

Food Safety Bill to Become Law in 2011

(28 December 2010) Several weeks ago, S. 510 passed the Senate but was found to have an unconstitutional provision and thus did not move swiftly to the House for passage. By most accounts, food safety was considered a dead issue in the waning days of the Lame Duck session of the 111th Congress.

However, in a surprise maneuver by Senate Majority Leader Harry Reid, food safety legislation was passed under a unanimous consent procedure on Sunday, December 19, 2010. Some are reporting that as few as two senators were in the Chamber at the time.

Senator Tom Coburn, the lone hold out to the Bill, who repeatedly stated his objections to S. 510 negotiated on a bigger picture issue – and did not object to the final passage. As we learned the next day, the Senate Democrats had the votes to pass a Continuing Resolution with the food safety tacked on, opening the door for hundreds of other ear marks to be added on. Sadly, only Senator Coburn was holding out on the Republican side, so with minor revisions that will be reported below, HR 2751 passed the Senate by a voice vote of Unanimous Consent. The negotiation was, to pass a modified version of S510 on another House bill in order to satisfy the Parliamentarian. This move saved tax payers billions in ear-marks this fiscal year.

In what was technically a legal maneuver, but by many American's perspectives, a slick political maneuver, **HR 2751**, originally entitled, **Consumer Assistance to Recycle and Save Act** was used as the vehicle to pass food Safety. The Senate leadership took HR 2751 which has originated in the House so they could resolve the constitutional provision that requires all bills that create new taxes come from the House, they changed its name to **FDA Food Safety Modernization Act** and removed all the provisions of the original bill which was to "...accelerate motor fuel savings nationwide and provide incentives to registered owners of high polluting automobiles to replace such automobiles with new fuel efficient and less polluting automobiles" and converted it to the Food Safety Bill.

The original version of HR 2751 focused on fuel recycling had passed the House in June 2009 with a vote of 298 to 119. The Senate passed the revised HR 2751 and returned it to the House for passage, no conference process took place. Instead, the House voted and passed HR2751 after one hour of debate by a vote of 215 to 144. The Bill has been sent to the White House for signature by the President to make it public law.

Ripped from the Headlines Legislation

CodexFund.com has reported throughout the 111th Congress Congressional action on food safety legislation that was introduced after a number of food safety alerts across the United States. This type of legislation can be known as 'ripped from the headlines' legislation because the stories in the media about tainted spinach, tainted eggs, and adulterated products from China were used in concert with the behind the scenes push by FDA supporters who want to see the agency get more power and staff to get Congress to act. What gets lost in most of these discussions is typically, the issues arose as a result of a failure for those in positions of authority to do fulfill their duties.

Using the egg recall as an example, one government agency who inspected the farm in which the eggs were produced in unsanitary conditions, failed to notify the FDA who had new broader authorities under the recently finalized egg production regulations. Furthermore, the concerns about products imported from China are not new concerns. These concerns have been expressed for two decades, and the authority to inspect imported food products existed through these two decades. What did not exist was the will by the authorities to be more aggressive with imported food inspections and implement existing laws.

Standing Up For US Law

As a result of the consistent and persistent grass roots efforts of the Codexfund.com and other organizations, a year ago, Senators Tom Harkin and Orrin Hatch confirmed during Committee proceedings that the US Food and Drug Administration (FDA) were not allowed to simply to adopt or harmonize recommendations of the Codex Alimentarius Commission. They confirmed that only Congress could change the laws as they relate to dietary supplements. This was a great victory for us. Throughout 2010, we have educated legislators about your concerns with proposed food safety legislation. We worked hand in hand with key legislative staff and members to make improvements, and to remove deleterious provisions. We repeatedly delivered thousands of letters throughout the year to alert Senators about concerns with S. 510, the food safety bill. These efforts were important in stemming the tide of those who were pushing from the pro-government control positions.

Nine months into 2010, Senator Harkin introduced a revised version of S. 510 known as the Manager's Amendment. In this revision, a seemingly minor edit, with major implications was made regarding Codex. Section 306 for example originally included a provision which called for the Secretary of Health in coordination with the Secretary of Agriculture and other agencies to "develop a comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments, and their respective food industries, from which foods are exported to the United States" to include, "Recommendations to harmonize requirements under the Codex Alimentarius." . Because of your efforts, the Codex provision was changed to read, "*Recommendations on whether and how to harmonize requirements under the Codex Alimentarius.*" This tiny edit means that harmonization with Codex on all food categories is not automatic. A subsequent conforming amendment detailed below again reiterates that no harmonization activities can undermine DSHEA.

