

To: Our Clients and Friends

December 1, 2009

Senate Health, Education, Labor, and Pensions (HELP) Committee Mark Up of S. 510, *The FDA Food Safety Modernization Act*

On Wednesday, November 18, 2009, the Senate Health, Education, Labor, and Pensions (HELP) Committee held an executive session to mark up S. 510, The FDA Food Safety Modernization Act. S. 510 was introduced by Assistant Majority Leader, Senator Dick Durbin (D-IL) in March of 2009 and currently has 11 co-sponsors¹. The U.S. House of Representatives passed similar legislation in the Food Safety Enhancement Act of 2009 (H.R. 2749) on July 30, 2009.

Opening Statements and Introductory Remarks

Senator Tom Harkin (D-IA), Chairman of the HELP Committee, opened the executive session of the with statistics from the Centers from Disease Control and Prevention that estimate that food-borne disease causes approximately 76 million illnesses in the United States each year, including 325,000 that result in hospitalization and 5,000 that result in death. Senator Harkin said that these facts must be a call to action.

Senator Harkin went on to thank all of the committee members for their efforts on the legislation, noting that the whole committee made an effort to work together and that almost every committee member made a significant contribution to the bill (and acknowledged them individually, including Senator Oren Hatch (R-UT) for his work on ensuring harmony with laws governing dietary supplements, and Senator Christopher Dodd (D-CT) for his work on food allergen labeling). He highlighted that, importantly, the legislation included provisions for essential preventative controls, surveillance and response measures, and control of imports. Senator Harkin then asked to be added as a cosponsor to S. 510.

Senator Harkin also took a moment to note that the Dietary Supplement Health and Education Act (DSHEA) and other laws govern dietary supplements, and not the Codex (a set of international standards for, among other things, dietary supplements). While the laws governing dietary supplements in the United States are adequate, there is still an issue with these laws not being in harmony with international standards.

Senator Michael Enzi (R-WY), Ranking Member of the Senate HELP Committee also gave an opening statement, again noting the bipartisan and cooperative efforts in moving the bill forward. He expressed that, in addition to the provisions contained in the bill, he would direct the FDA to work more closely with states on food safety issues. He also emphasized the importance of giving proper attention to small businesses and traceability issues. Senator Enzi is most concerned with the burden on the FDA, and that Congress must be sure to properly fund FDA to carry out their duties under the legislation. Senator Enzi believes that user fees are an unfair tax and a conflict of interest because it asks the industry to pay for its own regulation and at the same time, makes FDA financially dependent on the very industry it seeks to regulate. Senator Enzi also asked to be added as a cosponsor of the bill.

¹ Senator Lamar Alexander (R-TN), Senator Richard Burr (R-NC), Senator Roland Burris (D-IL), Senator Saxby Chambliss (R-GA), Senator Christopher Dodd (D-CT), Senator Kirsten Gillibrand (D-NY), Senator Judd Gregg (D-NH), Senator Johnny Isakson (R-GA) Senator Edward M. Kennedy (D-MA), Senator Amy Klobuchar (D-MN), and Senator Tom Udall (D-NM).

Several other Senators also gave remarks, but generally kept them brief in order to move quickly through the mark up session. Senator Dodd emphasized the problem of food allergies (his daughter has a severe peanut allergy). Senator Judd Gregg (R-NH) emphasized giving the FDA resources to carry out their duties under the bill including monitoring authority, mandatory recalls, import controls, and improving the traceability of food. In the interest of time, Senator Harkin asked other members to submit their statements for the record, but several Senators wished to make brief comments. Senator Jack Reed (D-RI) expressed concern about increased use of antibiotics in animals that are not sick and how those antibiotics might transfer to humans. Senator Lamar Alexander (R-TN) noted that there should be a balance between highlighting the successes of schools in controlling food allergies with helping other schools implement good systems. Senator Pat Roberts (R-KS) expressed concern about the impact of this bill on trade agreements with other countries, particularly Mexico and Canada and noted that there must be public involvement in developing regulations under the bill, and those regulations must be based on science and public input.

Amendments

Chairman's Mark

Senator Harkin introduced the Chairman's amendment in the nature of a substitute. The amendment was accepted unanimously.

