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

Re: Requirements for Additional Traceability Records for Certain Foods; Proposed Rule

The Farm and Ranch Freedom Alliance (FARFA) is a nonprofit organization dedicated to promoting common-sense policies for local, diversified agriculture.

FARFA was deeply involved in the discussions surrounding the passage of the Food Safety Modernization Act (FSMA) in 2010. While recognizing the need for additional traceability on certain foods, FARFA believes that FDA's proposed rule goes beyond the statutory intent, as well as imposing requirements that will ultimately be counter-productive to the safety of the food supply.

Congress recognized in the 2002 Bioterrorism Act that foods can be traced without imposing requirements on the very first or last links in the chain, namely the farmer/rancher and the entity that sells or serves the food to the consumer. Congress re-affirmed that approach to traceability in FSMA.

Moreover, Congress recognized the importance of protecting small food businesses from expensive regulations that are not needed for small operations. Congress incorporated what is known as the "Tester Amendment" in FSMA. Notably, while the Tester Amendment is often referred to as exempting "small-scale, direct-marketing farms," the exemption is broader than that. The Tester Amendment exempted (1) very small facilities, i.e. food manufacturing and distribution businesses, and (2) small farms that sold *primarily* direct to consumer and to local retailers, but who could also have additional wholesale sales.

In the first round of rulemaking under FSMA, FDA respected these priorities. The agency maintained the 2002 definition of "facility" in adopting new requirements applicable to facilities. And in defining the "very small business" exemption for the Tester Amendment in the Preventive Control Rules, FDA identified that food businesses grossing less than $1 million annually were "very small businesses" in the context of our food system.

Yet in these newest proposed regulations, FDA is contradicting these principles and imposing costly, burdensome requirements on farms, retail food establishments, and very small businesses.

These requirements pose a problem not only for the regulated entities, but also to consumers. By unnecessarily burdening small businesses, FDA's proposed rule inherently favors large-scale operations, further encouraging consolidation of our food system. Yet the consolidated system is precisely what has led to so many foodborne illness outbreaks. If implemented, this proposed rule will <u>reduce</u> food safety levels in our country in the long run.

FARFA urges several changes to the proposed rule. The three most important recommendations are:

1. Include a full exemption for very small businesses (not just an exemption from the electronic spreadsheet requirement) and broaden the exemption so that it is consistent with the definition of very small business under the Preventive Controls Rule.

2. Exclude all farms, not just those sales that are direct-to-consumer.

3. Exclude all retail food establishments, not just the foods purchased directly from farmers.

In addition, FARFA urges the following changes:

4. Exempt foods that are "identity preserved" from farm to consumer through on-farm packaging that ensures the produce is not altered or contaminated in a manner that makes it unclear who produced it or what the label states; remove the requirement for individually sealed plastic packaging.

5. Remove the electronic spreadsheet requirement for all regulated entities.

6. Modify the requirements for "first receivers" (those businesses that take possession of "high risk" foods from the farmer or manufacturer), so that they are not required to keep records that go beyond what is already required for the farms and food manufacturers they receive items from.

7. Finally, if FDA does not exclude farms as requested above, FARFA urges the agency to at least remove the requirement for GPS coordinates for where the crops are grown.

More details on each requested change are set out below. First, though, there is a common factor that impacts all of them: the need for scale-appropriate regulation. FSMA Section 204 (d)(1)(E) requires that the rule must "be scale-appropriate and practicable for facilities of varying sizes and capabilities with respect to costs and recordkeeping burdens." But FDA's proposed rule, with its extensive record-keeping requirements and narrow exemptions and partial exemptions, does not meet this requirement.

The proposed rule is clearly written with large businesses and their complex, long supply chains in mind. First, it covers an overly wide range of foods, primarily on the basis of their involvement in large outbreaks. Yet in many cases it was not the food itself that was somehow inherently high risk, but the fact that it was handled in a centralized, consolidated facility that commingled foods from numerous different sources (allowing minor contamination to spread and multiply), and then packaged and shipped long-distances under dozens of different brand names. In categorizing all of these foods as "high risk," FDA has expanded the scope of Section 204 unnecessarily.

The proposed rule then compounds the problem by imposing requirements that do not take size into account. The proposed requirements are not feasible for small businesses, nor are they appropriate to the level of risk posed by local and regional distribution chains. It is notable, and very problematic, that FDA only gathered input from a handful of large businesses and associations that represent large food businesses and farms, with national and international

supply chains.[1] The stakeholder input was not reflective of small, independent retailers, local food hubs, cottage food producers, or small, diversified farms. The proposed rule's requirements reflect that lack of input and are not scale-appropriate as directed by Congress.

