Center for Science in the Public Interest, Center for Foodborne Illness Research & Prevention, Consumer Federation of America, and The Pew Charitable Trusts

March 31, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals [Docket No. FDA-2011-N-0922, 78 Fed. Reg. 64736 (Oct. 29, 2013)]

The Center for Science in the Public Interest, Center for Foodborne Illness Research & Prevention, Consumer Federation of America, and The Pew Charitable Trusts appreciate this opportunity to comment on the proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals **[Docket No. FDA-2011-N-0922**].

SUMMARY

This comment covers the proposed rule requiring facilities that manufacture animal feed to operate under a food safety plan. It makes the following points:

- As a general matter, the proposed rule does a good job of interpreting and applying section 103 of the FDA Food Safety Modernization Act to the animal food sector.
- Definitions and exemptions under Subpart A of the proposed rule should be revised to define "very small business" as a business with less than $250,000 of annual sales. Documentation that a business meets the definition of a qualified facility should be submitted annually.
- Subpart B on Current Good Manufacturing Practices should require employee and supervisor training, and make all sanitation measures binding.
- Hazard Analysis and Risk-Based Preventive Controls under Subpart C must include supplier verification programs and verification testing.

- Authority to withdraw an exemption in Subpart D must be viewed as expansive authority and exercised early and preemptively when problems are detected at a qualified facility.
- Recordkeeping and record retention requirements in Subpart F should be revised to account for unique circumstances of qualified facilities.
- Facilities should be required to submit facility profiles and food safety plans.

COMMENT

The proposed rule implements the preventive food safety system established by section 103 of the FDA Food Safety Modernization Act (FSMA). Among FSMA's provisions is the requirement for each facility producing food for animals to conduct a hazard analysis and identify hazards that may be unintentionally or intentionally introduced, establish preventive controls to significantly minimize or prevent those hazards, and monitor the performance of those controls.[1] The goal of these provisions is to enable the Food and Drug Administration (FDA) to better protect animal health by focusing on preventing food safety problems rather than reacting to them after they occur.[2] The processing of animal feed is included because food is defined in the statute as meaning "articles used for food or drink for man or other *animals*."[3] (Emphasis added) Additionally, there is a regulatory concern that human illness may occur if contaminated animal food is handled by people when feeding farm animals or pets.[4] We believe the proposed rule as a whole does a good job of interpreting FSMA to achieve its laudable goals. With regard to specific provisions within the proposed rule, we offer the following comments.

I. Subpart A—General Provisions.

We support the definitions in this section with a recommendation that *very small business* should be defined as a business that has less than $250,000 in total annual sales of

[1] FDA Food Safety Modernization Act, sec. 103, § 418(a), 124 Stat. 3889 (2011).
[2] Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, 78 Fed. Reg. 64736, 64738 (Oct. 29, 2013).
[3] Food, Drug, and Cosmetic Act of 1938 § 201(f)(1), 21 U.S.C. § 321(f)(1) (2010).
[4] 78 Fed. Reg. 64739.

food adjusted for inflation. We believe FDA may only define the term in this way under FSMA's language. This is because well-established canons of statutory interpretation require FDA to strictly and narrowly interpret statutory exemptions particularly when they affect public health and safety.[5]

We disagree with the assumption in the preamble that because the animal food sector is skewed more toward medium and larger facilities the definition of *very small business* should differ from that for human food. Instead, the definition should be controlled by the terms of § 418(l) of the Food, Drug, and Cosmetic Act (FDCA). The three options proposed in the rule are based on the structure of the domestic sector. That ignores how the definition may apply to 3,785 ingredient suppliers and 458 pet food manufacturers located in other countries. Any such entity that qualifies as a *very small business* would not be required to implement preventive measures. Instead, they would only be responsible for complying with possibly inadequate food safety laws of the country where the facility is located.[6]

FDA should not allow what was intended as a narrow exemption to swallow up the food safety purpose of the larger law. Yet, that is precisely what happens if FDA adopts a broad definition of *very small business*.

We do not have similar concerns with regard to the exemptions in § 507.5 as they follow statutory mandates and are strictly construed and narrowly applied.

We are concerned that the documentation requirement for qualified facilities in § 507.7 is inadequate. It requires qualified facilities to submit documentation initially within 90 days of the effective date for complying with FSMA and biennially thereafter at the time they register. Biennial submission conflicts with the structure of § 418(l) of the FDCA, which provides for a calendar year exemption. Therefore, FDA should provide for

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[5] *USV Pharmaceutical Corporation v. Richardson*, 461 F.2d 223, 227-28 (4th Cir., 1972)(citing "the principle that statutory exemptions, particularly as applied to statutes concerned with public health and safety, are to be strictly and narrowly construed").

