

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

February 24, 2014

Mr. Michael R. Taylor
Deputy Commissioner
Foods and Veterinary Medicine
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Taylor:

Thank you for appearing before the Subcommittee on Health on Wednesday, February 5, 2014, to testify at the hearing entitled "Examining the Implementation of the Food Safety Modernization Act."

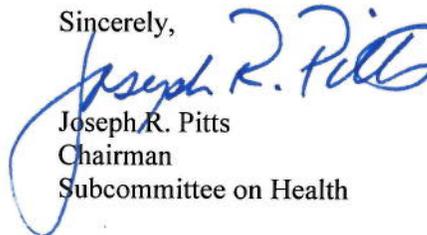
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Monday, March 10, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Sydne.Harwick@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

Attachment 1—Additional Questions for the Record

The Honorable Joseph R. Pitts

1. The foreign supplier verification proposed rule is focused on the ingredient risk. We believe that industry should also be looking at supplier risk. Does FDA agree that industry should look at both ingredient and supplier risk when making decisions on how to allocate supplier verification resources?
2. The auditing and record-keeping requirements in the foreign supplier verification proposed rule is correctly focused on the source of the problem in foreign food plants. But FDA has no authority over foreign food plants, and therefore, will rely on holding food importers responsible. How will FDA verify that only safe food is being imported? How will FDA plan to expand import testing in a cost-effective and timely manner?
3. FSMA specifically recommends that the FDA take advantage of the capacity and expertise of certified contract testing laboratories to effectively and efficiently expand import testing. What are the FDA's plans for third-party testing domestically?
4. In your testimony, you stated that "FSMA will only be as effective as its on-the-ground implementation." To date, what has FDA done to develop and implement a comprehensive training program for its inspection workforce to ensure FSMA is enforced effectively, uniformly and fairly at both the federal and state level? What are the agency's plans and timeline for inspector training moving forward?
5. Under the proposed rule for preventative controls, food facilities need to have "qualified individuals" write and implement their food safety plans. How is FDA planning to train its investigators so they know how to evaluate the merits of a facility's food safety plan from a risk based standpoint? Will FDA investigators have the same training as qualified individuals?
6. It is essential that FSMA regulations are enforced consistently from one region to another, and by both federal and state officials. What is FDA doing to ensure this happens?
7. FSMA does not provide FDA with authority to mandate submission of facility profiles or electronic/remote access to records. While the preventive controls proposed rule does not explicitly require submission of facility profiles or electronic/remote access to records, it does request comment on whether FDA should require these in the final regulation. Is FDA still considering requiring these in the final rule and if so, under what authority?
8. In the preamble to the preventive controls proposed rule, the FDA "tentatively concludes" that is appropriate to apply Part 11 to FSMA electronically maintained records. Then, FDA asks for comment on whether there are circumstances that warrant not applying Part 11 requirements. FDA did not apply Part 11 requirements during the Bioterrorism Act rulemaking process because it would have required companies to significantly redesign and replace existing systems. Please explain why the FDA has taken a different position here in its "tentative conclusion," and whether the FDA intends to move forward with requiring compliance with Part 11 for FSMA records under all of the proposed rules?
9. The preventive controls proposed rule requires that records be kept for at least two years. Is this requirement prospective—and therefore would only apply to records created after the effective date of the final rule?

The Honorable G.K. Butterfield

1. The FDA and food companies can agree that the timely sharing of information is important. However, we have all been reading about the danger of computer hackers and the theft of business and trade secrets as well as personal data.
 - a. As the Agency considers the exchange of food safety records electronically, should we be concerned about the protection of confidential business information and trade secrets?
 - b. Can you guarantee that the FDA can secure its own data systems and prevent criminals—foreign and domestic—from stealing trade secrets?
 - c. Could a data breach result in counterfeit products?
2. I represent a district that still has pockets of persistent poverty. Many of my constituents in eastern North Carolina struggle from paycheck to paycheck and some have been unemployed for some time. This question is about new rules required by FSMA. I favor regulation when and where it is necessary to protect the public's health and wellbeing. But it's important to remember that regulations come with a cost. Often those costs are passed onto the consumer in the form of higher prices.

Considering the amount of work the Agency has done, the work that needs to be accomplished and the work required to consider technical public comment, can the Agency assure this committee that the final rules won't unnecessarily impact consumers like some in my district who can least afford it?