Objections to the Bill reached across many constituencies. The health freedom/dietary supplement community was the first to speak out. They were followed closely by the small farmers, organics community, and after both Bill O'Reilly and Glenn Beck talked about the issue, even the Tea Party began voicing concerns. Objections included the cost, the growth of government, and the reality that expanding government regulations affects small businesses adversely and will also drive the cost of food higher. The affect on road side food stands and Farmer's Markets was addressed

The Final Food Safety Bill

There was one change from the Bill that originally passed the Senate and that which was passed under HR 2751. In Section 743, a limitation on the use and amount of fees the FDA can charge related to issuing food exportation certificates.

The Congressional Research Service Provided the following summary of the Bill:

*FDA Food Safety Modernization Act - **Title I: Improving Capacity to Prevent Food Safety Problems** - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to expand the food safety activities of the Secretary of Health and Human Services (HHS), including to authorize the Secretary to inspect records related to food.*

Exempts certain establishments that sell food directly to consumers, such as roadside stands, farmers markets or participants in a community supported agriculture program, from specified requirements of this Act.

Requires each owner, operator, or agent in charge of a food facility to identify and implement preventive controls to significantly minimize or prevent hazards that could affect food manufactured, processed, packed, or held by such facility. Sets forth provisions governing exemptions from such requirements for certain facilities.

Requires the Secretary to: (1) issue guidance documents to reduce the risk from the most significant foodborne contaminants; and (2) establish minimum standards for the safe production and harvesting of fruits and vegetables based on known safety risks. Authorizes the Secretary to issue exemptions and variances from such standards.

Directs the Secretary to assess and collect fees related to: (1) food facility reinspection; (2) food recalls; (3) the voluntary qualified importer program; and (4) importer reinspection. Directs the Secretary to develop voluntary food allergy and anaphylaxis management guidelines for schools and early childhood education programs.

***Title II: Improving Capacity to Detect and Respond to Food Safety Problems** - Requires the Secretary to: (1) allocate resources to inspect facilities and imported food according to the known safety risks of the facilities or food; and (2) establish a product tracing system to track and trace food that is in the United States or offered for import into the United States.*

Requires the Secretary, acting through the Director of the Centers for Disease Control and Prevention (CDC), to enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses.

Gives the Secretary the authority to order a recall of an article of food.

***Title III: Improving the Safety of Imported Food** - Requires U.S. importers to perform risk-based foreign supplier verification activities to verify that imported food is produced in compliance with applicable requirements related to hazard analysis and standards for produce safety and is not adulterated or misbranded.*

Requires the Secretary to establish a program to expedite review and importation of food offered for importation by U.S. importers who have voluntarily agreed to participate in such program.

Authorizes the Secretary to: (1) require a certification that an article of food imported or offered for import complies with applicable requirements of this Act; and (2) enter into arrangements and agreements with foreign governments to facilitate the inspection of registered foreign facilities. Requires food to be refused admission into the United States if permission to inspect the food facility is denied by the facility owner, operator, or agent or the foreign country.

Sets forth provisions governing the establishment of a system to recognize bodies that accredit third-party auditors and audit agents to certify that foreign entities meet applicable FFDCa requirements for importation of food into the United States.

Title IV: Miscellaneous Provisions - *Authorizes appropriations for FY2011-FY2015 for the activities of the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities in the Office of Regulatory Affairs of the Food and Drug Administration (FDA). Directs the Secretary to increase the field staff of such Centers and Office.*

Establishes whistleblower's protections for employees of entities involved in the manufacturing, processing, packing, transporting, distribution, reception, holding, or importation of food who provide information relating to any FFDCa violation.

Without question, this Bill gives the FDA a lot more power than most citizens are comfortable with. Furthermore, it will be expensive and grow the size of the FDA staff tremendously. FDA is expanding its reach onto foreign soil and creating massive databases of information about every aspect and organization involved with the growth, manufacture and production of food ingredients and products. There will be massive new paperwork requirements for businesses to comply with, and fear that once the FDA does one inspection they will insist on re-inspections, which the business will have to pay for. The cost of food products for consumers many of whom are struggling to survive will most certainly rise. Furthermore, the expanded levels of bureaucracy may cost jobs and mean the end of some small businesses who cannot stay afloat while conforming to the new law.

Dietary supplements were specifically mentioned in several sections of the law. This information is provided below.

Dietary Supplement Specific Language

While all food regulations also effect dietary supplements, unless they are specifically exempted, the following language in the new law is specific to dietary supplements.

