November 20, 2013

VIA FAX AND CERTIFIED MAIL

Leslie Kux
Assistant Commissioner for Policy
Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments to HHS FDA on Petition, Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Docket No. FDA-2011-N-0920); and Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (Docket No. FDA-2011-N-0921).

Dear Ms. Leslie Kux,

Concerned citizens and students of Vermont Law School welcome this opportunity to comment on the Food and Drug Administration's (FDA) proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls Rule) and proposed Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (Produce Rule). We would like to thank you for this opportunity to address our concerns publicly.

Residents of California, New Jersey, Ohio, and New York composed this comment keeping in mind their connections and knowledge of Vermont, West Virginia, and North Carolina agriculture. As students at Vermont Law School our environmental interests and expertise align with farmers, fishermen, trade organizations, farm and conservation organizations and food co-ops. Our scholarship is abundant and diverse and includes expertise in livestock, fruit and vegetable farming, organic, conventional, sustainable agriculture.

Many of these entities will benefit from state implementation of FSMA. State agencies retain the authority, and the framework to fulfill the compliance measures within FSMA. However, any coordinated efforts, such as inspections, monitoring, or education, must be fully funded by the

federal government. This funding is vital to regulating FSMA and, more broadly, promoting the vision of an "Integrated Food Safety System."[1] Increasing this cooperative relationship between state and federal agencies would improve compliance with the preventive-based controls, as well as the extensive outreach required by the proposed produce rule.

We commend FDA's efforts in building on existing voluntary industry guidelines for food safety. However, we submit on behalf of many environmental enthusiasts, representing six states, the following concerns of the proposed rules:

1. To promote a functioning integrated food system, the role of inspections should be divided between the state agencies and the FDA. In regard to Produce Rule §117.175 the role of the FDA should be to develop inspection-training programs, provide oversight of state inspection programs, and improve the science of risk-based food contamination prevention. The role of the state agencies should be to implement the federal inspection program and enforce "qualified facility" violations. Capitalizing on these existing strengths will enhance the effectiveness of FSMA.

2. The "qualified individual" proposed in the rule §117.115(b) should be an officer or employee of a state agricultural agency. A state officer best meets the requirements under the definition of a qualified individual, because they have specialized knowledge concerning that state. In appointing a representative of the state to this position, the objectives of the proposed draft rule will be met with more efficiency.

3. States should have a more active role in product monitoring and tracing under the proposed Produce provision II.H.1. Utilizing existing state public policy infrastructure while maintaining centralized oversight within the FDA will increase efficiency under the proposed rules. A state agent could address particularized concerns known to the state, while using existing outreach methods to educate producers.

[1] U.S. FOOD AND DRUG ADMINISTRATION, IMPROVING FDA'S EFFORTS TO ACHIEVE AN INTEGRATED FOOD –SAFETY SYSTEM AND IMPLEMENT FSMA (2009).

Introduction

Our central issue is the type of cooperation that the FDA requires from state agencies, local governments, and interested organizations. Section 205(b)(1)(A) of FSMA states the Secretary shall coordinate with "[f]ederal, State and local foodborne illness surveillance systems."[2] Further, §205(c) of FSMA states "[t]he Secretary shall develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies…."[3] Therefore, FSMA clearly directs there to be a coordinative effort with state and local officials to order to develop an "Integrated Food Safety Program."[4] First, we believe that this coordinative effort should capitalize on the state and federal capabilities. Second, the FDA should expand states' existing authority as well as capacity to prevent foodborne contamination. We believe this two-prong approach will dramatically increase "qualified facilities" compliance with FSMA and state agency cooperation.

Imbedded in this two-prong approach are the critical elements of *authority*, *capacity*, and *education*. The element of authority relates to a state agency's legal authority to regulate FSMA. Currently, the statutory language neither grants nor denies states the authority to implement FSMA. Delegation from the federal government to state agencies, within the framework of "cooperative federalism," requires specified language in the federal statute. This delegated authority incentives states to enact similar legislation that will allow for effective implementation of the federal standard. Our recommendations focus on Vermont; however, we believe our analysis is applicable to other New England states. In focusing on Vermont, there are two state agencies that are responsible for promoting food safety: Vermont Agency of Agriculture: Food and Markets (VAAFM) and the Vermont Department of Health (VDH).

