TO: FDA Division of Dockets Management Produce Rule FDA-2011-N-0921, Facilities Rule FDA-2011-N-0920, Guidance for Egg Industry-Salmonella (Outdoor Access) FDA-2000-N-0190

First, the will of Congress must be preserved. The Food Safety Modernization Act was meant to protect the public, not industrial-scale fruit, vegetable and egg producers. For produce, the intent of Congress (via the Tester/Hagan amendment) must be respected with due process for smaller farmers if the FDA ever decides to revoke their exemption.

Furthermore, the FDA must apply rulemaking and guidance that will address the root causes of pathogenic contamination in produce and eggs. The FDA has grossly inflated the number of foodborne illnesses that emanate from farming production (seed to harvest) rather than from contamination that takes place later, in processing and distribution. Please consider my comments below:

1. The FDA draft rules do not address a major root source of pathogenic contamination of produce: intensive feeding/confinement of livestock (Concentrated Animal Feeding Operations - CAFOs): There is nothing inherently dangerous about fresh fruits or vegetables. To make humans sick, fresh produce must be contaminated with fecal matter. This can happen when employees do not practice proper sanitation or, more likely, from environmental contamination. All too often, in states like California that host both large industrial dairies and feedlots along with large-scale vegetable producers, dangerous pathogens from these giant CAFOs end up reaching farm fields (via irrigation water, wind-blown fugitive dust, vehicles or direct manure application). Conventional farms also are allowed to use sewage sludge from municipal waste treatment plants that may still harbor dangerous pathogens as well as unwanted heavy metals.

2. The draft rules fail to target risky practices: Fresh-cut produce (bagged spinach and lettuce, etc.) is inherently riskier, causing over 90% of the E. coli O157:H7 (a particularly deadly strain) illnesses stemming from contaminated produce, according to CDC/FDA data. Yet fresh-cut is not covered in the Produce Rule: it is exempt because it is "processed." Fresh-cut is also not addressed separately in the facilities rule (processing). Intense regulations of many other produce types, without a history of contamination, is unjustified, placing a financial burden on farmers and wasting valuable resources. The rule separates out sprouts, correctly, as high hazard but fails to regulate the single most controllable sprout safety factor: ensuring clean seeds grown for sprouting.

3. The draft rules show a bias against biodiversity: The proposals would "sterilize" farmland removing habitat for wildlife and beneficial insects which offer biological controls of pests (rather than using toxic agrichemicals). The FDA tends to view farms as food processing facilities: closed controlled environments which need to be sterilized.

4. The draft rules show a strong bias against organic farming methods: The draft rules fail to discuss how scientific evidence demonstrates that increasing organic matter and biodiversity in the soil can help control pathogenic bacteria. The rule denigrates the effectiveness of thorough manure composting while allowing sewage sludge (banned in organics) in fresh vegetable and fruit production. And it will accept imports of produce grown with sewage sludge, from around the world, into the U.S.

5. Agribusiness/government regulation may economically crush our country's safest family-scale farms (organic and/or local direct distribution): The FDA's own economic analysis of the draft rules acknowledges that certain produce farms and food processors will be driven out of business, and that the cost to a small farm might be as much as $12,000 per year. Large industrial operations already have, as they should, quality control staff and laboratories. Small and medium sized operations do not, due to limitations in terms of economy of scale. The egg guidance lacks a cost analysis of the favorable marketing position that large CAFOs will have over organic producers who want to offer legitimate outdoor access.

6. The FDA is engaging in "food safety theater" rather than investing in hard research to focus limited resources on the riskiest farms and processors: The FDA lacks the data to properly assess the risks on organic farms - or on any farms for that matter - yet insists on applying uniform standards, favoring a sterility paradigm based on inadequate science, to all farms. Adequate research is imperative before placing widespread regulatory burdens on family farmers! The FDA wants farmers to use expensive testing protocols that have been proven NOT to identify the very human pathogens that have caused outbreaks and illnesses.

7. The egg guidance lacks scientific merit and will hasten a shift of organic production to CAFOs: The draft guidance makes it expensive and impractical to provide legitimate outdoor access for commercial-scale organic flocks. At the same time, in consort with the USDA, the FDA institutionalizes tiny screened structures as meeting the legal requirement for "access to the outdoors." The FDA has ignored published research that suggests public safety would be improved by addressing giant older buildings, caged production and forced molting.

The record of contaminated produce causing outbreaks, post-harvest (including on-farm processing), is vast and compelling. The record for contamination-caused outbreaks from planting to harvest is minimal. Useful farm food safety rules need to be practical, effective, efficient and proportionate. These draft rules are not.

I urge the FDA to seriously consider the comprehensive comments submitted by The Cornucopia Institute, National Sustainable Agriculture Coalition, Farm and Ranch Freedom Alliance, and other important representatives of the family farm community.

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