3. Commissioner Hamburg distributed a memo on February 3, 2014. That memo outlined changes and modernization of the FDA. One of the biggest changes is moving the FDA to commodity-based and vertically-integrated regulatory programs.
 - a. What was the impetus for the changes?
 - b. Do you think that the shift to commodity-based regulatory programs will improve FDA review and response times, particularly for drug and device applications?
 - c. Has the FDA set a deadline for when this transition should be complete?

The Honorable Marsha Blackburn

1. I was one of 33 House members who wrote you last fall asking for an administrative fix to a language problem in the Food and Drug Administration Amendments Act (FDAAA) of 2007 affecting animal food ingredient approvals. It has to do with your agency's interpretation of language related to a statutory requirement you set regarding pet food ingredient "standards." Your response to our letter was that you are working on it, but you hadn't quite figured out what to do. What is the status of the FDAAA fix? When can we—and the industry—reasonably expect you to fix the FDAAA problem?

The Honorable Peter Welch

1. We understand from farmers that the cost of implementation of these rules may put them out of business. Are you certain your economic costs for compliance estimates are accurate?

2. What role will the states play in implementing FSMA? Is there an opportunity to begin the implementation process now, in advance of the finalization of the rules?
3. Do you plan to construct an adjudication or conflict resolution process to address the inevitable conflicts between federal regulators, state regulators, and/or the regulated community? If so, will you describe in detail—or at least give a preliminary outline of—what that process would look like?
4. FSMA was designed to ensure a level playing field between domestic and imported foods. Can you assure Congress that domestic and imported foods will be treated equally?
5. We have heard that you have said we will need to educate before we regulate. How do you plan to implement this goal? What is your timeline?
6. Will you please explain how the agency will fix the “farm” definition so that it includes many activities that are regularly part of farming but that, as proposed, triggered the “facility” definition?

The Honorable Michael C. Burgess

1. FDA’s budget appropriations have grown from \$1 billion to over \$2.5 billion in the last seven years. Despite last year’s sequester, FDA received from Congress an increase of \$96 million over the amount provided in FY 2013 and \$3 million about the agency’s budget request. Of this \$900 million was targeted to the food safety work of the Center for Food Safety and Applied Nutrition (CFSAN).

The Administration’s proposed FY 2014 budget for FDA included a proposal to impose a food facility registration and inspection fee to fund agency activities related to FSMA. While maintaining the safety of the U.S. food supply is the highest priority for both Congress and the FDA, I am concerned about how the Agency is using the funds that have already been allocated for food safety. Will you provide documentation and accounting for the \$900 million that was targeted to the CFSAN?

2. FSMA directs FDA to write new regulations for facilities that manufacture, process, pack, or hold human food. Facilities are required to maintain a written food safety plan and comply with the Preventive Controls rule, which includes specific food allergen controls.
 - a. How will FDA execute these preventive controls for allergens?
 - b. Will there be thresholds or standard levels?
3. In the FSMA proposed rules, the FDA has proposed requiring submission of facility profiles with hazards and controls information as well as providing FDA with remote access to company manufacturing and related records. It is clear that the statute allows the FDA to access company record during the course of an on-site authorized inspection.
 - a. Will you describe what statutory authority the FDA has in FSMA to require companies to provide FDA with remote access to company manufacturing and related records?
 - b. What additional information does FDA feel it needs to obtain through remote access to records that it could not obtain during an on-site inspection?

- c. I am concerned that this additional regulatory burden and time-consuming process does not provide a commensurate benefit to overall food safety. How do you propose companies prioritize these additional activities over the usual activities that directly enhance food safety?