Under the general powers of the VAAFM, the Secretary may conduct examinations, adopt, and enforce rules to implement the laws administered by the secretary.[5] In addition, general powers granted to the Secretary of Agriculture provide that "[t]he secretary shall promote the

[2] 21 U.S.C. 2224 § 205(b)(1)(A).
[3] 21 U.S.C. 2224 § 205(c).
[4] U.S. FOOD AND DRUG ADMINISTRATION, IMPROVING FDA'S EFFORTS TO ACHIEVE AN INTEGRATED FOOD – SAFETY SYSTEM AND IMPLEMENT FSMA (2009).
[5] VT. STAT ANN. tit. 6 § 1(a)(2), (10) (2013).

agricultural interests and education throughout the state…."[6] However, the VDH has the duty to "[p]rovide methods of administration and such other action as may be necessary to comply with the requirements of federal acts and regulations…."[7] Although authority is implicit in state statutory language and FSMA promotes an "Integrated Food Safety Plan", states require explicit authority to implement FSMA. Further, we recommend that the states have the flexibility to address particularized concerns and that any delegated responsibility should be supplemented with full federal funding.

Inherent in implementing these preventive and prospective regulations is ongoing outreach by state departments, providing education and training to farmers and local communities. An expansion of current food safety programs is necessary to adequately meet the demand of FSMA. The proposed rules are designed to create more comprehensive food safety regulations. Specifically, the proposed Produce Rule §117.175 necessitates routine onsite food safety inspections, and part II, subpart H increases the recordkeeping needed for product tracing.[8] In addition, Preventive Controls Rule §117.155 requires training of a "qualified individual" to inspect every registered facility; and §117.140 calls for increased monitoring.[9] In order to effectively implement the proposed rules, the FDA should expand its existing relationships with state agencies.

Last, we view education as a critical component to ensuring greater compliance of FSMA. Currently, Vermont has an extensive agriculture education network. VAAFM's Consumer Protection Division acts as a hub, distributing information to producers and processors regarding current food safety policies. Extension agencies or agricultural community organizations perform most of the outreach. Those entities heavily rely on federal or state funds. These outreach programs are essential to help farmers understand appropriate food safety regulations. More importantly, they help increase compliance and food safety enforcement.

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[6] VT. STAT ANN. tit. 6 § 3 (2013).
[7] VT. STAT ANN. tit. 18 § 5(2) (2013).
[8] Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Rule), 78 Fed. Reg. 3632, 3608 (proposed Jan. 16 2013).
[9] Proposed Rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventative Controls Rule), 78 Fed. Reg. 3762 (proposed Jan. 16, 2013).

Our comments will specifically address the elements of authority, capacity, and education to recommend the most effective ways to implement FSMA. We ask the FDA to expand as well as clarify state and local involvement in a number of key provisions. Further, the FDA should grant state agencies the flexibility to address particularized concerns, while recognizing that state agencies are best suited to train and educate farmers on compliance measures.

Comments

I. FDA SHOULD DIVIDE THE ROLE OF INSPECTION BETWEEN STATE AGENCIES AND THE FDA.

A. State agencies are a necessary component for the development of an Integrated Food Safety System.

FDA is authorized to conduct inspections under § 702(a)(1)(A) of the Food, Drug & Cosmetics Act (FD&C Act).[10] There are two areas, relating to inspections, within the Preventative Controls Rule and the Produce Rule that we wish to comment on. First, in the Preventive Controls Rule, the FDA requested comment on § 117.175—Records Required for Subpart C. FDA's specific request was whether more detail would be appropriate by "providing for substitution of a regulatory inspection (e.g., by FDA or a comparable State regulatory agency or foreign food safety authority), for an onsite audit."[11] The second comment is on the Produce Rule. The Produce Rule is unclear as to how state agencies and federal agencies will cooperatively conduct inspections. The Produce Rule, part XII, subsection Q: Enforcement and Compliance states that "FDA is committed to working with…State agencies… to facilitate compliance through education, technical assistance and regulatory guidance."[12] We view both of these sections to be interdependent. Without clarifying the state's role in this implementation process, we cannot comment on whether states would be better suited to regulate the inspections. Therefore, we seek to comment on both these rules in order to develop a better understanding of state agencies' expected role in implementing FSMA.

