



Modernizing Food Safety

Interview with Margaret Hamburg, FDA Commissioner



RedPrairie is pleased to present this interview with Dr. Margaret Hamburg, the Food and Drug Administration's Commissioner, on current initiatives the agency is taking to modernize the food safety system in the U.S.

How can the FDA and industry do a better job of modernizing the food safety system in the U.S.?

FDA can only do so much with its existing authorities. To do a better job, we will require new powers, some of which are included in the bills pending in Congress. And we need to work with members of the food industry, many of whom have been making important innovations in food safety practices and technology, and all of whom bear primary responsibility to produce and market safe food.

What are your concerns about the Food Safety Modernization Act (S.510) that is before the Senate and the Food Safety Enhancement Act (H.R. 875) that the House concerned this summer?

From FDA's perspective, there are three key questions to ask about food safety legislation:

First, does the legislation support a new food safety system focused on prevention? Second, does it provide FDA the legal tools necessary to match its existing and new responsibilities? And third, does it provide or anticipate resources for the Agency to match its new responsibilities?

What legal tools will the FDA need to support its existing and new food safety responsibilities?

We need authority to ensure proper implementation of modern preventive controls in all food facilities. Many firms already implement such controls, but we need to ensure that what is now the food industry's best practices become increasingly the common practice for all.

We also must have better tools to foster compliance with science-based standards. For example, if problems occur, we need to have prompt access to food safety records, modern traceback and administrative detention tools, and mandatory recall authority.

And we need new powers to modernize and substantially strengthen the FDA's ability to ensure that food imports meet U.S. food safety standards. This includes authorities to hold importers accountable for managing their supply chain and preventing food safety problems from entering the United States, conducting more overseas inspections, working more closely with foreign governments, and developing rigorous, independent and accredited third-party certification systems to supplement FDA's overseas and border inspections.

But none of these authorities and innovative measures will provide the desired protections unless they are supported by new and adequate resources. To carry out more inspections, to strengthen our laboratory testing infrastructure, and to enhance our inspectional and scientific expertise will require additional funding. We need to build up FDA's foods program resource base over a period of years to the necessary level and then sustain it for the long term.

We are pleased that the adopted House bill includes a fee-based revenue stream, but we need to keep working with the administration and Congress to ensure adequate budgets for food safety.

What kind of basic standards do you believe need to be implemented to prevent contamination?

To prevent contamination, we believe that facilities need to have a comprehensive food safety plan and to adhere to science-based safety standards.

Your emphasis has been on prevention, but you also are looking to modernize trace back and trace forward capabilities to make that process more expedient in response to contaminated foods. How can industry help accomplish that?

As the legislation envisions, there are a number of ways that industry can help expedite efforts to track foodborne illness. For example, facilities should register annually so that the Agency has accurate information about who is making food for American consumers; commercial importers should comply with good importer practices; and companies also should provide access to their food records during routine inspections. This is essential to enable FDA to identify problems and require corrections before people become ill. It also enables the Agency to verify during routine inspections that firms are maintaining proper records.

For us to implement a product tracing system for food, FDA needs enhanced information that will help the Agency trace foods more quickly during an outbreak. The current requirement to keep records for the immediate previous source and immediate subsequent recipient (one up/one back) requires the Agency to go to each point in the distribution chain during an outbreak to trace the source and distribution of the contaminated product, which is not a sufficiently expedient process when trying to prevent more people from becoming ill.

The ability to trace the path of any food, including tomatoes, other fresh produce, and peanut butter, back through every point in the supply chain or forward through the supply chain, is crucial for limiting foodborne illness in an outbreak; for preventing future outbreaks; and for reducing the impact on the segments of the industry whose products were not associated with the illnesses.

You have testified that the FDA will improve risk communication during a food safety event so that the public can respond promptly to FDA alerts and protect themselves from harm. How do you plan to do this?

FDA's current and planned actions will enable FDA to communicate more effectively with consumers during food-related events; and provide more rapid alerts to all stakeholders during food-related events.

For more information

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How would an integrated national system of inspection, verification and enforcement – as outlined in your strategic framework – work?

Under this system, FDA and federal, state, territorial, tribal and local regulatory agencies will conduct food facility inspections under the same set of standards. FDA will work with its regulatory partners to develop uniform national standards, including inspection, investigation, and testing protocols; training and certification requirements; establish program audit criteria; and create performance metrics to ensure program objectives are met. System integrity and credibility will be maintained through regular program oversight and accountability at all levels. Federal and state inspections will be conducted in accordance with a public health risk driven national work plan that FDA will develop with its regulatory partners. An integrated system will result in more coordinated response efforts to better respond to multi-state outbreaks when they occur.

To be fully successful, the national food safety system must be built with continuous input from FDA's regulatory and public health partners. It must be sustained through multi-year funding that will be provided to state and local regulatory and public health partners to build the necessary state and local infrastructures, contain adequate legislative authorities to facilitate information sharing and communication among all partners, and include infrastructure for a national electronic information-sharing mechanism.

These actions will result in a national food safety system that reduces foodborne illness, identifies sources of risk throughout the system, and reduces time to detect and respond to outbreaks. A public health driven, collaborative, and leveraged approach to food safety activities and responsibilities will be reflected in improved public sector resource utilization at a national level, which provides additional capacity for ensuring a safe and secure food supply.

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