CDA Produce Safety Rule Implementation Considerations

June 2016

Contents

The Colorado Department of Agriculture (CDA) recently submitted a 5-year cooperative agreement proposal to FDA for implementation of FDA's Produce Safety Rule (PSR). The PSR is a new federal regulation for the previously unregulated produce grower industry, and most states do not have an existing system in place for on-farm inspections.

The 5-year cooperative agreement work plan will be a work in progress, with many situations and challenges to address that could not be foreseen during the writing of the cooperative agreement proposal. This paper offers additional insights and considerations for PSR implementation that were beyond the scope of the original cooperative agreement.

Legislative Authority

CDA currently (pre-FSMA) has on-farm authority to perform inspections through the Organic Certification and Industrial Hemp Certification programs. [redacted] may choose to implement a produce safety program under FDA Commissioning or Credentialing authority rather than create an independent state authority. CDA has the FDA commissioned staff in place to do this.

According to the PRS Comments *Section XXII. Subpart Q-Comments on Compliance and Enforcement, C. Coordination of Education and Enforcement,* in the *Response to comment 414,* the Food, Drug & Cosmetic Act (FD&C Act) expressly authorizes FDA to conduct examinations and investigations on behalf of the FD&C Act through FDA qualified commissioned officers and employees (Figure 1.).[1] The FDA Food Safety Modernization Act (FSMA) amended section 415 of the FD&C Act which requires food facilities to register with FDA.

Based on this information, it appears that CDA's FDA commissioned employees have the authority to conduct on-farm inspections, and it is likely no legislative changes need to be make to implement the PSR in [redacted] Of course, the Assistant Attorney General must make the final determination on this.

A May 2016 GAO report on Food Safety stated that "Until the requisite non-federal authorities are obtained, FDA officials told us that they are able to commission some non-federal officials to conduct certain implementation activities under federal authority."[2]

A produce safety program operating under federal commissioning could be a short-term option to meet PSR inspection and enforcement dates while seeking to change state statutes, if desired by [redacted] stakeholders.

74520 Federal Register / Vol. 80, No. 228 / Friday, November 27, 2015 / Rules and Regulations

Session Law 2013–365 (Senate Bill 63) (NC Farm Act of 2013) as providing protection to farmers by entitling them to "a rebuttable presumption that the commodity producer was not negligent when death or injury is proximately caused by consumption of the producer's raw agricultural commodity" under certain conditions.

(Response) We are aware that North Carolina has passed this law in their State, and that other States may choose to establish similar laws. However, State law tort duties are not relevant for purposes of this rule.

C. Coordination of Education and Enforcement (§ 112.193)

address the degree to which FDA will enforce the rule, and the extent to which States will be involved. Several comments request clarification, including on the framework for coordination, timeline for inspection-related activities, expectations from State agencies, and securing necessary funds and resources. Several comments favor FDA working with State governments using existing established efforts, including State-industry educational and regulatory interfaces and assistance programs, as well as education and standards of current protocols developed by extension services, State departments, other

to work closely with States to implement the produce safety rule. We agree that our State counterparts have substantial knowledge about the farms in their jurisdiction. FDA intends to work collaboratively with our federal and State regulatory partners to use available inspection resources to

for compliance with this rule. Section 702(a)(1)(A) of the FD&C Act (21 U.S.C. 372(a)(1)(A)) expressly authorizes FDA to conduct examinations and investigations for the purposes of the FD&C Act through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof (such as a locality), duly commissioned to act on behalf of FDA. Qualified State, territorial, tribal, or local regulatory officials may be commissioned or serve under contract with FDA to conduct examinations, inspections, and investigations for purposes of the FD&C Act. In addition, section 702(a)(2) [21 U.S.C. 372(a)(2)] expressly authorizes FDA to conduct examinations and investigations for the purposes of the FD&C Act through officers and employees of another federal department or agency, subject to certain conditions set forth in that section. We expect to continue to cooperatively leverage the resources of

government agencies in this and other

final produce safety rule should include issuance of a tribal regulatory authority for training and implementation and limit the authority of State law enforcement officers on tribal lands, or exclude tribal lands altogether from State enforcement unless at the request of the tribe.