1. **Include a full exemption for very small businesses (not just an exemption from the electronic spreadsheet requirement) and broaden the exemption so that it is consistent with the definition of very small business under the Preventive Controls Rule.**

To address the concerns of small businesses, the proposed traceability rule only exempts businesses that sell less than $25,000 annually in food, and it considers either a full or a partial exemption for businesses with 10 or fewer full-time employees. This is wholly inadequate.

In contrast, FDA defined "very small business" in the Preventive Controls Rule as those that sell less than $1 million in food annually. At the time that rule was adopted, the Small Business Administration classified businesses that had fewer than 500 employees as "small" in the food manufacturing industry. Under the most recent SBA classifications, what constitutes a "small" food manufacturer depends on the precise type of food but ranges from 500 to 1,250 employees.[2]

The FDA should exempt businesses that sell less than $1 million in food annually, to make this rule consistent with the Preventive Controls Rule. Alternatively, or in addition, the agency should exempt businesses with 50 or fewer full-time employees (1/20 – 1/10 the size of a "small business" in the food industry as classified by SBA).

Moreover, the exemptions for very small businesses should be full exemptions from all the requirements. An exemption only from the requirement for an electronic spreadsheet is insufficient; the remaining extensive recordkeeping requirements would be unaffordable, and often entirely infeasible, for the tiny staffs of these very small operations.

Note that the partial exemptions for those **sales** that are direct-to-consumer or part of programs such as farm-to-school are insufficient to address the issues. As recognized in the Tester Amendment to FSMA, many farms and small food businesses that sell primarily direct to consumer also have a small portion of wholesale sales. Asking these small, local businesses to undertake extensive recordkeeping for the portion of their sales that are not direct to consumer is unnecessary from a risk analysis, as well as unduly burdensome.

2. **Exclude all farms, not just those sales that are direct-to-consumer.**

In directing FDA to establish additional recordkeeping requirements for foods that are deemed to be high risk, Congress described numerous specific types of situations to which the new requirements should not apply. But before getting to those exemptions, Congress set out specific parameters as to the potentially regulated entities:

> "[T]he Secretary shall publish a notice of proposed rulemaking to establish recordkeeping requirements, in addition to the requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c) and subpart J of part 1 of title 21, Code of

[1] FDA Memorandum, ''Summary of Meetings With Stakeholders on Development of Additional Recordkeeping Requirements for Certain Foods Under Section 204(d) of the FDA Food Safety Modernization Act,'' July 20, 2020.
[2] See SBA Table of Size Standards, Sector 31.

Federal Regulations (or any successor regulations), for ***facilities*** that manufacture, process, pack, or hold foods that the Secretary designates [as high-risk foods]" [emphasis added].

This statutory language explicitly states that the enhanced recordkeeping requirements only will apply to "facilities."[3] This term has consistently **not** applied to farms over the last 19 years, since its first usage in the 2002 Bioterrorism Act, which defines facility as: "any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. **Such term does not include** farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels …."[4]

In the almost 20 years since the passage of the Bioterrorism Act, the term "facility" has consistently excluded farms and retail food establishments. Throughout FSMA, Congress makes clear the term "facilities" does not include farms that are not processing or manufacturing food.

Farms that conduct manufacturing or processing activities are categorized as "farm-mixed-type-facilities" throughout the FSMA regulations. These farms are appropriately covered under the rule unless they fall within another exemption (such as by selling direct to consumer).

3. Exclude all retail food establishments, not just for foods purchased directly from farmers.

Just as with farms, retail food establishments have been excluded from the term "facility" since the 2002 Bioterrorism Act. These businesses – whether they are grocers, restaurants, cottage food producers or others – have a primary business purpose of selling direct to consumers. While the proposed rule includes a partial exemption for retail food establishments, it only covers foods sold directly from the farm to the retail food establishment. But requiring these businesses to keep extensive records on numerous other products and ingredients is not consistent with the language of FSMA nor with an assessment of the risks posed.

4. Exempt foods that are "identity preserved" from farm to consumer, without requiring that individual items be in sealed packaging.

FSMA specifically directed FDA to exempt "identity preserved" foods that are packaged on the farm and maintain their farm labeling all the way to the consumer. Unfortunately, in the proposed rule, the agency is proposing a very strict interpretation that effectively requires sealed plastic packaging.

Under FSMA, the on-farm packaging simply must ensure the produce is not altered or contaminated in a manner that makes it unclear who produced it or what the label states.[5] FSMA does **not** state that the packaging must remain in place until the food reaches the consumer's home. It merely states that the on-farm packaging must maintain the integrity of the product.[6] Therefore, as long as the product is not altered, and the label remains intact, so too does its

[3] 21 U.S.C. § 2223(d).
[4] 21 U.S.C. 350d(c)(1); PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002, Public Law 107-188, 107th Congress, 116 STAT. 668;
[5] 21 U.S.C. § 2223(d)(6)(B).
[6] 21 U.S.C. § 2223(d)(6)(B).

exemption. FDA goes beyond the statutory language in the proposed rule, requiring the packaging "remain in place until the food reaches the consumer."

