Comment Template

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

Re: Comment on the Requirements for Additional Traceability Records for Certain Foods; Proposed Rule; FDA-2014-N-0053-0184

I am a ____ [farmer, food business, organization who works with farmers or food businesses across [state],…].

[INTRODUCTION: Customize your comment with your story: What is the name of your farm or business? What do you grow or what does your food business sell, or what types of growers do you work with or purchase produce from? How long have you been in business? Where do you sell your products and or who do you purchase products from? What does your current traceability recordkeeping system look like? What is your interest in the proposed traceability rule regulations?]

Congress specifically gave farms and small food businesses protections in FSMA from unfair recordkeeping requirements. I am writing because FDA's Additional Traceability Records for Certain Foods Proposed Rule ("Traceability Rule") ignores those protections. If this violation of FSMA's small business protections is implemented, it will hurt [my farm/food business, farmers in my community, the farms or food hubs that I buy food from, etc.…].

I am specifically concerned about the following issues I have outlined below. The Final Traceability Rule should:

- Exclude farms from all of the traceability requirements under the rule.
- Only apply to foods where the risk of foodborne illness is inherent in how the food is made.
- Ensure value-added foods made on-farm with FSMA-compliant labels are exempt throughout the supply chain.
- Remove electronic recordkeeping requirements.

Sincerely,

[Your full name, business name if applicable, city and state]

Comments on the Traceability Proposed Rule:

1. The Rule Should Not Apply to Farms

FDA should follow the specific language of FSMA and exclude farms from coverage under the Traceability Proposed Rule. FSMA Sec. 204(d)(1) specifically says that it applies to 'facilities.' Congress has consistently mandated since the Bioterrorism Act of 2002 that FDA should not apply food traceability rules for food manufacturing facilities to farms. Throughout FSMA, Congress makes clear the term 'facilities' does not include farms that are not further processing or manufacturing food in a way that falls within the "facilities" definition. FDA cannot ignore the plain language of the law. FDA must revise Sec. 1.1300 of the Traceability Proposed Rule by limiting the entities covered by the rule to 'facilities' as that term is defined in the FSMA Preventive Controls Rule for Human Food.

FDA must also revise all sections that apply to farms that are not facilities and should make clear in the exemptions under Sec. 1.1305 that farms that are not facilities are exempt from this rule. Sec. 1.1325 and Sec. 1.1350(b)(2) are also in violation of FSMA, and these requirements should also be deleted. The rule should be limited to food that is transformed or created by a facility, not food that is grown and sold as is by a farm or shipped by a farm.

Customize Your Comment & Help FDA Understand Why this Matters:

- *Are you a farm worried about having to comply with a rule that is not meant for you, but instead for further processed, value-added products? If you had to comply and keep detailed records of the GPS coordinates where you grow any item on this Food Traceability List, and detailed information for every shipment of these items you send, how much time and money would this cost you?*

2. Issue: Revise the Food Traceability List to Comply with Congressional Intent.

FDA should follow the intent of FSMA and limit the definition of high-risk foods to foods where the production conditions—primarily in food processing—inherently create a foodborne illness risk. The Traceability Proposed Rule's definition of high-risk foods inappropriately includes Raw Agricultural Commodities that are not inherently dangerous, merely because those crops have been involved in outbreaks. Outbreaks in tomatoes, peppers, leafy greens, and melons have not been caused by the nature of growing those vegetables. Congress instead emphasized food manufacturing risks in FSMA Sec. 204(d)(2)'s list of risk factors. FDA must revise its methodology for assessing high-risk foods to conform to Congressional intent to prioritize foods with riskier processing and manufacturing steps.

Customize Your Comment & Help FDA Understand Why this Matters:

- Do you grow, ship, and/or receive cucumbers, tomatoes, peppers, leafy greens, or melons? All of these items are on the Food Traceability list, with little consideration for whether or not further processing or different types are more inherently riskier than others. Explain to FDA the concerns you have with grouping these items altogether, without consideration for the true "risk" depending on varying conditions and varieties.

- Will you start to have problems sourcing items on this list? Will distribution customers want to pay less or stop buying those crops, causing market shifts to other products with similar risks but less requirements?

3. Ensure value-added foods made on-farm with FSMA-compliant labels are exempt throughout the supply chain.

The Traceability Rule should state that businesses are not required to keep traceability records and create a lot code for any food that is exempt from the rule under FSMA section 204(d)(6)(B). If a farm product is exempt because it meets Congress' labeling and packaging exemption in FSMA section 204(d)(6)(B), businesses throughout the supply chain should not be required to keep detailed records for that product. The exemption Congress provided would be meaningless if buyers were still forced to keep enhanced traceability records for those identity-preserved foods: Buyers will simply require exempt farm and small business suppliers to provide the detailed, farm-level records as a threshold for purchasing products. In the final traceability rule, FDA must fully exempt products and businesses that Congress protected in Sec. 204(d)(6) by maintaining those exemptions across the supply chain, to ensure businesses that Congress exempted from this rule are truly exempt.

Customize your comment and help FDA understand why this matters:

- Do you make and package food on your farm that is sold under your farm's brand and address? Does your business sell food produced and packaged on farms and sold under the farms' labeling?
- Explain to FDA the types of labels used on these farm-produced foods to ensure products are fully traceable to the farm.
- If you had to keep additional records like lot codes, GPS coordinates, etc for every shipment of these items you send, how much time and money would this cost you?

4. Do not Require Electronic Records or Other Technology

The Proposed Traceability Rule's requirement to provide the FDA with an electronic spreadsheet of all required records, if requested, within 24 hours is in clear violation of FSMA Section 204(d)(1)(C) and FSMA Section 204(f)(3). FDA must delete this requirement in the Traceability Proposed Rule Sec. 1.1455(b)(3). FDA must ensure that additional technology is not included as a requirement in the final rule, or it will be a violation of FSMA.

Customize your comment and help FDA understand why this matters:

- Are you a small business that is worried about this requirement? How much would this requirement cost your business?
- Are you a farm that does not have the technology or staff in place to meet this requirement?

- Explain to FDA the impact this requirement and additional technology requirements might have on your business.