[6] We are not ignoring the requirement under the Foreign Supplier Verification Program of FSMA that importers also assure products are not adulterated. This requirement is merely a statement of existing law since putting adulterated product on the U.S. market is an offense under the FDCA.

annual submission of the documents required to show eligibility for the qualified facility exemption.

We are concerned that § 507.10 uses a term that is not adequately defined in its exemption for storage of food that is not exposed to the environment. The final rule should specify that the phrase "not exposed to the environment" means packaged with food grade material that is impermeable to outside bacteria or other contamination.

II. Subpart B—Current Good Manufacturing Practices.

We support the Current Good Manufacturing Practices (cGMPs) proposed by FDA in this rulemaking. In response to the specific request for comment, we support required training for employees and supervisors, including a requirement for records that document such training. The most compelling reason to require training is an agency finding that ineffective employee training was the root cause of 32 percent of cGMP-related recalls from 1999-2003.[7] We also support the proposed alternative of making the subpart's sanitary controls binding. This is needed to keep irresponsible businesses that engage in shoddy, cost-cutting practices from pushing the industry into a race-to-the-bottom.

III. Subpart C—Hazard Analysis and Risk-Based Preventive Controls.

We support provisions of Subpart C that implement the hazard analysis and risk-based preventive controls required by FSMA section 103 with certain exceptions. We support including provisions that require facilities to have supplier verification programs and to use environmental and product testing as a verification step. The proposed rule does not include either requirement.

Facilities should have supplier verification programs because the public has no way of knowing if suppliers are complying with the law while the businesses that process food are well positioned to prevent their suppliers from passing hazards through the food chain.

[7] Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3720 (Jan. 16, 2013).

FSMA anticipates that FDA will require the use of environmental monitoring to verify that the preventive controls are "effectively and significantly minimizing or preventing the occurrence of identified hazards. . . ."[8] The proposed rule includes a well-articulated discussion and rationale for the use of testing and other verification tools in its appendix.[9]

We urge the agency to require supplier verification and testing in the final rules governing food for humans as well as animals.

IV. Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility.

We support the process described in subpart D for withdrawing a qualified facility's exemption under authority found in § 418(l)(3)(A) of the FDCA**.** FDA should view this authority expansively, using it early and preemptively to protect public and animal health.

V. Subpart F—Requirements Applying to Records that must be Established and Maintained.

FDA should revise § 507.100 because it does not require a qualified facility to keep accurate, detailed monitoring records. The provision ignores the fact that qualified facilities may operate under either one of two conditions. They may choose to operate under modified food safety plans or under non-Federal food safety laws. A modified food safety plan includes requirements to implement and monitor preventive controls. Yet, as a result of the broad records exemption, the rule inadvertently exempts these qualified facilities from keeping records that are necessary to the operation of the modified plan.

FDA should also revise the requirements for record retention in § 507.108 to ensure that qualified facilities keep financial and sales records for at least four years. As proposed, the rule only requires a facility to retain records for at least two years after the date they were prepared. This fails to account for a qualified facility under § 418(l)(1)(C) of the FDCA which must document that the average value of food it sold over the prior three years

[8] FDA Food Safety Modernization Act, sec. 103, § 418(f), 124 Stat. 3890, (2011) (codified at 21 U.S.C. 350g(f) (2013)).
[9] 78 Fed. Reg. 64834.

did not exceed $500,000 annually. Although § 507.7 requires a qualified facility to maintain the records it relied upon to document its status, an operator may misunderstand how the retention schedule in § 507.108 applies to this responsibility. FDA can address this concern by specifying a minimum of four years for records retention by qualified facilities.

VI. Miscellaneous Issue: Submitting a Facility Profile to FDA.

FDA has requested comments on whether to require facilities to submit to the agency a facility profile or a subset of information contained in a food safety plan. We support such a requirement. With regard to submitting food safety plans, we believe such a requirement would be beneficial during implementation of the rule and later during routine inspections.

CONCLUSION

We thank the leadership and staff of FDA for its diligent effort to craft an effective food safety regulations based on the provisions of section 103 of FSMA. The proposed rule closely follows the requirements of section 103, which is largely self-executing in its provisions. With the exception of departures from that self-executing language in the area of supplier verification and verification testing, the rule does a good job of interpreting the animal food industry's responsibilities to plan for and produce safe food. We encourage FDA to incorporate improvements recommended in this comment so that the public can have confidence that the food safety system for both humans and animals in the United States delivers on the Commissioner's promise "to build a modern, effective, and proactive food safety… regulatory system for the 21st century."[10]

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[10] Margaret A. Hamburg, Remarks at the Foods Program Science and Research Conference (Aug. 1, 2012).