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

Docket No. FDA-2014-N-0053—Requirements for Additional Traceability Records for Certain Foods.

To Whom It May Concern:

Center for Food Safety (CFS) submits the following comments on behalf of itself and its members in response to the U.S. Food and Drug Administration's (FDA) proposed rule, Requirements for Additional Traceability Records for Certain Foods.¹ CFS is a nonprofit, public interest advocacy organization dedicated to protecting human health and the environment by curbing the proliferation of harmful food production technologies and promoting sustainable agriculture. As a membership organization, CFS represents over 970,000 farmer and consumer members who reside in every state across the country, and who support safe, sustainable food systems.

Background on the Food Safety Modernization Act

When Congress passed FSMA in 2011, it was the first major overhaul of our country's food safety laws in the U.S. since the late 1930s. The purpose of FSMA is to move our food safety regulatory system from one that has largely been reactive to one that is proactive in order to substantially reduce the number of foodborne illnesses in the U.S. According to the Centers for Disease Control and Prevention (CDC), every year, as a result of foodborne diseases, 48 million people get sick, 128,000 are hospitalized, and 3,000 die.² Serious long-term effects associated with several types of food poisoning include kidney failure, chronic arthritis, and brain and nerve damage.³ During the years leading up to FSMA's passage, continuous high-profile outbreaks related to various foods, ranging from spinach to peanut products to eggs, underscored the dire and urgent need for oversight improvements.⁴

¹ 85 Fed. Reg. 59984 (Sept. 23, 2020).

² Ctrs. for Disease Control & Prevention, *Foodborne Germs and Illnesses* (Mar. 18, 2020), <https://www.cdc.gov/foodsafety/foodborne-germs.html>.

³ FoodSafety.gov, *Food Poisoning*, <https://www.cdc.gov/foodsafety/foodborne-germs.html>.

⁴ Gardiner Harris and William Neuman, *Senate Passes Sweeping Law on Food Safety*, N.Y. Times, Nov. 30, 2010, <https://www.nytimes.com/2010/12/01/health/policy/01food.html>.

To achieve these objectives, Congress set explicit statutory deadlines for FDA to promulgate new food safety regulations to address the various components of the food supply chain. These included rules for preventive controls for human and animal food, produce safety, sanitary transportation, and imports. Another rule, the one at issue here, requires FDA to identify those foods that are considered a “high-risk” for being the source of a foodborne illness outbreak and to establish additional recordkeeping requirements for those foods.

Unfortunately, the positive public health outcomes that were the original intent behind FSMA went largely unrealized as FDA missed all of the statutory deadlines for new rules. A statute without its implementing regulations is an empty vessel. Thus, in 2012, CFS sued FDA after the agency missed seven deadlines for major food safety regulations. Eventually, this led to a settlement with new court-ordered deadlines for FDA to promulgate these food safety rules.⁵

While FDA moved forward with promulgating the rules at issue in the *FSMA I* case, there were other missed deadlines that required subsequent litigation by CFS to compel FDA to follow through on Congress’s directives regarding the designation of and recordkeeping requirements for high-risk foods as well as establishing a food safety laboratory accreditation program.⁶ Only with full implementation of FSMA with rigorous enforcement will Congress’s objective of reducing the rate and severity of foodborne illness outbreaks be achieved.

The rule must refer to “high-risk” foods rather than “food traceability.”

Section 204(d) specifically requires FDA to “designate high-risk foods” for which additional recordkeeping requirements are required and to “publish the list of foods designated . . . as high-risk foods” on the FDA website.⁷ Under the proposed rule, however, FDA attempts to revise the statutory language away from “high-risk” foods to the more general “food traceability.”⁸ In fact, instead of proposing a definition for “high-risk” foods, FDA only proposes a definition for a “food traceability list.”⁹ And while FDA makes some references to “high-risk” foods in the preamble to the proposed rule, the phrase does not appear in the proposed rule itself.

FDA’s attempt to read “high-risk” foods out of the rule is unexplained and inconsistent with the plain language and purpose of the statute. It also is inconsistent with the risk-based

⁵ See Consent Decree, *Ctr. for Food Safety v. Hamburg*, 4:12-cv-04529-PJH (N.D. Cal. Feb. 25, 2014) (“*FSMA I*”).

