**SAMPLE COMMENT:**

**Proposed FDA rule threatens small farms & food businesses**

Submit your comments to FDA online at <https://beta.regulations.gov/commenton/FDA-2014-N-0053-0184>. You can copy and paste your comments into the text box, or you can upload a file with your comments.

**Deadline: Monday, February 22, 2021, at 11:59 pm Eastern Time.**

The highlighted sections are for you to personalize.

**SAMPLE COMMENT**

I am a \_\_\_\_ [farmer, restaurant owner, cottage food producer, food business …].

[INTRODUCTION: Briefly explain why you care about these regulations. What do you farm or what does your food business sell? Do you source locally? Are you a consumer who prioritizes getting food from businesses you know and trust, and don’t want new regulations to hurt your 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 – the farmer/rancher and the entity that sells or serves the food to the consumer (grocers, restaurants, and other “retail food establishments”). Congress re-affirmed that approach to traceability in the Food Safety Modernization Act in 2010. Moreover, Congress recognized the importance of protecting small food businesses from expensive regulations that are not needed for small operations. And in adopting the initial regulations under FSMA, 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 all these principles and imposing costly, burdensome requirements on farms, retail food establishments, and very small businesses.

If FDA’s Additional Traceability Records for Certain Foods Proposed Rule (“Traceability Proposed Rule”) 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 urge the agency to make the following changes:

1. Limit the scope of the rule to “facilities,” as that term is used in the other FSMA regulations.

* Exclude farms, unless they conduct activities that would classify them as “farm mixed type facilities”; and
* Exclude retail food establishments, whose primary purpose is to sell or serve food directly to consumers.

1. Exempt very small businesses, defined consistent with other FSMA rules and the Small Business Administration’s classifications.
2. Exempt foods that are “identity preserved” from farm to consumer, *without* requiring that individual items be in sealed plastic packaging.
3. Remove the electronic spreadsheet requirement.
4. If farms are included, remove the requirement for GPS coordinates for where the crops are grown.
5. Modify the requirements for “first receivers,” so that they are not required to keep records that go beyond the underlying requirements for the farms and food manufacturers they receive items from.

[You can stop here, if you like. Add a sentence or two about why this matters to you. Or you can Include more detailed comments on any of the specific items that are particularly important to you – we have additional background info and guidance directly below to help you.]

Sincerely,

[Full name, business name if applicable, state]

**Additional Guidance for Your Comments on the Traceability Proposed Rule**

We’ve provided more background and sample wording for you to adapt for your personalized comments. These are numbered to correspond with the list in the above sample letter.

1. **This rule should not apply to farms or retail food establishments.**

The section of FSMA that authorizes FDA to create additional requirements for traceability of high-risk foods specifically states that it applies to “facilities.” This term has consistently **not** applied to farms over the last 19 years, since its first usage in the 2002 Bioterrorism Act. Throughout FSMA, Congress makes clear the term “facilities” does not include farms that are not processing or manufacturing food in a way that falls within the “facilities” definition. FDA cannot ignore the plain language of the law.

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, that only covers foods sold directly from the farm to the retail food establishment. But consumers know who they bought the food from. Requiring these businesses to keep extensive records on numerous products and ingredients is not consistent with the language of FSMA nor with an assessment of the risks posed.

**Personalize & explain 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?
* Are you a restaurant or cottage food producer? If you had to comply and keep detailed records on the source of all the “high-risk” ingredients you use, and when you prepared each product or dish with them, how much time and money would this cost you?

**2. Provide “very small business” exemptions that are consistent with other FSMA rules.**

The proposed traceability rule only exempts businesses that sell less than $25,000 annually in food and states that it *might* exempt those with 10 or fewer full-time employees.

In contrast, FDA defined “very small business” in the Preventive Controls Rule as those that sell less than $1 million in food annually. The Small Business Administration classifies businesses that have fewer than 500 employees as “small” in the food manufacturing industry. The exemption in this proposed rule is absurdly low when placed in context of our agricultural and food system.

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 (one-tenth the size of a “small business” in the food industry as classified by SBA).

**Personalize & explain why this matters:**

• Are you a small food business? Explain the negative impacts this rule would have on your business.

**3. 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.

The examples FDA provides on what packaging is acceptable for this exemption are expensive, resource intensive, and may not be possible for many farmers. For example, FDA recommends that to meet this exemption, farms individually wrap each cucumber in sealed plastic wrap, with the appropriate labeling.

This type of packaging is not only costly but creates concerns about waste and harmful environmental impact. So long as the products are traceable back to the farm through the label information, there should not be major concerns about the packaging requirements.

**Personalize & explain why this matters:**

• Do you or the farmers that you purchase food from use more sustainable and safe containers like clamshells or vented crates? What packaging do you use? How much would it cost for you if you were to individually wrap each item in plastic?

• Explain to FDA the financial and environmental impact this might create.

• Explain to FDA what types of labels you use to ensure products are fully traceable to the farm.

**4. Do not require electronic records or other technology.**

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.

**Personalize & explain 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?

**5. Remove the GPS requirement.**

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 tightly 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.

**Personalize & explain why this matters:**

* Are you a diversified farm? How many different crops do you raise on what acreage, in a typical year?
* If you raise any of the listed produce – leafy greens, tomatoes, melons, peppers, or herbs – are they interspersed with other crops? Are they always grown in the same spot or moved around? How much time would it take you to keep records of the GPS coordinates for each crop?

**6. Modify requirements for first receivers.**

The proposed rule imposes significant burdens on a “first receiver,” namely the first person (other than a farm) who purchases and takes physical possession of a listed food. These would not only include identifying the person the food was received from, but also the lot code and all the people who originated, harvested, cooled, and packed the food, as well as the location, date, and time of the harvesting, cooling, and packing.

In practical terms, that means that the farm that sells the food to the first receiver must also keep all these records. Exempt farms (such as those selling less than $25,000 of produce) will effectively be forced to undertake the additional expense and hassle to keep these records if they wish to sell to anyone other than individual consumers.

Put another way, local-sourcing businesses, such as value-added producers and restaurants, will have to either stop sourcing from small farms or require that their suppliers compile all this information for every lot of food they sell.

**Personalize & explain why this matters:**

* Are you a small farm that sells to local businesses and would have to keep additional records under this provision? What would it cost you? How would that affect your profit margin?
* Are you a business that buys ingredients from small farms? Do you think that they would be able to manage the time and expense of providing the information you would need as the “first receiver?” What would it cost you?