

The Food Safety Modernization Act was meant to protect the public, not industrial-scale fruit and vegetable and producers.

- 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. 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).
- 2. The draft rules fail to target risky practices. Fresh-cut and bagged products should require uniquely specific regulation from farm to fork something not acknowledged or addressed by the FDA in their proposed Rule. 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). A separate regulation of growers and fresh-cut processors would free over 90% of farmers in the United States that produce unprocessed fruits and vegetables from onerous regulations more appropriately designed for large growers producing for a hazardous processing category. We need to target our limited regulatory budget where it is needed most.
- 3. 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 \$13,000 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.
- **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 conventional 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.** The Rule separates out sprouts, correctly, as high hazard. But it fails to regulate the single most controllable sprout safety factor ensuring clean seeds grown for sprouting.
- **6.** The draft rules show a bias against biodiversity. The proposals encourage 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.
- 7. 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.
- 8. The intent of Congress (via the Tester/Hagan amendment) must be respected. The amendment generally exempts farm operations with less than \$500,000/yr. in gross sales from the proposed rules. But if a small owner-managed farm, delivering directly to consumers or local stores, does anything the FDA doesn't like, the agency can, without any due process, almost immediately force small farms to comply with the same expensive testing and record-keeping that larger operations must maintain. The FDA must ensure due process for farmers accused of improprieties.
- 9. The record for contamination-caused outbreaks on American farms from planting to harvest is minimal. 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. Useful farm food safety rules need to be practical, effective, efficient and proportionate. These draft rules are not.