⁶ See Consent Decree, *Ctr. for Food Safety v. Azar*, 4:18-cv-06299-YGR (N.D. Cal. June 11, 2019) (“*FSMA 2*”); Consent Decree, *Ctr. for Food Safety v. Azar*, 3:19-cv-05168-VC (N.D. Cal. Feb. 11, 2020) (“*FSMA 3*”).

⁷ 21 U.S.C. § 2223(d)(2).

⁸ 85 Fed. Reg. at 59991 (“Table 2—Tentative Food Traceability List”).

⁹ *Id.* at 60031.

modeling that formed the basis of FDA’s tentative draft approach to review and evaluate data to designate high-risk foods.¹⁰ The final rule must be consistent with the language and intent of the statute, which requires FDA to designate and disclose a list of “high-risk” foods.

Tentative High-Risk Food List

Section 204(d) of FSMA requires FDA to include food for both humans and animals in its list of high-risk foods.¹¹ In the proposed rule, however, FDA declined to include animal feed in its risk-ranking model.¹² FDA claims that this is because there is no federal agency that tracks foodborne illness outbreaks in animals the way CDC does for humans.¹³

But FDA cannot just ignore what Congress directed it to do with unmistakable clarity. And regardless, FDA should have enough information to determine whether certain types of animal feed belong on the list of high-risk foods. Animal feed is at “the beginning of the food safety chain in the ‘farm-to-fork’ model.”¹⁴ Contaminated animal feed is one of the “main causes” of foodborne pathogens at the farm level.¹⁵

There is “considerable evidence that animal feed is frequently contaminated with foodborne bacterial pathogens.”¹⁶ It is also “well established that bacteria from colonized food animals can be transmitted to humans through the food supply” and there have been numerous incidents of human illness that was traced back to contaminated animals feed.¹⁷ Animal feed is a known source for a number of infections for farm animals that can lead to human illness, including *Salmonella enterica*, *Toxoplasma gondii* and *Trichinella spiralis*.¹⁸

¹⁰ *Id.* at 59990-59991; *see also* FDA’s Draft Approach for Designating High-Risk Foods as Required by Section 204 of FSMA (Feb. 2014).

¹¹ 21 U.S.C. § 2223(d)(1).

¹² 85 Fed. Reg. at 59991.

¹³ *Id.*

¹⁴ Crump, J.A., et al., *Bacterial Contamination of Animal Feed and Its Relationship to Human Foodborne Illness*, *Clinical Infectious Diseases* (Oct. 1, 2002), <https://academic.oup.com/cid/article/35/7/859/307143?login=true>.

¹⁵ *Foodborne zoonotic diseases*, European Food Safety Authority, <https://www.efsa.europa.eu/en/topics/topic/foodborne-zoonotic-diseases>.

¹⁶ Crump, et al., 2002.

¹⁷ *Id.*

¹⁸ Food and Agric. Org. (FAO) of the United Nations, *Food safety and quality – Animal feed*, <http://www.fao.org/food/food-safety-quality/a-z-index/animal-feed/en/>; *see also* FAO and World Health Org., *Animal Feed Impact on Food Safety*, p. 16 (2008).

At a minimum, FDA should include on the list of high-risk foods animal feed that is derived from recycled waste products and poultry manure. This includes recycled animal wastes that are fed back to the species from which they are derived. “By recirculating animal by-products and waste, we may be creating new niches and opportunities for foodborne pathogens to enter the food supply and spread.”¹⁹ It is important that FDA mandate additional recordkeeping requirements for such feed, as Section 204(d) of FSMA requires.

Regarding human food on the tentative high-risk food list, CFS recommends FDA revise the listing for nut butters so that it includes all butters that are known to contain allergens.

FDA must disclose the cost/benefit of requiring electronic records.

