Agri Pulse
Agri-Pulse Communications, Inc.

06-03-09

FDA head, Congress & industry back radical food safety reform

By Jon H. Harsch

© Copyright Agri-Pulse Communications, Inc.

Broken, antiquated, failure, underfunded – these are some of the words used to describe the U.S. food safety system in a House Energy & Commerce subcommittee hearing held Wednesday on the "Food Safety Enhancement Act of 2009." Despite the bill's sponsors acknowledging that the bill is an incomplete draft and despite complaints today from committee Republicans that Democrats ignored Republican concerns in writing the bill, Subcommittee Chair Frank Pallone (D-NJ) and Ranking Member Nathan Deal (R-GA) agreed on plans to complete committee work on the bill next week.

There's agreement on completing the bill quickly because Democrats, Republicans and the food industry agree that urgent action is needed and agree "on the concept" although not on all the details. Energy and Commerce Committee Chair Henry Waxman (D-CA) said at the hearing that "food safety is so critical" that he has "carved out time" between the committee's just finished work on controversial climate change legislation and his next priority task: comprehensive health care reform.

First up at the hearing was the Obama Administration's newly appointed Food and Drug Administration (FDA) Commissioner Dr. Margaret Hamburg, just seven days on the job. She testified that the draft legislation marks a major step forward for food safety, public health and consumer confidence because it is designed to shift the FDA from responding to outbreaks of food-borne illness to a risk-based preventive approach. She said: "The draft legislation would indeed transform our nation's approach to food safety from responding to outbreaks to preventing them. It would do so by requiring and then holding companies accountable for understanding the risks to the food supply under their control and then implementing effective measures to prevent contamination."

Dr. Hamburg warned, however, that "even with the President's support, even with the full efforts of HHS and USDA and other Federal, state, local, tribal, and territorial food safety partners, and even with the backing of consumer groups and industry, our efforts will fall short unless Congress modernizes food safety laws to deal with the challenges of the 21st century."

Republican committee members expressed their support for the concept of switching FDA to a preventive approach and granting it new authorities. But they expressed concern that some provisions of the bill are poorly defined and others could impose

costly new burdens on small businesses. Rep. Ed Whitfield (R-KY) warned that giving FDA broad authority to order mandatory recalls and to access company records could create problems. He also expressed concern that FDA might use its new powers to limit the use of antibiotics in livestock. Dr. Hamburg assured the congressman that FDA will use discretion regarding recalls and accessing company records. She then volunteered that the livestock industry's use of antibiotics is a "huge concern. . . a high priority for me" which "merits a lot of attention by FDA."

Republicans expressed concern that $375 million per year raised by the bill's proposed $1,000 fee on each food-industry facility could become a slush fund used for activities unrelated to food safety. Hamburg assured the committee that the $375 million would fall far short of covering the additional FDA inspections that the bill would require. Rep. Steve Buyer (R-IN) sought assurances that Dr. Hamburg would support taking the same firm action to deal with tainted or counterfeit pharmaceutical products that the bill proposes for contaminated food products. He accused her of "equivocation" when she said she wasn't prepared to answer pharmaceutical questions yet but would work on finding "appropriate solutions."

Asked her views on whether it would make sense to consolidate FDA with USDA's Food Safety & Inspection Service, Hamburg said that the first priority should be to "strengthen food safety within FDA." She gave a firm answer when asked her view of for the first time giving FDA authority to order mandatory recalls. She said that while voluntary recalls have been effective, "backstop" mandatory authority is needed since some FDA requests for voluntary recalls have been challenged legally, resulting in long delays "putting consumers at risk."

Reps. Edward Markey (D-MA) and Bart Stupak (D-MI) both asked Hamburg to comment on the hot issue of BPA use for food and beverage containers. Hamburg confirmed that the FDA already is "taking another look at the BPA issue." She added that as both a mother and a physician, her advice to parents concerned about their children's health is to "look for alternatives" to BPA-lined food and beverage cans.

Pamela Bailey, President and CEO of the Grocery Manufacturers Association (GMA), joined other food industrial officials in praising the draft bill. She said that the bill "will provide the U.S. Food and Drug Administration with the resources and authorities it needs to help make prevention the foundation of our food safety approach and bolster consumer confidence in the safety and security of the food supply." She said reforms are long overdue. As an example of problems, she noted that FDA hasn't had the resources needed to update its list of good food manufacturing practices since 1986.

In comments echoed by other witnesses, Bailey concluded that while the bill needs some improvements, "We strongly support in concept many of the proposals in the draft, including those that require food companies to have a food safety plan; proposals for FDA to set safety standards for fruit and vegetables; proposals to improve the safety of imported food and food ingredients; a risk-based approach to inspection that recognizes the important role played by states and competent foreign authorities; and proposals to give FDA strong enforcement powers to deal with companies that have violated food safety laws, including mandatory recall authority when needed. Together, these reforms will prevent contamination, raise the bar for the entire food industry and deter bad actors. In addition, we have also offered important modifications to the draft to committee staff and will continue to work with them on a bipartisan basis to address those provisions."

The proposed bill's key provisions include:

- **Creates an up-to-date registry of all food facilities**: Requires all facilities operating within the U.S. or importing food to the U.S. to register with the FDA annually.

- **Generates resources to support FDA oversight of food safety**: Requires registered facilities to pay an annual registration fee of $1,000 in order to generate revenue for food safety activities at the FDA.

- **Prevents food safety problems before they occur**: Requires all facilities operating within the U.S. or importing food to the U.S. to implement safety plans that identify and protect against food hazards. FDA would have the authority to specify minimum food safety plan requirements and to audit food safety plans.

- **Increases inspections of food facilities**: Sets a minimum inspection frequency for all registered facilities. High-risk facilities would be inspected at least once every six to 18 months; low risk facilities would be inspected at least once every 18 months to three years..

- **Improves traceability of food**: Enhances FDA's ability to trace the origin of tainted food in the event of an outbreak of food-borne illness. FDA would be required to issue regulations that require food producers, manufacturers, processors, transporters, or holders to maintain the full pedigree of the origin and previous distribution history of the food and to link that history with the subsequent distribution history of the food; and to establish an interoperable record to ensure fast and efficient traceback.

- **Provides strong, flexible enforcement tools**: Provides FDA new authority to issue mandatory recalls of tainted foods. Strengthens criminal penalties and establishes civil monetary penalties that FDA may impose on food facilities that fail to comply with safety requirements.

- **Enhances FDA's ability to block unsafe food from entering the food supply**: Strengthens FDA's authority to administratively detain unsafe food products. Grants FDA "quarantine" authority under which the agency may restrict or prohibit the movement of unsafe food products from a particular geographic area.

- **Requires country-of-origin labeling and disclosure**: Requires all processed food labels to indicate the country in which final processing occurred. Requires food manufacturers to identify the country of origin for all ingredients on their websites. Requires country-of-origin labeling for all produce.

- **Grants FDA new authority to subpoena records related to possible violations**.

For a summary of the Food Safety Enhancement Act, the 116-page text of the draft legislation, copies of testimony and video of the June 3rd House hearing, go to:
http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1640&catid=132&Itemid=72

#30