[10] 21 U.S.C. § 372(a)(1)(A).
[11] Preventative Controls Rule, 78 Fed. Reg. 3762.
[12] Produce Rule, 78 Fed. Reg. 3632, 3608.

We believe that in order for the FDA to respond to the challenges of conducting inspections the FDA must delegate greater responsibility to state agencies. There is already a trend in the FDA to inspect fewer facilities and delegate more responsibility to state agencies.[13] The Health and Human Services reported that in 2009 state inspectors conducted fifty-nine percent (59%) of FDA's food inspections, compared to only forty-two percent (42%) in 2004.[14] Further, the report found that the FDA failed to meet its audit inspections for one-third of the states it was contracted.[15] Moreover, FDA's inspection scheme is not timely enough to be considered effective.[16] Last, the relationship and coordinative efforts between the state agencies and federal agencies has been described as "lacking."[17] Thus, one solution to address this shift in responsibility would be to grant states more discretion to implement an inspection program according to FSMA.

Two challenges in implementing a federal law with state control are *economies of scale* and *delegation of responsibility*. For instance, economies of scale are challenges in regulating the Clean Air Act (CAA) creating profound inefficiencies in the program.[18] Money and time are wasted across the United States because each locality is required to monitor air quality.[19] Instead, critics argue that a centralized entity would function more efficiently. Second, responsibility can be more effectively delegated when the federal government can provide greater over-sight and the state agencies perform the individual inspections.[20] Centralized food safety oversight will ensure a uniform inspection standard and consistent food regulation across state lines. Also, federal agencies have greater availability to funding and scientific expertise.

Delegating greater discretion and responsibility to the states will reduce the problems of

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[13] DEP'T. OF HEALTH AND HUMAN SERVICES, OFFICE OF THE INSPECTOR GEN., VULNERABILITIES IN FDA'S OVERSIGHT OF STATE FOOD FACILITY INSPECTIONS (2011).
[14] *Id.*
[15] *Id.* at iii.
[16] Lincoln Cohoon, New Food Regulations: Safer Products or More Red Tape?, 6 J. HEALTH & BIOMEDICAL L. 343, 353 (2010).
[17] Richard A. Merrill & Jeffrey K. Francer, Organizing Federal Food Safety Regulation, 31 SETON HALL L. REV. 61, 123 (2000).
[18] Robert L. Glicksman, *From Cooperative To Inoperative Federalism: The Perverse Mutation Of Environmental Law And Policy*, 41 WAKE FOREST L. REV. 719, 733-34 (2006) (citing Daniel C. Esty, *Revitalizing Environmental Federalism*, 95 MICH. L. REV. 570, 600 (1996)).
[19] *Id*.
[20] Robert L. Glicksman, *From Cooperative To Inoperative Federalism: The Perverse Mutation Of Environmental Law And Policy*, 41 WAKE FOREST L. REV. 719, 733 (2006).

economies of scale and delegation of responsibility. Here state agencies will be closer to the facilities and have knowledge of the local food system. The issues relating to FDA's lack of follow up in the audit program can be addressed through closer oversight of the state agency and the "qualified facility." Further, a state agency geographically closer to the inspecting facilities will provide the opportunities to enhance personal relationships between the regulator and regulatee. These types of relationships will lead to educational opportunities; and ultimately, act as a catalyst to compliance. Last, the FDA should promote the existing trend of delegating more responsibility to the states. If the FDA is already moving in this direction, we encourage the FDA to be open and clear with the states on the type of inspection assistance it seeks. Regulating FSMA is an ideal opportunity to articulate this shift and provide states with the adequate resources to develop the "Integrated Food Safety System."