The proposed rule does not require the use of electronic records.²⁰ While this is consistent with the statutory prohibition²¹ against prescribing specific technologies for recordkeeping, FDA nevertheless “encourage[s]” the use of electronic records because it can “greatly facilitate the analysis of information during investigations into foodborne illness outbreaks and speed the completion of traceback and traceforward operations.”²² Indeed, sharing of standard key data elements (KDEs) electronically “allows all entities in the supply chain access to reliable information on the traceability of a product.”²³

Despite the benefits of electronic records, it is unclear whether FDA properly assessed those benefits in the proposed rule’s cost/benefit analysis. For example, FDA claims that implementation of the proposed rule would result in an estimated 84 percent reduction in traceback time during an outbreak investigation.²⁴ However, FDA does not disclose whether that estimated reduction depends on a particular portion of covered entities transitioning to electronic records. This information is critical because if FDA assumes for purposes of assessing benefits that all entities will transition to electronic records, then FDA’s estimated reduction in traceback time is likely too high because not all entities will transition to electronic recordkeeping. This could be important information for Congress to consider additional legislation to, for example, provide FDA discretion to require certain entities to keep electronic records.

¹⁹ Jennifer Ackerman, *How Safe is Our Food?*, National Geographic (May 2002), <https://www.nationalgeographic.com/science/article/food-safety>.

²⁰ 85 Fed. Reg. at 59992.

²¹ 21 U.S.C. § 2223(d)(1)(C).

²² 85 Fed. Reg. at 59992.

²³ *Id.*

²⁴ *Id.* at 60021.

FDA should not provide a blanket exemption for transporters (proposed 21 C.F.R. § 1.1305(k)).

FDA proposes to exempt transporters from the recordkeeping requirements for high-risk foods.²⁵ FDA's rationale is two-fold. First, FDA's proposed definition for "transporter" is based on a narrow interpretation of covered entities under the statute. Second, FDA claims that transporters should be exempt from the proposed rule because in "most" of its investigations of potential foodborne illness outbreaks, the agency has not found it necessary to inspect records maintained by food transporters.²⁶ This is because, according to FDA, the agency has been able to obtain the tracing information it needs from other persons in the food's supply chain.²⁷ CFS does not believe this suffices to broadly exempt transporters from these recordkeeping requirements.

FDA's proposed definition of "transporter" is "a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air."²⁸ But a person who has "possession, custody, or control" of an article of food is undoubtedly a person who "holds" foods under the statute.²⁹ Indeed, the definition of "hold" includes "to have possession" and "to maintain control" of as well as "custody."³⁰ FDA's proposal to exempt transporters from the requirements of Section 204(d) is contrary to the plain language of the statute.

Moreover, the fact that FDA has purportedly been able to obtain needed tracing information from other persons in the supply chain during previous outbreak investigations does not mean that there would not be added benefits of having transporters comply with the requirements of Section 204(d). Transporters are a major part of the food supply chain and "the overall numbers of incidents or outbreaks attributable to transportation failures appear to be vastly underreported."³¹ Exempting transporters entirely from the rule could needlessly hamper future outbreak investigations, the very thing the statute seeks to make more efficient.

²⁵ See 85 Fed. Reg. 59999.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*; see also *id.* at 60004.

²⁹ See 21 U.S.C. § 2223(d)(1).

³⁰ See Merriam-Webster, "hold," <https://www.merriam-webster.com/dictionary/hold>.

³¹ Food Safety Magazine, *Transportation: The Squeaky Wheel of the Food Safety System* (Oct. 1, 2003), <https://www.food-safety.com/articles/4206-transportation-the-squeaky-wheel-of-the-food-safety-system>.

FDA’s proposed waivers should allow for public participation regardless of how the waiver is sought.

FDA proposes two methods for obtaining waivers from the requirements of the proposed rule. First, an individual entity may submit a written request for a waiver.³² Second, a citizen petition may be filed requesting a waiver for a type of entity under proposed 21 C.F.R. § 10.30.³³

While the citizen petition method provides for public notice and comment (proposed 21 C.F.R. § 1.1435), there is no public notice and comment when an individual entity submits a written request for a waiver (proposed 21 C.F.R. § 1420). This is inconsistent with the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Administrative Procedure Act (APA). The FFDCA requires the Secretary to publish waivers in the Federal Register and any reasons for the waiver.³⁴ This demonstrates Congress’s intent to have the public involved in the waiver process.