The Honorable John Shimkus

1. Is it true that finished product testing may not be identified as necessary in a facility's food safety plan based on the relevance for the facility, food, and information from other verification activities but under the proposed Preventative Controls rule those products would be subject to mandatory finished product testing?
2. During your testimony, you noted that "certain kinds of testing programs... can be important" in food safety systems, while stating that it is "well-understood that those testing programs have to be based on particular risk considerations." The Committee agrees that testing should be risk-based and that a "one size fits all" approach will not work. Although the FDA did not provide proposed testing language on which industry could comment, would you agree that prescribing specific testing for all possible variables is not practicable?
3. In your opening statement, you said the Agency "intends to publish and seek comment on revised rule language on key provisions of the Preventive Controls rule... on which our thinking has evolved." I believe it is important for the FDA to seek additional comment from stakeholders on specific regulatory language that was left out of the initial proposal. Will this revised proposed rule allow for an academic discussion and response to detailed testing, supplier verification, and economic adulteration rules?
4. FDA inspectors and investigators will need to be well educated in how to properly audit food safety systems. Historically, investigators have primarily inspected food facilities for physical evidence of hazards. Under the proactive nature of FSMA, FDA personnel will need to undergo a paradigm shift. They will need to be effective in understanding and evaluating the effectiveness of a facility's food safety system and they will need to evaluate through records review and physical inspection, whether the facility is complying with that system. Please provide a timeline for the Agency's implementation of a comprehensive training program for FDA inspectors, including state and local partners.
5. The Committee is concerned that the final rule may establish costly testing requirements that focus resources away from the most critical food safety activities. How will you ensure the final rule should provide that the necessity, location, and frequency of pathogen testing in the processing environment and on equipment, including product contact surfaces, is based upon the risk of the product, process, and hygienic status of the production environment, as well as risk information provided from other verification activities?
6. During the hearing, you noted that the Agency is working with industry to "figure out how to exchange information," stating that there is "no lack of sensitivity" to the issue of protecting confidential business information. Viewing facility records is most meaningful when it is done within the context on an on-site inspection. Does the Agency plan to require access to information outside the context of an inspection? If electronic records access is necessary, what security measures does the Agency plan to put in place to prevent unauthorized release of confidential business information?
7. FSMA limits FDA's ability to mandate auditor reporting to Reportable Food Registry conditions and narrow situations where third-party auditors must be accredited under the FDA Third-Party

Auditor Accreditation proposed rule. Will other audits, including consultative audits, be subject to reporting requirements to FDA? If so, under what circumstances?

The Honorable Leonard Lance

1. The Committee is aware of and encourages the FDA's work with the cosmetics industry to develop a new regulatory framework to insure safety of personal care products while allowing innovation in product development. Will any proposed new regulatory requirements involve new revenue sources to the Agency?
2. In my judgment, a key element of proposed new regulations, and an important part of a new regulatory framework, would be national uniform requirements. Does FDA support having national safety standards for cosmetics?
3. For years, the Agency has been asked to establish safety levels of ingredients, such as for lead in lipstick. A lack of action in this area results in consumer confusion and regulatory uncertainty for manufacturers. Will the Agency provide the Committee with a timeline for completion of safety level determinations under the proposed new regulations?

The Honorable H. Morgan Griffith

1. The Food Safety Modernization Act uses the term "reasonably foreseeable," but there are concerns that FDA may use the term "reasonably likely to occur" (RLTO) to define a threshold for determining preventive controls. The proposed RLTO standard lends itself to regulatory rigidity and perhaps absurdity. During the hearing, you stated that there is "a way to solve this and manage this" concern so that those facilities with advanced food safety systems do not have to change their already effective practices. How does FDA plan to address this concern, and when can the Committee expect a successful resolution?

The Honorable Gus Bilirakis

1. Currently, over 200 Food and Drug Administration (FDA) regulations incorporate food ingredient standards the United States Pharmacopeia (USP) publishes in the Food Chemicals Codex (FCC). FDA from time to time updates these references, and the Agency has also worked closely with USP on important issues including adulteration of food ingredients (e.g., glycerin). In the hearing, FDA stated that a national standard of identity is useful, but FDA was limited due to resources. Would FDA be willing to work specifically with USP and stakeholders on the issue of economically-motivated adulteration of honey, to help protect its integrity and see if an appropriate national quality standard could be developed and placed in regulation?

Attachment 2—Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable John D. Dingell

1. Please submit a survey of what you need in the way of money to properly implement the Food Safety Modernization Act.
2. Please submit a detailed response describing what resources you need to meet the hiring targets set by FSMA and how many full-time equivalent employees FDA needs and plans to hire.

The Honorable Tim Murphy

1. A couple years ago, the Centers for Disease Control said there was a reduced or different risk in foreign imported products versus the United States. Does that difference still exist? Is there a difference in seafood, meats, fruits, and vegetables? Any categories in terms of which are at higher risk, or does it vary?