Recommendations:

- In the Preventative Controls Rule, we recommend that the states should have the authority and discretion to implement food safety inspections.

- In the Produce Rule, part XII, subpart Q: Enforcement and Compliance, the FDA should clarify and specify how it seeks to work with state agencies. We recommend that this working relationship would be structured in the following ways: (1) FDA develops the standards and training for inspections and (2) the FDA grants authority for the states to implement the individual inspections, (3) and the federal agency funds ALL necessary expenses for implementation of the program.

B. The qualified individual should be an officer or employee of the state.

The proposed rule §117.155(b) requires that a "qualified individual" must be trained in how to implement the risk-based preventive controls.[21] To become a "qualified individual" a person must complete an FDA accredited standardized curriculum or have sufficient job experience. The trained individual is required to execute certain procedures deemed necessary by the FDA. The FDA does not require that the "qualified individual" be an employee of the facility, so we

[21] Preventive Controls Rule, 78 Fed. Reg. 3762.

therefore submit that "qualified individuals" are members of a local state department. Agents of local state departments have the best connection to local farmers and the state. The federal government will benefit from training and funding state officials to be "qualified individuals." Overall, it will strengthen the cooperative relationship between the federal government and the states.

Authorizing state agency employees to be a "qualified individual" would ensure the highest compliance and state cooperation for the following reasons: (1) farmers feel most comfortable working with state employees rather than federal employees, (2) there would be extensive hardship on farmers in order for them to contract out and hire a "qualified individual", and (3) it is more efficient to have a member of the local state department travel to farms.

While there are no initial fees for registering with FSMA or for the initial FDA inspection, failing to pass an inspection can accrue expensive costs for farmers. The FDA can collect fees for certain domestic food facilities, importer re-inspections, recalls and general re-inspections. The fee for the 2013 year for any of these infractions is $221 or more an hour. At this time small businesses cannot have these fees waived. Failing to provide a fee waiver puts a substantial burden on small farmers who may not fully understand how to comply with the regulations of FSMA.[22]

Without fully understanding these compliance measures the comprehensive objective of FSMA is not met. Farmers need to be educated on how to understand and comply with FSMA versus just being expected to understand and submit the correct documents. However, having each farmer expected to hire its own "qualified individual", would raise the concern of *economies of scale*. We view the most efficient use of resources would be authorizing a state agency to act in this capacity. It will be more efficient and beneficial to have a member of the local agriculture department go to farms and educate farmers on how to make a food safety plan or how to comply with all the stringent rules of FSMA.

[22] U.S. FOOD AND DRUG ADMINISTRATION. FEES. (2013).

We propose for state agencies to fulfill this capacity. State agencies will be better suited to develop scale-appropriate and scale-specific training program. A tailored training program would reflect the differences among growing regions, commodities, and production practices. Many states have existing infrastructure that provides these types of services through organizations, universities and extension agencies. Supplemental federal government funding would only increase the effectiveness of these existing programs.

i. FSMA's requirements for a "qualified individual" are similar to the authority granted to the Vermont Secretary of Agriculture

Vermont laws delegating authority to the Secretary of Agriculture are similar to the requirements of FSMA's "qualified individual." Vermont laws give authority to the Secretary of Agriculture to make sure local farmers follow the regulations of the state. The job of the Secretary mimics that of the "qualified individual." We propose that the federal government train and fund state secretaries of agriculture to be qualified individuals under the standards set forth in FSMA.

Under 6 V.S.A. §1 determines the general powers of the secretary of agriculture. [23] The Secretary acts as qualified individual in a sense because he or she is responsible for the execution and enforcement of all laws relating to agriculture. The Secretary has the authority to conduct inspections, investigate suspected violations, institute proceedings to enforce laws.[24]

The responsibilities of the Secretary mimic that of the "qualified individual." In efforts to improve efficiency and existing relationships with the farming community, the Preventive Controls Rule should specify that the "qualified individual" may be a state agent. This agent already takes on a similar role and would relieve farmers of the expense to hire a "qualified individual." Thus, we compel the FDA, in the interest of effective compliance, to grant this authority to the state agencies.