(Response) FDA recognizes the importance of engaging tribal regulatory authorities for successful FSMA implementation on tribal lands. FDA intends to work collaboratively with tribal regulatory partners to develop the appropriate education, enforcement, and training needed to facilitate compliance with the produce safety regulation on tribal lands (see FDA's recently released FSMA training strategy at *www.fda.gov/fsma*). We do not expect to use State officials to conduct inspections on FDA's behalf on tribal lands, but rather we intend to work with tribal authorities to commission tribal officials, as appropriate, to conduct these inspections.

(Comment 416) One comment requests adding to § 112.193 a list of entities, including State and federal partners, that will be working with FDA to implement the rule, as well as a timeframe for when operations will begin.

(Response) FDA declines to establish

Figure 1 Produce Safety Rule , Comments *Section XXII. Subpart Q* - C. Coordination of Education and Enforcement

Federal commissioning could also be long-term solution, whereby FDA will take a more active role in determining CDA's inspection schedules and risk-based farm priorities. Under this scenario, FDA would be responsible for compliance and enforcement decisions. From the GAO report comment noted above, this may not be FDA's desired long-term arrangement.

No matter the legislative authority a produce safety program operates under, protocols will need to be developed to address grower disputes, variance exemption requests, etc. The protocols should be developed with FDA collaboration, and can be expected differ depending on the legal authority in place.

If not clearly defined through the regulatory mechanism chosen, CDA may also need to identify the legal authority to create a registry of regulated farmers, solve disputes, approval of variance and exemption requests and other compliance and enforcement activities

Farm Inventory

Identifying farms initially to create the farm inventory database will be challenging and ongoing, but consistently updating it will also be a challenge. Data gathering can take multiple forms: self-assessment online survey (example: Vermont), farm registry instrument, or some other method. All options should be consistent for merging data into one database, and also to be consistent with FDA requirements for data sharing.

In addition to the common information, (name, mailing address, phone number, email address), data collected should inform implementation of PSR, and information collected should also provide information to allocate program resources, determine inspection requirement, and plan education, outreach and technical assistance activities, among other program needs.

Collaboration with FDA is required on the data to be gathered, yet below is a recommendation of data points to consider during the farm inventory development. This list is not all inclusive, and for some points, explanation will be required so that growers can accurately answer them. Recommended questions include:

- farm business size,
- percentage of sales direct-to-consumer,
- crop(s) grown (dropdown list of covered and non-covered),
- water source,
- pack and hold activities,
- what quadrant of state is the farm (or crop) located in, etc.

Because farms may grow multiple crops, collecting data for 5 crops per farm would be suggested. Dropdown lists would keep data uniform, with an 'other' fillable field as needed. Farms may grow a mix of covered and non-covered crops (which may change from year to year) and this tracking capability should be included.

Multi-Purpose Database

The farm inventory can also serve a dual purpose of providing contact to all farms on upcoming educational and outreach activities and additional resources available online. A listserve might be one option to consider.

According to the GAO Food Safety report, FDA acknowledges that farm inventory databases will need to consistently be updated and verified through in-person inspections (pg 29). Because of the program's emphasis on education, and the likelihood that these in-person inspections will take place on the farm, CDA could incorporate an education, outreach, technical assistance opportunity or potentially OFRR (scaled up or down depending on resources and need) into the farm inventory verification process.

Information Sharing

Information sharing with the FDA is required throughout all components of the PSR cooperative agreement. While all details are yet to be determined for how to share data, any opportunity to create a database that is scalable for multiple uses would ultimately save time and resources.

The GAO Food Safety report included information on a new information sharing system FDA has in development – the Observation Corrective Action Reporting system (OCAR). OCAR is intended to be an inspection, compliance and enforcement repository for regulated businesses and a regulator training resource portal. Industry businesses will also be able to access the portal to retrieve their inspection reports and input corrective action plans. When fully operational (anticipated to be 2019), OCAR will provide information sharing between FDA, non-federal regulatory personnel and industry (pg 35-36). To the extent possible, developing a farm inventory database that could be integrated with OCAR would be beneficial, saving regulator data entry time and ensure data collection is consistent through the cooperative agreement's Competition A and Competition B activities.

Education & Outreach

The overarching goals of the FDA FSMA rules is improving food safety and protecting public health, no matter the farm size. Industry and regulator education, outreach and technical assistance is a large component of implementing FDA's food safety rules, including the Preventative Controls for Human and Animal Food and the Produce Safety rule.