination and disposal standards and protocols to help state and local governments prepare for a food or agriculture emergency.

**Section 210—training of state, local, territorial and tribal food safety officials.** The *FDA Food Safety and Modernization Act* would require the Secretary to:

- Administer training and education programs for State, local, territorial, and tribal food safety official employees.

This training relates to the regulatory responsibilities and other policies established by this legislation.

**Section 211—grants to enhance food safety.** The *FDA Food Safety and Modernization Act* would authorize the Department of Health and Human Services to:

- Make grants to states, localities, and Indian tribes to improve local food safety programs;
- Improve state laboratories; and
- Train state officials to conduct food safety inspections.

### ***Title III: Improving the Safety of Imported Food***

**Section 301—foreign supplier verification program.** The *FDA Food Safety and Modernization Act* would require importers to:

- Perform food safety supplier verification activities to mitigate risks in imported foods; and
- Prohibit the importation of food by an importer if they do not undertake food safety supplier verification activities.

Importers of seafood, juice, and low-acid canned food that comply with existing regulations would be deemed to be in compliance with this section.

**Section 302—voluntary qualified importer program.** The *FDA Food Safety and Modernization Act* would allow 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.

**Section 303—authority to require import certifications for food.** The *FDA Food Safety and Modernization Act* would allow the FDA to:

- Require certification or other assurance of safety for high-risk food imports.

The legislation also includes a provision which states that FDA may refuse admission of a food import lacking required certification.

**Section 304—prior notice of imported food shipments.** The *FDA Food Safety and Modernization Act* would require:

- HHS to issue an interim final rule that would require prior notice for an imported food to include the name of any country that refused entry of the food.

**Section 305—building capacity of foreign governments with respect to food.** The *FDA Food Safety and Modernization Act* would require the FDA to:

- Develop a comprehensive plan to help expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries.

**Section 306—inspection of foreign food facilities.** The *FDA Food Safety and Modernization Act* would allow the FDA to:

- Enter into agreements and arrangements with foreign governments to facilitate the inspection of foreign facilities; and
- Refuse entry of food from a foreign facility or country that fails to permit inspection by the United States.

**Section 307—accreditation of third-party auditors and audit agents.** The *FDA Food Safety and Modernization Act* would direct the FDA to:

- Recognize accreditation bodies to accredit third parties to certify that foreign food facilities are in compliance with U.S. food safety standards; and
- Use third party certification for participation in the Voluntary Qualified Importer Program or to fulfill import certification requirements established by the FDA.

**Section 308—foreign offices of the FDA.** The *FDA Food Safety and Modernization Act* would direct the FDA to:

- Establish offices in at least five foreign nations to improve the agency's presence overseas and positively impact the safety of FDA-regulated products.

**Section 309—smuggled food.** The *FDA Food Safety and Modernization Act* would require the Secretary of HHS to consult with the Secretary of DHS, Commissioner of Customs and Border Protection, and the Assistant Secretary for Immigration and Customs Enforcement to:

- Develop and implement a strategy to better identify smuggled food and prevent its entry into the United States.

#### ***Title IV: Miscellaneous Provisions***

**Section 401—funding for food safety.** The *FDA Food Safety and Modernization Act* would:

- Increase funding for FDA food safety functions; and
- Direct the FDA to incrementally increase field staff by 2014.

**Section 402—whistleblower protections.** The *FDA Food Safety and Modernization Act* would prohibit 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.

**Section 403—jurisdiction.** The *FDA Food Safety and Modernization Act* would clarify that:

- Amendments made by this bill do not change jurisdiction between FDA and USDA; and
- FDA retains its current food safety authority under the FDCA and the Public Health Service Act.

**Section 404—compliance with international agreements.** The *FDA Food Safety and Modernization Act* stipulates that:

- Nothing in the act is to be construed in a manner that is inconsistent with agreements with the World Trade Organization or other international treaties or agreements.

## Legislative History

On March 3, 2009, **S. 510** was introduced by Senator **Durbin** and the bill was referred to the Health, Education, Labor, and Pensions Committee. When introduced, the bill enjoyed bipartisan support and six original cosponsors: Senators **Dodd**, **Kennedy**, Alexander, Burr, Gregg, and Isakson.

On November 18, 2009, the Health, Education, Labor, and Pensions Committee approved the legislation by voice vote.

On December 18, 2009, the Health, Education, Labor, and Pensions Committee reported the legislation to the Senate floor with an amendment. When placed on the Senate calendar, the legislation had garnered further bipartisan support with nine additional cosponsors: Senators **Bingaman**, **Burr**, **Gillibrand**, **Harkin**, **Klobuchar**, **Udall (NM)**, Chambliss, Enzi, and Hatch.

The Health, Education, Labor, and Pensions Committee released a Manager's Amendment to **S. 510** on August 12, 2010.

## Expected Amendments

The DPC will distribute information on amendments as it becomes available to staff listservs.

## Administration Position

At the time of publication, the Administration had not released a Statement of Administration Policy on **S. 510**.

## Resources

Democratic Policy Committee, “Recent Food Safety Incidents in FDA Regulated Products,” available [here](#).

Democratic Policy Committee, “Food Safety Statistics Index,” available [here](#).

Democratic Policy Committee, “Democratic, Republican, and Non-Partisan Food Safety Recommendations Addressed in Senate’s Food Safety Bill,” available [here](#).

Democratic Policy Committee, “Food Safety and Agricultural Producers,” available [here](#).