[23] VT. STAT ANN. tit. 6 § 1.
[24] *Id*.

Recommendations:

- Inspections under FSMA should be implemented in the following manner:
    1) FDA develops the standards and training for inspections and
    2) The FDA grants authority for the states to implement the inspection and the federal agency would fund all necessary expenses for implementation of the project.

- To ensure a functioning integrated food system, the role of inspections should be divided between the state agencies and the FDA: each capitalizing on strengths of their respective roles. The role of the FDA should be delegated to develop and implementation of inspection train programs, oversight of state inspection programs, and forwarding the science of risk-based food contamination prevention. While the state agencies are to be delegated the authority of conducting the inspections to the qualified facilities.

- The "qualified individual" proposed in the rule should be an officer or employee of a state agricultural agency. According to the Preventive Controls Rule, a "qualified individual" would be in charge of developing and applying a food safety system at each facility. The "qualified individual" must, at a minimum, be required to complete training with a standardized curriculum or otherwise be qualified through job experience to develop and apply a food safety system. We submit, in the spirit of cooperative federalism, that a representative from the state department of agriculture be this "qualified individual."

II. FDA SHOULD TAKE ADVANTAGE OF EXISTING STATE AND PUBLIC POLICIES THAT CAN ACT IN CONJUNCTION WITH THE PROPOSED MONITORING OF FOOD SAFETY PLANS AND PRODUCT TRACING.

A. FDA should expand its food safety research and development capacities while granting states greater authority to inspect facilities because of its existing capacity and authority.

The Produce Rule, part XII, subpart Q: Enforcement and Compliance states that "FDA is committed to working with…State agencies… to facilitate compliance through education,

technical assistance and regulatory guidance."[25] This vague language presents serious concerns to state government and local entities. The Produce Rule fails to specify the type of relationship or level of involvement the FDA seeks from state governments. Further, the proposed rule does not specify which state agencies will work with the FDA. Recognizing these concerns we propose the FDA use a regulatory model that capitalizes on the strengths of both the federal and state governments.

i. First, the FDA should regulate FSMA from a Federal perspective and focus its resources on food safety research and inspection training development.

The factors effecting food safety do not vary between facility and facility. "[A]n operation's size, the growing practices used, or its proximity to customers does not determine whether the food offered is safe."[26] The policy behind FSMA recognizes the core variables of risk-based food contamination prevention that are independent of the farm's size and location. Further, a uniformed standard may be developed to apply to all "qualified facilities." As noted early, federal agencies have greater access to funding and scientific expertise necessary to establish a stringent baseline. Therefore, we recommend that the role of the FDA should focus its resources on food safety research developing inspection guidelines. This information should be used to ensure the prospective and preventive goals of FSMA.

ii. Second, the FDA should grant clear authority to each state agency to implement the inspections because the states have the potential to expand existing food safety infrastructure.

Vermont has some existing capacity for the Vermont to implement FSMA. The Vermont State government contains two agencies that have the responsibility to manage food safety: (1) The Vermont Agency of Agriculture: Food and Market (VAAFM) and (2) The Vermont Department of Health (VDH).

The VAAFM is an independent agency that contains a centralized state-local relationship.

[25] Produce Rule, 78 Fed. Reg. 3632, 3608.
[26] Letter from American Feed Industry Association, et al., to Tom Harkin, Chairman, and Michael B. Enzi, Ranking Member, Health, Educ., Labor and Pensions (PELP) Comm. (Nov. 15, 2010).

Currently, the VAAFM conducts contamination inspections that are commodity specific. This agency inspects 6,895 retail outlets twice a year.[27] The Agency inspects eggs, potatoes, apples, strawberries, maple products, irradiated foods, and refrigeration and freezer units.[28] Agency representatives organize quality control workshops throughout the year, collaborate with state universities and their students, and provide technical assistance to individual producers and groups.

