



SAFE FOOD COALITION

July 6, 2011

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket #FDA-2011-N-0366

The members of the Make Our Food Safe Coalition and the Safe Food Coalition appreciate the opportunity to comment on the inspection and enforcement provisions of the FDA Food Safety Modernization Act (FSMA).¹

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 is monitoring food production facilities. A November 2008 Consumers Union poll² reported that two-thirds of consumers surveyed thought that FDA should be inspecting food facilities once a month. A May 2011 poll by The Pew Charitable Trusts showed that an overwhelming majority of voters (86%) favored FDA increasing inspections of food facilities.³

In the debate on FSMA, Congress clearly recognized that FDA’s previous inspection history was insufficient and so Congress gave the agency a new mandate for inspection which required a minimum frequency of inspection based on risk. Increasing the inspection frequency was the number one priority for coalition members and, in fact, coalition members supported a higher frequency of inspection than what was ultimately signed into law.

In FDA’s announcement of its June 6 public meeting on inspection and enforcement, FDA asked for public input on what inspection approaches the agency could use to satisfy the domestic and foreign inspection mandates, including work with State and local governments.

It is important to note that FDA inspection will change under the FSMA. FDA will be developing new federal standards for preventive process control that plants must follow. FDA will also be developing

¹ The following groups have endorsed these comments: American Public Health Association, Center for Foodborne Illness Research & Prevention, Center for Science in the Public Interest, Consumer Federation of America, Consumers Union, Food & Water Watch, Government Accountability Project, National Consumers League, The Pew Charitable Trusts, STOP Foodborne Illness (formerly S.T.O.P. – Safe Tables Our Priority), and Trust for America’s Health.

² Consumers Union, “Food Labeling Poll 2008.” November 11, 2008,
<http://www.greenerchoices.org/pdf/foodpoll2008.pdf>

³ <http://www.makeourfoodsafesafe.org/tools/assets/files/Me10250a-national.pdf>

new federal performance standards for pathogen reduction that plants must meet. Historically, FDA inspection resources were largely focused on reacting to foodborne illness outbreaks and the agency would spend days at a plant collecting evidence sufficient to build a legal case that a product was adulterated. Under FSMA, which is a preventive approach to food safety, inspectors will monitor a plant's preventive control plan in order to determine whether those controls are adequate and work as intended, and whether they meet new federal standards. This should result in a different kind of FDA inspection than what has been done in the past, and could conceivably lead to greater efficiencies and effectiveness in the inspection program.

As part of its inspection program, FDA needs to improve its information technology capabilities so that data collection is enhanced. Since FSMA gives FDA the authority to set pathogen performance standards as part of its enforcement tool box, it will need data to set those standards. A modern information technology infrastructure will assist the agency in achieving that goal. We also urge the agency to make the development of any new information technology system transparent so that stakeholders can make recommendations on the components that need to be included.

Reliance on Foreign Governments to Conduct Inspections Requires Verification

When it comes to overseeing the safety of food exported to the U.S., FDA faces a difficult task. The agency's resources currently allow it to inspect between one and two percent of all imported food at the border. The goal of the FSMA, however, is to create a food safety system that emphasizes prevention of food safety problems to reduce the risk that contaminated food enters commerce. Both foreign food facilities and domestic facilities will be required to comply with new federal standards for preventive process controls intended to minimize the risk of contamination and with new federal performance standards for pathogen reduction.

As with domestic food facilities, foreign facilities must be inspected to assure that food companies are meeting their obligations under the law and that they are producing food safely. The FSMA requires FDA to double the number of inspections it conducts of foreign facilities each year for the next five years. For the first year FDA is required to conduct 600 foreign inspections, a small number compared to the hundreds of thousands of foreign food processing facilities that export food to the United States.

With regards to foreign inspections, we would like to reiterate comments made by coalition members at the March 29 import public meeting. We have the greatest confidence in FDA inspections, followed by inspections by other U.S. government agencies, and then inspections by a trusted foreign national government. We especially urge the FDA to work with other federal agencies to meet the FSMA inspection schedules for imports. FDA should also keep in mind the following principle: Any entity conducting inspections on behalf of FDA should have public health as its primary focus and personnel engaged in inspection activities must be properly trained. The entity and personnel must also be completely independent and free from any conflicts of interest with the food industry.