By providing one process that requires public notice and comment and another that does not, FDA is setting up a waiver program that will almost certainly result in written requests for waivers that are not subject to public notice and comment. This could make the petition process a virtual nullity and shield waiver decisions from public scrutiny. FDA should provide for public notice and comment regardless of how the waiver is sought.

FDA should provide a petition process for modifying and revoking waivers

FDA should also consider providing a petition process for revoking or modifying a waiver. As written, the proposed rule provides that only FDA can make a determination on its own initiation about whether an existing waiver should be modified or revoked. There should be a citizen petition process that allows presentation of data to the agency for reconsidering waivers.

FDA must consider the environmental consequences of the proposed rule in accordance with the National Environmental Policy Act (NEPA).

NEPA requires all federal agencies to prepare an environmental impact statement (EIS) for all major federal actions affecting the quality of the human environment.³⁵ If an agency is unsure whether an action requires an EIS, it must prepare an environmental assessment (EA) unless the action is covered by an existing categorical exclusion.³⁶ FDA claims that the proposed

³² 85 Fed. Reg. at 60036.

³³ *Id.*

³⁴ 21 U.S.C. § 350e(d)(2).

³⁵ 42 U.S.C. § 4332(C).

³⁶ 40 C.F.R. § 1501.5(a).

rule is covered by its categorical exclusion found at 21 C.F.R. § 25.30(h).³⁷ CFS does not agree that this action should be excluded from documentation in an EA or EIS.

FDA's regulations implementing NEPA require at least the preparation of an EA for the issuance of FDA regulations (or an exemption or variance from FDA regulations) unless a specified categorical exclusion applies.³⁸ The categorical exclusion that FDA relies on here states that the issuance of procedural or administrative regulations or guidance are "ordinarily" categorically excluded for procedures like the submission of applications for FDA review.³⁹ This is not an appropriate categorical exclusion for this proposed rule.

Rather, this fits squarely in 21 C.F.R. § 25.20(g) for preparation of an EA. The proposed rule concerns FDA regulation of high-risk foods in order to "rapidly and effectively" prevent or mitigate the consequences of a foodborne illness outbreak.⁴⁰ This is not akin to procedural or administrative regulations for how to submit an application with FDA. Thus, FDA should prepare at least an EA for the proposed rule.

There are certainly environmental costs and benefits associated with the proposed rule that should be documented. For example, whenever there is a major food recall, "all those recalled foods head straight to the landfill."⁴¹ And "it's not just the contaminated produce, meat and poultry that end up in the landfill after a recall that contribute to the environmental impact" but "all of the water, energy and other resources that went into produced that food is also wasted."⁴² An estimated 52 million tons of food end up in landfills each year.⁴³ According to the Environmental Protection Agency, landfills were responsible for one sixth of the nation's methane emission in 2016.⁴⁴

FDA expects that the proposed rule would allow the agency to conduct more "targeted recalls" and reduce the likelihood of unnecessary "market withdrawals" of uncontaminated food that

³⁷ 85 Fed. Reg. at 60025.

³⁸ 21 C.F.R. § 25.20(g).

³⁹ 21 C.F.R. § 25.30(h).

⁴⁰ 21 U.S.C. § 2223(d)(1).

⁴¹ Jodi Helmer, *Food Waste Is an Oft-Ignored Impact of Food Recalls*, FoodPrint (Mar. 12, 2019), <https://foodprint.org/blog/the-oft-ignored-environmental-impact-of-food-recalls-food-waste/#:~:text=Although%20recalled%20foods%20account%20for,generated%20from%20the%20recall%20itself>.

⁴² *Id.*

⁴³ Carolyn P. Rice, *When food waste becomes a pollutant*, Stanford University (May 28, 2019), <https://earth.stanford.edu/news/when-food-waste-becomes-pollutant>.

⁴⁴ *Id.*

winds up in a landfill because of an overly broad recall.⁴⁵ This would reduce the amount of methane released from landfills and also save water, energy, and other resources that went into producing the food in the first place. These are quantifiable environmental benefits that FDA should account for, among others, before it finalizes the rule.

Thank you for the opportunity to provide comments.

Respectfully submitted,

A handwritten signature in cursive script that reads "Ryan Talbott".

Ryan Talbott
Center for Food Safety

⁴⁵ 85 Fed. Reg. at 59986.