Consumer Federation of America

FDA's Role in Ensuring Safe Food: Discussion Forum
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Introduction

Thank you for opportunity to provide a consumer perspective on these important issues. My name is Chris Waldrop and I am the director of the Food Policy Institute at Consumer Federation of America. CFA is an association of nearly 300 nonprofit consumer organizations that was established in 1968 to advance the consumer interest through research, education and advocacy.

Transparency and Public Participation are Critical

The FDA Food Safety Modernization Act grants the agency important new authorities to better protect consumers from foodborne disease. Without quick, coherent, complete implementation of the Act, the new powers are meaningless. Consumer groups were some of the most vigorous supporters of the FSMA. We want to work with the agency throughout the implementation process. Our continued support for the law and for helping the agency secure sufficient resources, however, depends in large part on the vigor and integrity of the implementation process.

While many of provisions in the new food safety legislation don't go into effect for months or years, numerous polls show that consumers expect FDA to be protecting the food supply. A July 2009 poll[1] conducted for the Pew Charitable Trusts found that 83% of voters said the federal government should be responsible for ensuring that food is safe to eat. And 89% of consumers supported the federal government instituting an array of new food safety measures similar to the ones in the FSMA.

The agency must move expeditiously to develop multiple new rules, guidance documents and reports to Congress. At the same time, it is absolutely critical that the process is open and transparent with multiple opportunities for public participation in the agency's decision-making.

Public discussion improves the final product and avoids delays caused by disgruntled stakeholders who feel by-passed by the agency. In the mid-1990s during the development of the Food Safety and Inspection Services' HACCP regulation, all stakeholders engaged in a lengthy public process to help shape the final rule. Both industry and consumer groups have testified since to the benefits of that approach. More recently, FSIS held a series of public meetings on its proposal for a new "risk-based" inspection system. Through the course of that open process, the agency determined that it needed to first design a better information infrastructure in order to develop the necessary data to inform its regulatory decision-making. In addition, soliciting public input at the beginning can often speed the

[1]Hart Research/Public Opinion Strategies, "American's Attitudes on Food Safety." Poll commissioned by The Pew Charitable Trusts, July 2009, http://www.makeourfoodsafe.org/tools/assets/files/ME9615a-pub.pdf .

process in the end. If FDA tries to put out new regulations without any public input, the agency risks delays in the end by complaints, Congressional questions about process, and even lawsuits.

FSMA Criteria and Data Collection to Inform Risk Decisions

The FSMA explicitly indicates six different areas in which FDA should act based on the "known food safety risks of food." These areas include: Produce Standards, Inspections, Border Inspections, Traceability, Imports, and a Certification Program.

We expect that FDA will engage in an open process and seek public input on the criteria the agency will use to define "known food safety risks." The agency should consider this concept of "known food safety risks" as one that can be changed as the agency gathers more and new data. "Known food safety risks" in the year 2011 are not the same as the known risks ten years ago; and new food safety risks will surely arise in the future.

In order to avoid unacceptable delays in implementation, the agency may have to initially rely on the limited data sources that are available currently. However, to fulfill the intent of the law FDA will have to invest in developing new data to support a truly risk-based system and on scientific, objective criteria on which to base risk determinations. The process should be deliberate and transparent beginning with a strategic data plan in which the agency identifies its data needs, develops a specific plan to gather the necessary data to meet those needs, and solicits public feedback on its plan.

This is especially important in developing attribution data, which is a key component of a risk-based, data-driven food safety system. Another IOM Standing Committee recently reviewed the plans of the Food Safety and Inspection Service for moving to a risk-based inspection system[23]. FDA should review these Committee reports as well, as they provide extensive recommendations regarding the need for transparency, clarity, regular evaluation of available data, and further data collection. With respect to attribution data, the Committee recommended that FSIS work with CDC and the FDA to use "sporadic-case and outbreak data in conjunction with subtype data to facilitate estimation of attribution of sporadic cases to specific agents." Section 205 of the FSMA instructs FDA to work with CDC and other Federal, state and local agencies to improve surveillance. FDA should work with CDC and FSIS and help fund efforts to develop better attribution data from better sources, rather than relying primarily on expert elicitation and outbreak data, which is insufficient.

Several other provisions in the FSMA will help drive the development of new data streams. Section 104 the Performance Standards section, is a key driver of continuous data improvement. It requires the FDA to "review and evaluate the relevant health data and other relevant information…to determine the most significant foodborne contaminants." FDA is instructed to do this review not less frequently than every two years. This two year review will allow the agency to inform the "known food safety risks" with new and additional data and make any necessary adjustments and changes in its risk rankings.