In order to meet the new foreign inspection requirements in the law, FDA may choose to rely on foreign governments to verify the safety of food being exported to the U.S. While it is true that many other countries already have sophisticated food regulatory systems, the recent problems with deadly *E. coli* in Germany demonstrate that even well-developed countries can still have serious food safety issues.

If the FDA plans to rely on foreign governments to inspect foreign facilities, we urge the FDA to look to the system employed by USDA's Food Safety and Inspection Service for beef and poultry imports. USDA determines whether a foreign government has laws and regulations that can assure the same level of

safety as required in the U.S. and then verifies that the foreign government is enforcing those laws and regulations. FDA should not simply take the word of a foreign government that it is inspecting to U.S. standards. Instead, FDA should conduct periodic reviews of foreign governments to assure that their systems are able to adequately oversee foreign food facilities importing to the U.S.

We also urge the agency to bolster its port-of-entry inspection capabilities. Currently, FDA is only able to inspect between one to two percent of food imports that reach our shores. This compares to the 100% visual inspection that USDA's Food Safety and Inspection Service conducts for meat and poultry imports and the 10% intensive inspection it conducts for those imported food products. FDA has touted its PREDICT information technology system as a tool that can better focus its import inspection activities at the ports-of-entry. Unfortunately, the system has run into software problems that have delayed its deployment across the country. We urge the agency to make every effort to correct those issues and make sure that PREDICT is capable of delivering on the promises the agency has made.

Reliance on States to Conduct Inspection Raises Serious Questions

Regarding domestic inspection, coalition members believe FDA has a responsibility to carry out an increased frequency of inspections as mandated in the FSMA. We strongly oppose passing on this responsibility to the States without resolving some key issues. We urge FDA to use state inspection resources as a supplement to, and not in lieu of, a robust federal inspection program.

Coalition members have a number of concerns about efforts to rely on States to conduct inspection on behalf of FDA. In particular, we would like to highlight three areas FDA must address before the agency should feel confident that it can rely on States to conduct inspections on the agency's behalf: standardization, accountability and resources.

1. Standardization – 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.⁴ ⁵ State surveillance of foodborne illness differs⁶, as does state reporting of foodborne illness outbreaks.⁷ 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 2007-2008.⁸

Despite FDA's increased reliance on the States to conduct food inspections over the years, there is variation among even those States contracting with FDA to conduct inspections. An Institute of Medicine/ National Research Council 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."⁹

⁴ Association of Food and Drug Officials, "State Food Safety Resource Survey," 2009 Edition.

⁵ Office of Inspector General, "FDA Oversight of State Food Firm Inspections." Department of Health and Human Services, OIE-01-98-00400, June 2000.

⁶ Produce Safety Project, Safe Tables Our Priority, "State Surveillance of Foodborne Illness." <http://www.producesafetyproject.org/admin/assets/files/PSP-STOP-Report.pdf>

⁷ Center for Science in the Public Interest, "All Over the Map," January 2011.

⁸ Trust for America's Health, "Ready or Not? Protecting the Public's Health from Diseases, Disasters and Bioterrorism," 2010.

⁹ Institute of Medicine and National Research Council, "Enhancing Food Safety: The Role of the Food and Drug Administration." The National Academies of Science, June 2010.

FDA has recently developed its Manufactured Food Regulatory Program Standards as a tool to better understand and monitor a State's food safety inspection system. FDA has indicated it will use the Standards to improve its contracts with States. However, coalition members require more detailed information about how FDA plans to use these standards before we can adequately assess them. How will FDA assure that State inspectors are meeting federal standards for conducting inspections? Will there be additional training for State inspectors on the new federal standards for preventive controls? What will FDA do in those States that don't apply for a contract with the agency? How will FDA communicate to the States its high-risk designations for food facilities and food products? Could States develop their own high-risk designations that could differ from FDA's list? How will FDA pay States to carry out adequate contracts that meet federal standards? What happens if a State does not meet the requirements of the MFRPS?

If FDA intends to rely on the States, the agency must be assured that state inspectors are conducting inspections to the same standard as FDA inspectors under the new federal requirements for preventive process controls and performance standards. This will require standardization across state programs with which FDA contracts to conduct inspections. FDA should not contract with States that are unable to meet federal standards for inspection. Adequate training of state inspectors to meet federal standards is a critical component of this effort.