New Dietary Ingredients

Since the passage of DSHEA in 1994, the FDA has failed to publish guidelines on new dietary ingredients. Section 113 addresses concerns of a number of legislators regarding steroids being marketed as supplements.

“(c) NOTIFICATION.—

“(1) IN GENERAL.—If the Secretary determines that the information in a new dietary ingredient notification submitted under this section for an article purported to be a new dietary ingredient is inadequate to establish that a dietary supplement containing such article will reasonably be expected to be safe because the article may be, or may contain, an anabolic steroid or an analogue of an anabolic steroid, the Secretary shall notify the Drug Enforcement Administration of such determination. Such notification by the Secretary shall include, at a minimum, the name of the dietary supplement or article, the name of the person or persons who marketed the product or made the submission of information regarding the article to the Secretary under this section, and any contact information for such person or persons that the Secretary has.

“(2) DEFINITIONS.—For purposes of this subsection— ‘(A) the term ‘anabolic steroid’ has the meaning given such term in section 102(41) of the Controlled Substances Act; and ‘(B) the term ‘analogue of an anabolic steroid’ means a substance whose chemical structure is substantially similar to the chemical structure of an anabolic steroid.’”

(b) GUIDANCE.—Not later than 180 days after the date of enactment of this Act, the Secretary shall publish guidance that clarifies when a dietary supplement ingredient is a new dietary ingredient, when the manufacturer or distributor of a dietary ingredient or dietary supplement should provide the Secretary with information as described in section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the evidence needed to document the safety of new dietary ingredients, and appropriate methods for establishing the identity of a new dietary ingredient.

International Harmonization Issues Will Not Affect DHSEA

In Section 305, entitled Building Capacity of Foreign Government with Respect to Food Safety, a clarification again was included that DSHEA is protected.

SEC. 305. BUILDING CAPACITY OF FOREIGN GOVERNMENTS WITH RESPECT TO FOOD SAFETY.

(a) IN GENERAL.—The Secretary shall, not later than 2 years of the date of enactment of this Act, develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries, from which foods are exported to the United States.

(b) CONSULTATION.—In developing the plan under subsection (a), the Secretary shall consult with the Secretary of Agriculture, Secretary of State, Secretary of the Treasury, the Secretary of Homeland Security, the United States Trade Representative, and the Secretary of Commerce, representatives of the food industry, appropriate foreign government officials, nongovernmental organizations that represent the interests of consumers, and other stakeholders.

(c) PLAN.—The plan developed under subsection (a) shall include, as appropriate, the following:

- (1) Recommendations for bilateral and multilateral arrangements and agreements, including provisions to provide for responsibility of exporting countries to ensure the safety of food.*
- (2) Provisions for secure electronic data sharing.*
- (3) Provisions for mutual recognition of inspection reports.*
- (4) Training of foreign governments and food producers on United States requirements for safe food.*
- (5) Recommendations on whether and how to harmonize requirements under the Codex Alimentarius.*
- (6) Provisions for the multilateral acceptance of laboratory methods and testing and detection techniques.*
- (d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417).***

Section 103 –Hazard Analysis

The hazard analysis and extensive documentation requirements of Section 103 do not apply to dietary supplements.

(g) DIETARY SUPPLEMENTS.—Nothing in the amendments made by this section shall apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of sections 402(g)(2) and 761 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2), 379aa–1).

Exemptions Can Be Lifted

While small businesses, farmer’s markets, road side stands and dietary supplements were exempted from certain provisions, the Congress included an exemption to the exemption.

In the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to an exemption under this subsection, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, the Secretary may withdraw the exemption provided to such facility under this subsection.

What Can We Do Now?

There will over the next few years be a series of public meetings and proposed rules issued to implement this law. Codexfund.com will monitor these activities, keep you informed and alert you when and how to take action to have your voice heard.

With more than 50 new members of Congress coming to Washington in January, we will be busy educating and re-educating legislators and staff about issues that matter to Codexfund.com supporters. We are developing a proactive legislative agenda for the 112th Congress which we will share early in 2011. Our goal is to facilitate a course correction within statutes and

regulations to favor the citizenry. Remember we are a government, 'of the People, by the People, and for the People'. Our desire is to implement that as it affects dietary supplements and health freedom. Your thoughts on this are always welcomed.

2011 New Years Website Update

With the launch of a new legislative year, and to prevent confusion, we will be archiving much of the information from the last year and launching a revised site shortly. If you have ideas or information you would like to see included, please let us know by emailing info@codexfund.com.