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[2] National Research Council, "Letter Report on the Review of the Food Safety and Inspection Service Proposed Risk-Based Approach to and Application of Public-Health Attribution." Institute of Medicine, 2009.

[3] National Research Council, "Review of Use of Process Control Indicators in the, FSIS Public Health Risk-Based Inspection System: Letter Report." Institute of Medicine, 2009.

Other FSMA areas that drive data collection include:

- Registration of Food Facilities (Sec. 102) – FDA will be able to gather new information about facilities under its jurisdiction.
- Targeting of Inspection Resources (Sec. 201) – FDA will need to know the compliance history of a facility and the effectiveness of a facility's preventive controls; and FDA will need to know the safety risks of foreign countries, the compliance history of the food importer, and the effectiveness of the foreign supplier verification program.
- Surveillance (Sec. 205) – Requires FDA to work with CDC and state and local authorities to "enhance foodborne illness surveillance systems to improve the collection, analysis, reporting and usefulness of data on foodborne illness."
- Voluntary Qualified Importer Program (Sec. 302) – FDA must consider eligibility based on compliance history of foreign suppliers, capability of the foreign country's regulatory program, and records of the importer.
- Authority to Require Import Certifications for Food (Sec. 303) – FDA must consider risk associated with a foreign country, and the capacity of a foreign government's regulatory program in determining whether an imported food must be certified.

Inspection is a Key Element of Prevention

Inspection is a key element of a preventive food safety system. Federal inspectors are "cops on the beat," overseeing food companies to assure that they are producing food in a safe manner. American consumers expect that the federal government constantly monitors food production facilities. A November 2008 Consumers Union poll[4] reported that two-thirds of consumers surveyed thought that FDA should be inspecting food facilities once a month. Increasing the inspection frequency was the number one priority for consumer groups during debate on the FDA food safety bill. We do not think the inspection frequency in the new law is sufficient to protect public health. We supported the bill as it passed the House, requiring inspection of high risk plants annually. What we got was an initial inspection sometime in the first five years the law is in effect. We all know that is not sufficient. We all know as well that FDA's record on inspection is less than good. Telling people that plants are inspected once a decade does not instill confidence in the safety of the food supply.

According to an April 2010 report by the Office of the Inspector General, the number of facilities, including "high risk" facilities that are inspected has declined over time[5]. The OIG also found that 56 percent of food facilities had gone five or more years without an FDA inspection. The Center for Science in the Public Interest analyzed FDA inspection data and found that neither increases in funding or increases in staffing levels resulted in increases in inspection[6]. CSPI also found that states were shouldering an increasing share of food safety inspections. A dedicated commitment to federal inspection is necessary if the FDA is to assure that food facilities are complying with the new law and regulations.

The FSMA directs the FDA to inspect high risk plants once in the first five years of the law and once every three years after that. FDA must not take that as a ceiling. It should be the floor, especially if a risk

[4] Consumers Union, "Food Labeling Poll 2008." November 11, 2008, http://www.greenerchoices.org/pdf/foodpoll2008.pdf

[5] Office of Inspector General, "FDA Inspections of Domestic Facilities." OEI-02-08-00080, April 2010.

[6] Plunkett D, "Inspection Metrics Project," Center for Science in the Public Interest. Presentation at public meeting on Measuring Progress on Food Safety: Current Status and Future Direction, Portland Oregon, October 20, 2010.

analysis determines that a plant should be inspected more often. Budgetary constraints should not influence FDA's definition of "high risk." That is, the agency should not adjust its definition of "high risk" merely to make it appear like it is meeting the statutory requirements. Consumers expect the agency to conduct actual inspections and not manipulate inspection numbers. A transparent, public process in how FDA determines risk could help alleviate this concern.

As Mike Taylor said in his FDLI speech on January 26, FDA inspection will change under the new law. Rather than having to spend days in a plant collecting evidence sufficient to build a legal case that a product is adulterated, FDA will shift to monitoring a plant's preventive control plan in order to determine whether those controls are adequate and working as intended. This should result in a different kind of FDA inspection than in the past.