Further, there are several state entities that fulfill an educational role. Most of the education and outreach efforts are performed by extension agencies or agricultural community organizations that receive federal or state funds. These outreach programs are essential to help farmers understand appropriate state and federal regulations increasing compliance and food safety enforcement. The University of Vermont (UVM) Extension works across the food system, from farm to table, to assist in supporting a safe and nutritious food supply. For example, the extension service provides forums and workshops on the Hazard Analysis and Critical Control Points (HACCP) plan, relevant to §103 of FSMA. This plan is a regulatory requirement for processing of some food products. The extension agency helps producers understand the importance of developing and implementing these plans, allowing food processors to produce food with a systematic and proactive approach to food safety. These workshops provide information on the prerequisite programs, conducting a hazard analysis, identifying critical control points and monitoring procedures which are applicable to the proposed preventative control rule. Thus, VAAFM possesses some existing capacity to implement programs outlined in FSMA.

The second state entity that is currently responsible for food safety is the Vermont Department of Health. The VDH operates under the authority of the Vermont Department of Human Services. It too is organized in a centralized state-local relationship. The Vermont Department of Health is enforces the labeling of foods and the supervising of local health officials. Under V.S.A. 18 § 4051-86, the Vermont Department of Health is authorized to regulate the labeling of food, drugs,

[27] Consumer Protection Division, VERMONTAGRICULTUE.COM, http://www.vermontagriculture.com/fscp/pidconsumer.htm (Last visited Apr. 13, 2012).
[28] *Id*.

and cosmetics.[29] Under these statutes, the state board of health regulates adulterated food and the mislabeling of food. This board takes a reactionary approach to food safety. After an incident of food contamination, the board has the ability to investigate the food contamination, regulate permits, and investigate facilities that are in violations of state health standards. Further, V.S.A. 18 § 4054, states any person found to have manufactured, sold or delivered, held, or offered the sale of any food, drug, device, or cosmetic that is adulterated or misbranded shall be imprisoned for not up to one year or fined up to $1,000.00 or both.[30]

In addition, under V.S.A 18 § 601-24, the VDH is authorized to govern local health officials. Under these statues, the Commissioner of the Vermont Board of Health may appoint a local health officer for each town or city.[31] The local public health advisor provides "boots on the ground" for any identified public health hazards. Upon receipt of information regarding a condition that may be a public health hazard, each advisor may enforce permits. Further, the advisor is authorized to prevent, remove, or destroy any public health hazard.[32] Thus, VDH possesses some existing capacity to implement programs outlined in FSMA.

There is some infrastructure for both the VAAFM and VDH to implement food safety programs; however, the authority to implement this law is unclear. Both the VAAFM and the VDH express deep concern regarding their role in the implementation process. One State official indicated that in order for the VAAFM to adequately implement FSMA greater funding would be required and the Vermont State Legislature would need to enact new laws that support FSMA's compliance. We compel the FDA to clarify the meaning of "working with a state agency" and ask the FDA to clearly state its intentions to cooperate with state agencies.[33]

[29] VT. STAT ANN. tit. 18 § 4051-71 (LexisNexis 2013).
[30] VT. STAT ANN. tit. 18 § 4054 (2013).
[31] VT. STAT ANN. tit. 18 § 601-24 (2013).
[32] VT. STAT ANN. tit. 18 § 602(a) (2013).
[33] Produce Rule, 78 Fed. Reg. 3632, 3608.

B. FDA should consider creating a centralized system for product tracing and the states should take on a stronger role in monitoring.

The Produce Rule, would require persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States establish and maintain records identifying previous sources and immediate subsequent recipients of food.[34] This proposed structure would impose a significant burden on qualified facilities. The new draft rules call for more procedure and protocol in creating food safety measures, thus there will be an increase in the amount of general surveillance and record-keeping. The burden of surveillance should not fall solely on farmers, but rather should be distributed amongst the states and the FDA. Authority should be explicitly granted to the states to conduct food safety monitoring and the FDA should maintain its product-tracing responsibility.