2. Accountability – 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.¹⁰ In its Field Management Directive on state contracts, FDA sets a goal of auditing seven percent of state contract inspections annually. However, in the most recent list of contract audits from 2009-2010, FDA only audited 5.8 percent of state contract inspections overall, and in 30 percent of state programs, FDA audited between zero and five percent of contract inspections.¹¹ Although the agency has been improving its audit rate in recent years, without proper oversight of state inspection programs, FDA cannot be assured that States are conducting adequate food safety inspection activities to federal standards. A rigorous evaluation of state inspection programs is essential to establishing confidence that States can conduct food safety inspections on FDA's behalf.

Transparency is another element of accountability. The Office of Inspector General also noted that FDA was not providing sufficient information to the public about which types of activities States were conducting on FDA's behalf.¹² The OIG recommended that FDA make the following information available:

¹⁰ Office of Inspector General, "FDA Oversight of State Food Firm Inspections." Department of Health and Human Services, OIE-01-98-00400, June 2000.

¹¹ <http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/PartnershipsContracts/StateContracts/AuditReportsonStateFoodContractInspections/UCM233959.pdf>

¹² Office of Inspector General, "FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability." Department of Health and Human Services, OEI-10-98-00400, June 2000.

- **The extent and nature of FDA’s reliance on State inspections**, including the States with which FDA holds contracts and agreements; information regarding the number and type of inspections and the risk of food firms being inspected by States under these arrangements; and the ratio of food firms inspected by FDA versus the States.
- **The extent and nature of FDA’s oversight of State inspections**, including FDA’s mechanisms to oversee State inspections and the extent to which the agency has carried out these responsibilities.
- **State performance**: FDA should make available its assessments of State performance, both assessments during audits as well as reviews of the States’ inspection reports, and could consider developing a list of state programs that meet certain performance standards.
- **Inspection results**: FDA could make available aggregate information of State inspection reports. This could include a summary of inspection classifications, trends in critical violations and compliance actions taken. FDA could take similar steps to make the results of its own inspections available.

3. Resources – 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.¹³ 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 FY2008-2009 to FY2009-2010.¹⁴ 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 2002¹⁵, 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.¹⁶ 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.^{17 18} Media reports further highlight the dire financial straits in which States find themselves. In July 2010, Florida state lawmakers were reported as deciding to end food safety inspections at nursing homes, daycare centers and hospitals, primarily for budget reasons.^{19 20} News reports from Minnesota this month raised concerns about a budget impasse in that state that could affect critical public health functions.^{21 22} 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

¹³ McNicol E, Oliff P, Johnson N, “States Continue to Feel Recession’s Impact.” Center on Budget and Policy Priorities, December 16, 2010.

¹⁴ Trust for America’s Health, “Ready or Not? Protecting the Public’s Health from Diseases, Disasters and Bioterrorism,” 2010.

¹⁵ 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>.

¹⁶ National Association of Country & City Health Officials, “Local Health Department Job Losses and Program Cuts: Findings from January/February 2010 Survey,” May 2010.

¹⁷ *Ibid*

¹⁸ *Ibid.*

¹⁹ <http://www.floridatoday.com/apps/pbcs.dll/artikkel?Dato=20100815&Kategori=NEWS02&Lopenr=101019017&NoCache=1&Ref=AR>

²⁰ <http://www.foodsafetynews.com/2010/07/florida-cuts-critical-food-safety-inspections/>

²¹ http://www.twincities.com/ci_18277805?source=most_viewed&nclick_check=1

²² <http://www.wired.com/wiredscience/2011/06/goodbye-team-d/>

given sufficient resources to provide substantial financial support to the States to carry out food safety activities on behalf of the FDA.

More importantly, States already conduct essential food safety inspections of retail and restaurant facilities, nursing homes, hospitals, schools and other institutions. This is critical public health work and there is no other entity to conduct those types of food safety inspections if state inspectors do not. A further concern is that State and local inspectors can be assigned to help address other areas when emergencies arise (such as pandemic flu), which reduces the amount of dedicated time to food safety tasks. The statistics above should raise serious concerns about whether States are even able to conduct sufficient retail and restaurant inspections already under their jurisdiction,^{23 24 25} much less take on additional inspection responsibilities. Coalition members are concerned that if FDA contracts with States to conduct inspections on the agency's behalf, state resources available for food safety inspections of retail establishments, restaurants and other institutions may be shifted to conducting contracted federal inspections, resulting in major cuts to fundamental state consumer protection and public health functions.