In light of FDA's new inspection mandate and in the spirit of interagency cooperation, FDA should consider contracting with other federal agencies to conduct inspections. FDA already coordinates with the National Marine Fisheries Service on seafood inspections[7]. Although the current program is a voluntary fee-for-service program, there is potential for a more structured regulatory collaboration between the agencies. FDA should also seek to coordinate with its sister agency, the Food Safety and Inspection Service, particularly considering the new focus on inspection of preventive control plans. FSIS has conducted inspections of preventive control programs for high-risk products for over a dozen years and its inspectors have extensive experience in this area. In fact, there are a handful of food processing facilities which have dual jurisdiction between FDA and FSIS because of the types of foods being produced. Those facilities would be an ideal place to initiate a collaborative effort, which could then be expanded to other plants. Such an approach could be implemented fairly easily and quickly in a cost-effective manner, in contrast to more time-consuming and expensive proposals.

Reliance on States to Conduct Inspection Raises Serious Questions

We are very leery of FDA's eagerness to pass off to the states responsibility for the new inspections required by the FSMA. Mike Taylor has said the FDA's inspection efforts will now focus on assuring process controls work. These are federal requirements being carried out by plants that have always been under federal jurisdiction. State and local governments have been responsible for retail and restaurants inspection, not applying federal law to processing plants. Even this committee made it clear that the FDA should not try to pass off this responsibility until the agency had established standards and provided a new stream of federal money to pay for the inspections. FDA should surely work with states and local governments to improve their performance of regulatory programs they have administered for years, such as retail and restaurant food inspection. But if FDA is going to rely on states to conduct inspections, they must be done to federal standards, paid for with federal money, with plants held responsible for meeting federal standards. Specific concerns include inadequate funding, lack of standards, conflicts-of-interest, and lack of accountability.

States Slash Funding for Public Health

Many states are struggling to balance their budgets in this difficult economic climate. Since FY2009, states have experienced budgetary shortfalls of over $430 billion and are likely to face large gaps in the coming years[8]. Public health departments and food inspection programs often fall victim to states' budget cuts. Thirty-three states were reported as having cut funding for public health from FY2008-

[7] Johnson R, "The Federal Food Safety System: A Primer." Congressional Research Service, December 15, 2010.
[8] McNicol E, Oliff P, Johnson N, "States Continue to Feel Recession's Impact." Center on Budget and Policy Priorities, December 16, 2010.

2009 to FY 2009-2010[9]. (Even prior to the recession, the Center for Science in the Public Interest found that states were reporting 33 percent fewer fully investigated outbreaks to the CDC in 2007 than in 2002[10], suggesting budget and staffing problems.) Fifty-three percent of local health departments reported that their core funding had been cut from 2009, and 47 percent anticipate cuts again in the coming year[11]. In 2008-2009, local health departments lost 23,000 jobs, plus an additional 13,000 employees were affected by cuts in working hours or mandatory furloughs[12]. These statistics should raise serious questions about whether States are in a position to conduct sufficient retail and restaurant inspections already under their jurisdiction,[13] [14] [15] much less take on additional inspection responsibilities. And while the current economic downturn has exacerbated state funding problems, state balanced budget amendments mean that funding for state public health and food safety programs is perennially at risk. Federal budget pressures and concerns about the deficit make it even more unlikely that FDA will be given sufficient resources to provide substantial financial support to the States to carry out food safety activities on behalf of the FDA.

State Food Safety Activities Vary

While some states demonstrate a strong commitment to food safety, state food safety activities (and funding for those activities) vary widely[16] [17]. State surveillance of foodborne illness differs[18], as does state reporting of foodborne illness outbreaks[19]. Twenty-one states were not able to rapidly identify E. coli O157:H7 and submit the lab results in 90 percent of cases within four days in the period 2007-2008[20]. Despite its increased reliance on the states to conduct food inspections, FDA has not established a set of standards for states to meet in order to conduct activities on behalf of the agency. This results in a variation among even those states contracting with FDA to conduct inspections. The NAS Committee recognized this lack of standardization and noted, "…these programs and their implementation must be evaluated against a minimum standard and ultimately standardized and harmonized[21]." The vision of an "integrated food safety system" will be nothing but a moth-eaten patchwork quilt without standardization and adequate funding for state programs. If FDA intends to move in this direction, the

[9] Trust for America's Health, "Ready or Not? Protecting the Public's Health from Diseases, Disasters and Bioterrorism," 2010.

[10] Center for Science in the Public Interest, "CSPI Finds a Troubling Decline in Foodborne Outbreak Investigations by State Health Officials." Press Release, December 23, 2009, http://www.cspinet.org/new/200912231.html.

[11] National Association of Country & City Health Officials, "Local Health Department Job Losses and Program Cuts: Findings from January/February 2010 Survey," May 2010.