i. FDA is better suited to implement a product-tracing program

A federal-run centralized record system, with state government access and oversight, would be most efficient for public health and safety. The new proposed rule will require a massive accumulation of more information and this is expected to heavily burden regulatory agencies. Thus, the FDA should consider adopting a technology platform that would allow efficient aggregation and analysis and that the platform should be accessible to other regulatory entities.[35]

There are two major benefits of having the FDA maintain such a surveillance system. First, the FDA already has the capacity to implement a large, centralized system. Today states are restricted by a decentralized piece meal product tracing system. This proposed system seeks to compile vast data sets across boundary lines and create access to all interested parties. While state health agencies generally share surveillance records with one another, the agencies would benefit from the efficiency of a centralized system.[36] This system would act as a hub for state health and agricultural agencies to access and share information creating a more comprehensive

[34] Produce Rule, 78 Fed. Reg. 3516.
[35] ITF PILOT PROJECTS FOR IMPROVING PRODUCT TRACING ALONG THE FOOD SUPPLY SYSTEM (2013), *available at* http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM341810.pdf.
[36] ASTHO STATE HEALTH PROFILE, VOL. 2 (2011), *available at* http://www.astho.org/profiles/.

and transparent access to resources. This transparent and centralized structure is critical to meeting the demand that FSMA requires.

Second, by allowing states access to this system, the FDA can coordinate with state officers to quickly eliminate the source of the contamination on the ground as soon as possible. Furthermore, a centralized system would help the FDA react to natural disasters, such as all the produce and vegetables ruined in the aftermath of Hurricane Irene. States would also have a distinct interest in records access if the source of the outbreak in another state was from their state and vice versa.

ii. State agencies are better suited to implement food safety monitoring programs.

The Preventive Controls Rule stipulates that the person in charge of a facility establish and implement written procedures for monitoring preventive controls.[37] We recommend that this monitoring responsibility should be delegated to the state agencies. The Produce Rule, part XII, subsection Q: Enforcement and Compliance pledges to work with food safety partners in the public and private sectors.[38] As stated above, we compel the FDA to direct greater responsibility to state agencies. A state-run monitor program will expand upon existing relationship with qualified facilities and educate farmers. For example, farmers may be uncertain or reluctant to have details of their farms reported in a larger federal database.

Further, state education entities can fulfill a monitoring capacity. There is already great strength in local educational tools that the FDA can depend on to help facilities meet their standards. For example, the University of Vermont's (UVM) Center for Sustainable Agriculture is a useful resource for local farmers. In particular, they are a good outreach source to help farmers practice Good Agricultural Practices (GAP)[39]. The Center is available to producers to help them with each stage of the process from assessment and planning to implementation. By reaching out to

[37] Produce Rule, 78 Fed. Reg. 3747-48.
[38] Produce Rule, 78 Fed. Reg. 3632, 3608.
[39] UVM CENTER FOR SUSTAINABLE AGRICULTURE PRODUCE SAFETY AND GAP RESOURCES, https://www.uvm.edu/~susagctr/?Page=whatwedo/producesafety/gapresources.html (last visited Apr. 14, 2013).

local educational resources with their level of standards, the FDA can help ensure greater compliance.

Recommendations:

- Clarify the language under the Produce Rule, part XII, subpart Q: Enforcement and Compliance state that "FDA is committed to working with…State agencies… to facilitate compliance through education, technical assistance and regulatory guidance." Additionally, define the meaning of "working with a state agency."

- Under §117.140 of the Preventive Controls Rule, authority should be explicitly granted to the states to conduct food safety monitoring and the FDA should maintain its product-tracing responsibility.

Conclusion

For these reasons, further state collaboration is needed to insure not only the efficiency and effectiveness of the proposed rules, but the prospective and preventive purpose of FSMA. Increasing state integration in these additional areas will help identify hazards, and specify the steps needed to minimize health and safety concerns. Allowing state agencies to implement some provisions of FSMA, will likely increase compliance and encourage stronger relations with consumers and farmers. This cooperation will lead to stronger, healthier, and safer communities.

Respectfully Submitted,

Concerned Citizens and Students of Vermont Law School
Ian Altendorfer, Taylor Curtis, Nancy Lin & Emily Whalen