FDA takes this to even more extreme lengths in the preamble, stating that individually wrapping the product in cellophane or plastic may be required to meet this exemption.[7] FDA specifically states that numerous commonly used packaging sources would not meet the requirement, such as crates, boxes, and vented clamshells.[8] But FDA's contention that these types of packaging do not maintain the integrity of the product is wrong, and indeed FDA offers no data or studies to support this conclusion.

When produce is packed in crates, boxed, or vented clamshells, and these packages are clearly labeled, retailers and others throughout the supply chain can easily identify if an alteration has occurred – thus meeting the statutory requirements for this exemption. Requiring individual sealed wrapping of the items is not only beyond the agency's statutory authority and an unnecessary burden on farmers, it is also terribly wasteful. The examples FDA provides on what packaging is acceptable for this exemption are expensive, resource intensive, and may not be possible for many small, sustainable farms.

It is vital to remember that Section 204 of FSMA directed FDA to provide for enhanced traceability of high risk foods – it did not direct FDA to impose requirements that somehow prevent all types of contamination throughout the food chain. Rather, the Produce Safety Rule and the Preventive Controls Rule were intended to create requirements for reducing contamination. This proposed rule should be limited to what is needed for traceability – and individual plastic wrapping most certainly is not.

5. Do not require electronic records or other technology, whether directly or indirectly.

The requirement to provide FDA, when requested, with an electronic spreadsheet of all required records within 24 hours is both unduly burdensome and contrary to the statute. In directing FDA to create additional traceability requirements, Congress specifically said that the agency could not "prescribe specific technologies for the maintenance of records." Small businesses, especially in rural areas, often lack the technology to meet this requirement without significant additional expense. FDA should abolish this requirement in the final rule.

In addition to the regulatory requirement for electronic spreadsheets, the agency statement in the preamble that it "strongly encourages" electronic recordkeeping and electronic data systems[9] is inappropriate and problematic. FDA staff and state agencies charged with implementing the regulations, as well as courts, take language in the preamble of a rule under serious consideration. In effect, FDA is trying to create requirements that it was specifically forbidden to do by Congress.

6. Modify requirements for first receivers who purchase from exempt sources.

The proposed rule imposes significant burdens on "first receivers," namely the first person (other than a farm) who purchases and takes physical possession of a listed food.

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[7] Fed. Reg at 59996
[8] Fed. Reg. at 59996
[9] Fed. Reg. at 60017.

In practical terms, this means that even exempt farms will be forced to keep all these records, or they will be unable to sell their products to anyone other than individual consumers. Indeed, the proposed rule explicitly directs first receivers that they must collect this information from exempt entities: **"**If you are the first receiver of a food on the Food Traceability List to which the originator of the food has not assigned a traceability lot code, you must establish a traceability lot code for the food and maintain a record of the traceability lot code linked to the information specified," which includes the location identifier and location description for the "originator" of the food; the business name, contact, and phone number of the food's harvester, the date(s) and time(s) of harvesting; the location identifier and description of where the food was cooled, plus the date and time of cooling (if applicable); and the location identifier and description of where the food was packed, and the date and time of packing if applicable.

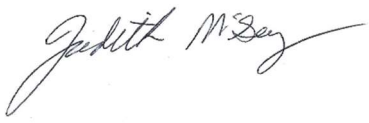
This is in stark contrast to the way supplier verification is handled under the Preventive Controls Rule. In that rule, while a facility is required to keep certain records about all foods that it receives, the rule makes specific provisions to allow the facilities to keep reduced records when buying from an exempt supplier.[10] Absent such a provision, the proposed rule largely nullifies the impact of any of the exemptions and cripples the movement toward local sourcing from small-scale operations.

7. Remove the GPS requirement for identifying farm fields.

The requirement to keep records that include the "growing area coordinates" are based on assumptions about large-scale, largely mono-culture agricultural operations, in which a single crop is grown on multiple acres. Diversified sustainable farms operate very differently. Crops are often interspersed with each other, and their planting locations rotated frequently. Depending on the climate, multiple plantings of the same crop may occur in the same year, but in slightly different areas of the farm. The requirement is both illogical and not feasible for these operations.

In seeking to meet its mandate under Section 204, the FDA has unfortunately gone too far in imposing unnecessary requirements on a much wider range of businesses that Congress intended. FARFA urges the agency to conduct additional stakeholder outreach in order to design a rule that is truly scale-appropriate. We stand ready to assist with that process.

Respectfully submitted,



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[10] Preventive Controls Rule Section 117.410(d)(2).