[12] *Ibid*

[13] Associated Press, "San Francisco restaurant inspections down," October 30, 2010, http://www.signonsandiego.com/news/2010/oct/30/san-francisco-restaurant-inspections-down/.

[14] Dirty Dining, "Restaurant Inspections Plunge," November 3, 2009, http://www.kitv.com/r/21503331/detail.html.

[15] Fretwell S, "Fewer checking for rats, bugs, rancid meat at eateries." *The State*, October 31, 2010, http://www.thestate.com/2010/10/31/1537776/fewer-checking-for-rats-bugs-rancid.html.

[16] Association of Food and Drug Officials, "State Food Safety Resource Survey,"2009 Edition.

[17] Office of Inspector General, " FDA Oversight of State Food Firm Inspections." Department of Health and Human Services, OIE-01-98-00400, June 2000.

[18] Produce Safety Project, Safe Tables Our Priority, "State Surveillance of Foodborne Illness." http://www.producesafetyproject.org/admin/assets/files/PSP-STOP-Report.pdf

[19] Center for Science in the Public Interest, "All Over the Map," January 2011.

[20] Trust for America's Health, "Ready or Not? Protecting the Public's Health from Diseases, Disasters and Bioterrorism," 2010.

[21] National Research Council, "Enhancing Food Safety: The Role of the Food and Drug Administration." Institute of Medicine, 2010.

agency should ensure that any proposals for standardization are conducted transparently and with full opportunity for public input.

A further concern is that food safety activities are not always housed in state public health departments; state departments of agriculture are sometimes the lead agency for food safety. According to the NAS Committee report, 19 state agriculture departments conduct primary food safety regulatory activities, although most states have divided authorities between agencies[22]. State agriculture departments are responsible for more than just food safety however; they have quality and marketing responsibilities and often provide technical assistance to food producers in their state. These dual, sometimes conflicting, responsibilities for both promoting agriculture and assuring the safety of agricultural products raises questions about whether these departments can carry out a mandate to base decisions solely on risk. Congress isolated the Food Safety and Inspection Service from USDA's marketing function to avoid similar problems. This was an appropriate judgment and one of the reasons we have reservations about an "integrated food safety system" utilizing state government, especially state departments of agriculture, to conduct food safety inspections.

FDA-Contracted States Not Held Accountable

A further problem in leveraging state resources to conduct FDA inspections is the lack of oversight of state inspection programs. The state of Georgia was conducting food safety inspections under contract with FDA, but failed to adequately inspect the Peanut Corporation of America. The resulting outbreak of *Salmonella* Typhimurium linked to contaminated peanut butter products sickened over 700 people and left 9 people dead.

A 2000 report from the Office of Inspector General found that FDA audited only a small number of state inspection programs and that its audit program lacked sufficient rigor to assure that states were conducting contracted inspections adequately[23]. In its Field Management Directive on state contracts, FDA sets a goal of 7 percent of contract inspections to be conducted annually. However in the most recent list of contract audits from 2008-2009, FDA only audited 5.5 percent of state contact inspections overall[24], and in 37 percent of state programs, FDA audited between zero and five percent of contract inspections. Without proper oversight of state inspection programs, FDA cannot be assured that states are conducting adequate food safety inspection activities. A rigorous evaluation of state inspection programs is essential to establishing confidence that states can conduct food safety inspections on FDA's behalf. Again, if FDA intends to move in this direction any state inspection audit program should be developed through an open and participatory process.

Conclusion

The FDA is now poised to implement the FSMA. Maintaining integrity throughout the process will be critical, and FDA should assure that implementation is conducted transparently via a public process that provides opportunities for extensive public participation in the agency's decision-making. In order to move forward expeditiously, FDA may have to initially make decisions based on limited data. However, the agency must invest in developing new and additional data to address its information needs through a strategic data plan. Specific provisions in the FSMA will help drive the agency's data collection needs.

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[22] *Ibid.*

[23] Office of Inspector General, " FDA Oversight of State Food Firm Inspections." Department of Health and Human Services, OIE-01-98-00400, June 2000.

[24] http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/PartnershipsContracts/StateContracts/AuditReportsonStateFoodContractInspections/UCM233959.pdf

FDA's new mandate for inspection is an essential element of a preventive food safety program. To carry out this mandate, FDA should seek first to coordinate with other federal agencies that have extensive experience in inspecting preventive process control programs. The agency should assure that it has clear strong federal inspection standards spelled out for use by the states and that only states that can meet these standards are selected. FDA should also include conflict-of-interest provisions and sufficient funding to support an acceptable level of inspection activity in the states chosen.