FDA Should Utilize Other Federal Inspection Resources

The FDA should look to other federal food inspection programs to assist the agency in implementing FSMA, not only in other countries (as noted above) but also domestically. The Government Accountability Office in the past has pointed to overlapping jurisdictions between USDA's Food Safety and Inspection Service (FSIS) and FDA. In 2005, the GAO identified some 1,400 plants where both FSIS and FDA inspection personnel had inspection responsibilities. Because of the continuous inspection mandate in the statutes governing meat and poultry products, there is no reason that FSIS inspectors could not also conduct inspections for FDA-regulated products in those dual-jurisdiction plants, allowing FDA to conduct inspections in other domestic plants under its jurisdiction. Resources would need to be provided to FSIS to conduct those inspections and FSIS inspectors would need to be trained in FDA regulations, but we strongly believe this would be an efficient use of expertise at the federal level.²⁶

Enforcement of Inspection Provisions

In addition, we would like to make several recommendations to FDA as it enforces its new inspection authority under FSMA. We strongly believe that incorporating these enforcement mechanisms into its inspection work will help FDA to more efficiently and effectively prevent recalls and ensure compliance with their regulations.

- Section 107 of FSMA allows for the collection of fees from facilities that have to be reinspected, or which are involved in recalls. This provision is important as it will give FDA another tool to ensure that facilities comply with FSMA requirements. We further recommend that these fees be set at an amount that would recover all costs associated with reinspection, including administrative costs.

²³ Associated Press, "San Francisco restaurant inspections down," October 30, 2010,

<http://www.signonsandiego.com/news/2010/oct/30/san-francisco-restaurant-inspections-down/>.

²⁴ Dirty Dining, "Restaurant Inspections Plunge," November 3, 2009, <http://www.kitv.com/r/21503331/detail.html>.

²⁵ 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>.

²⁶ Government Accountability Office. "Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources," GAO-05-213, March 2005.

With regards to foreign facilities that must pay the reinspection or recall fees, FDA should make clear that it will use its collection authority under section 743(e) aggressively and collect the fees from a food company's U.S. agent and the importer. To ensure collection, FDA should consider requiring U.S. agents and importers to be bonded, in addition to current bonding requirements, against potential default on payment of any fees due.

- Section 306 of FSMA governs the inspection of foreign facilities, including the refusal of those facilities to be inspected. We encourage FDA to promulgate a rulemaking on this issue, including a definition that explains what constitutes a "refusal of inspection." This definition should be broad enough to include any refusal to permit, or any action that hinders, an inspection to the extent it would be allowed in a domestic facility (i.e., anything that hinders a standard inspection should be viewed as a refusal of the entire inspection when in a foreign plant).
- The Coalition also requests additional information from FDA regarding how it will use its civil and criminal penalties in the inspection context. These two penalties are quite different, and one may be preferable to the other depending upon the situation. We urge FDA to solicit and incorporate public comment on the best use of civil and criminal penalties as effective enforcement mechanisms.

Conclusion

FDA should 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. If FDA is going to rely on States to conduct inspections on behalf of the agency, FDA must assure that it has strong federal inspection standards to be followed by the States and that only States that can meet these standards are selected. FDA must assure adequate oversight of state programs and provide sufficient funding to support an acceptable level of inspection activity in the States chosen without jeopardizing the important food safety work that the States already do.

Efforts to further involve the States should be conducted through a public process and should provide the public the opportunity to comment at various stages along the way. FDA should also post information on its website about which States are conducting inspection activities on behalf of the agency and a description of those activities. FDA should post the results of its state audits online so the public can know which States are meeting federal standards and which States are not.

Finally, FDA should actively seek to partner with other federal food safety agencies to supplement its inspection resources, especially in those food establishments where an established federal food safety regulatory presence already exists. For foreign inspections, while FDA could rely on trusted foreign national governments to conduct foreign inspections, the agency must be assured that foreign government oversight of food facilities is adequate and effective.