Additional Amendments

After the Chairman's Mark was unanimously approved, several Senators introduced amendments to S. 510. All of these amendments were subsequently withdrawn, with the idea that the concepts would be worked into the legislation as it moved to the Senate floor. Below is a description of the amendment and the accompanying commentary.

Brown #1

Senator Sherrod Brown (D-OH) introduced an amendment that would create increased food traceability forward and backward through the system. He referenced S. 425, which he introduced earlier this session, and noted that while Section 204 of S. 510 is a good start to improving food traceability, it does not go far enough. For example, there needs to be traceability for processed foods, such as peanut butter, particularly given the food safety emergency created by peanut butter. Senator Brown also recommended that the FDA have increased authority to trace food based on the outcome of a report by the Office of Inspector General (OIG) at the U.S. Department of Health and Human Services (HHS), where the OIG attempted to trace 40 products through the food system, and were only able to trace 4.

Murkowski #1

Senator Lisa Murkowski (D-AK) prefaced the discussion of her amendment by asked that food safety be considered in the context of small villages (of which there are many in Senator Murkowski's home state of Alaska) that depend on air transportation to get their food. However, her amendment concerned an expansion of the Country of Origin Labeling (COOL) law to include cooked and canned seafood products (which, although previously considered in the COOL regulations, were not included in the final rule). She emphasized that this issue is very important to Alaska and its fishing industry because canned salmon is the top form of salmon products, and so its absence from the final COOL regulations is a huge omission. She elaborated that Alaska is in major competition with Russia in this product category. Alaska Department of Agriculture requires that canned salmon be caught in Alaska, processed in the United States (where it is subject to Hazard Analysis & Critical Control Points (HACCP) standards) and never frozen. Foreigners can catch salmon in Alaskan waters, but then freeze it, send it to China for canning, and import it into the United States. Customers have no way to know the difference between these two products.

Merkley #1

Senator Jeff Merkley (D-OR) introduced an amendment to address the issue of claims on infant formula products. He emphasized that claims on these kinds of products is particularly important because: (1) infant formula, when used, is often an infant's sole source of food; and (2) the Women, Infants and Children (WIC) program, funded by tax-payer dollars, purchases 60 percent of formula and purchasing decisions are often based on these claims because they are appealing (i.e. "helps with colic"). Currently, manufacturers are not required to obtain FDA approval for claims on infant formulas, nor are they even required to substantiate these claims. FDA needs to be given the authority to regulate these claims and require that they be based on science.

Hagan #1

Senator Hagan (D-NC) introduced an amendment to protect small farmers from recall errors. She explained how the tomato recall that turned out to be a false alarm almost wiped out a small North Carolina farm. She emphasized that large-scale recalls must be done with extreme care, but we must also find solutions to protect small farms from the government's mistakes.

Roberts #2 and #3 (discussed together)

Senator Roberts opted to discuss the separate amendments together in the interest of saving time. He expressed his concern that the FDA's mandatory recall authority could have significant adverse effects on producers and farmers. Amendment #2 would direct FDA to develop regulations about how they will handle sensitive information – information that a firm is required to disclose by way of providing records related to all food during an FDA inspection or investigation – in order to prevent disclosure of trade secrets and proprietary information. These regulations should include some way of keeping a record of which records have been received by FDA. Amendment #3 would exempt farms and facilities from double regulation under USDA and FDA.

Brown #2 (co-sponsored by Senator Merkley)

In Senator Brown's absence, the amendment was presented by the amendment's cosponsor, Senator Merkley, who explained that 92 percent of consumers want to know where their food comes from. For this reason, Country of Origin Labeling (COOL) should be required for all processed food.

Conclusion and Resources

Since all of the amendments introduced in the committee meeting were subsequently withdrawn (as noted above), there were no votes on the amendments. After agreeing that a quorum was present, there was a motion to report the bill as amended (by the Chairman's Mark) and the Committee voted unanimously to do so. The Chairman's Mark of S. 510 (passed by unanimous vote) is available at http://help.senate.gov/Hearings/2009_11_18_E/WHI09A06.pdf. The Senate HELP Committee press release announcing mark up is available at http://help.senate.gov/Maj_press/2009_11_17.pdf

More Information

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