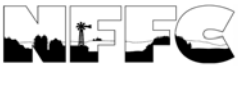

THE WESTON A. PRICE FOUNDATION

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Produce Standards Rule: FDA-2011-N-0921, and RIN 0910-AG35

Dear FDA:

The undersigned organizations represent farmers, food businesses, and consumers across the United States. We jointly submit these comments on the proposed rule for Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

I. Restrictions on traditional farming methods.

FDA's proposed rules have some fundamental problems that underlie multiple substantive requirements.

The FDA repeatedly places the burden on the farmers to prove that their methods are safe. The agency has failed to provide a sound scientific basis for many of the requirements, choosing instead to take an extremely risk-averse approach. Farmers are allowed to establish alternatives, but only after going through the expense of conducting or finding research and testing. In other words, in many cases, the farmers must do the FDA's job in order to continue using farming methods that have been used for decades or even centuries.

The FDA's approach to traditional farming methods, such as diversified livestock-crop farms, the use of working animals, and the use of biological soil amendments, is fundamentally flawed.

We urge the agency to remove the restrictions on sustainable methods of farming, absent data showing an actual, verified increased rate of foodborne illness; the simple fact that these methods include diverse microbiological communities is not a sound scientific basis for restricting them.

II. The proposed rule would effectively prevent most farmers from using important soil amendments such as manure and compost tea

The proposed regulation on biological soil amendments poses a significant problem for sustainable producers, threatening their ability to farm without the use of chemicals. The use of a wide range of biological soil amendments, from manure to different types of compost, is integral to raising produce with chemical-free methods. While producers in some parts of the county have reasonable access to vegetation-based composts (which will not be strictly regulated

under the proposed rules), animal-product-based composts are the primary option for sustainable producers in large parts of the country.

In the preamble to the proposed rule, the agency recognizes that the risk of pathogens may be different in a diversified system with competitive microflora (Refs. 171, 186, 187); the agency's proposed regulation, however, entirely fails to take this fact into account.

Manure is a proven low-risk fertilizer on organic farms. USDA's regulations for certified organic producers allow farms to use raw manure for fertilizer if it is applied three to four months prior to crop harvest. The FDA's proposed rule increases manure withdrawal period to nine months, making the application of manure extremely limited, if not useless. *See* proposed §112.56. Only if the soil amendment will not contact covered produce during or after application can the minimum application interval be waived; given the wide discretion provided to inspectors, it is unclear what must be shown to prove the lack of contact even after application.

In addition, FDA's proposed rule treats all of the following soil amendments as if they were raw manure:

- Compost made without specific heating periods (farmers often refer to this as "static composting," although the proposed regulations define that term differently);
- Vermicompost or "worm castings";
- Compost teas with any additives, even simple molasses or kelp meal
- Any compost that does not meet the precise methods and testing requirements specified in the proposed rule.

The practical effect of the proposed rule is to allow toxic chemicals to be easily used, while making the use of biological soil amendments difficult or even impossible for many farmers.

The FDA's proposal does not take into account the fact the increased microbial diversity limits the ability of pathogens to survive and multiply. For example, a 2010 study found that the use of soil fumigants results in higher survivial of *E. coli* O157:H7 in sandy soil, as compared to clay soil, which correlated to the greater effect of the soil fumigants on sandy soil; in other words, where the fumigants were more successful in killing soil microbiology, the pathogens flourished. *See* Ibekwe et al., *Influence of fumigants on soil microbial diversity and survival of* E. coli *)157:H7*, Journal of Environmental Science and Health, Part B: Pesticides, Food Contaminants, and Agricultural Wastes, 45:5 (2010). A 2013 study "demonstrated that highly diverse soil microbial communities act as a biological barrier against L. monocytogenes invasion." *See* Vivant et al., *Microbial diversity and structure are drivers of the biological barrier effect against* Listeria monocytogenes *in soil*, PLOS One, http://www.plosone.org/article/info:doi/10.1371/journal.pone.0076991 (Oct. 2013).[1] As the

[1] *See also* N. Paniel et al. 2010. *Assessment of survival of Listeria monocytogenes, Salmonella Infantis and Enterococcus faecalis artificially inoculated into experimental waste or compost.* Journal of Applied Microbiology, 108, 1797 – 1809; Van Elsas et al. 2011. *Survival of Escherichia coli in the environment: fundamental and public health aspects.* ISME Journal, 5, 173 – 183; van Elsas et al. 2012. *Microbial diversity determines the invasion of soil by a bacterial pathogen.* [E. coli O157:H7]. PNAS January 24, 2012. 109 (4) 1159 – 1164; Berendson et al. 2012. *The rhizosphere microbiome and plant health.* Trends in Plant Science. August 20, 2012. 17 (8) 1360 – 1385);

authors stated, "This suggests that erosion of diversity may have damaging effects regarding circulation of pathogenic microorganisms in the environment." In other words, FDA's unfounded bias against soil amendments such as compost, compost teas, and manures could have the effect of increasing the spread of pathogens in our environment and food supply, rather than the reverse.

We urge the FDA to:

1) Allow the application of compost with no waiting period between application and harvest;
2) Allow the application of manure and partially composted materials with a 120-day waiting period between application and harvest;
3) Treat compost teas with additives, vermicompost, and other biological inoculants the same as heat-cured composts.

III. The proposed rule creates unreasonable standards and testing requirements for agricultural water

The proposed rule provides that "all agricultural water must be safe and of adequate sanitary quality for its intended use." §112.41. The requirement that all water must be "safe" is, in practical terms, an impossible absolute.

The proposed rules require extensive testing if the farmer uses water that is not from a public water supply. If surface water is used, the farmer must test the water every 7 days during the growing season. For areas such as Texas and the south, the growing season can extend throughout the year, requiring 52 water tests. Since the testing must be done at an approved lab, the cost of the test would be increased by the expense and inconvenience of shipping the samples or driving significant distances each week to take the samples to the nearest accredited lab. The cost of such testing would be several thousand dollars per year.

It would be logical to allow the frequency of testing to be reduced if the water source consistently meets the standards during some initial period of time. Yet the proposed rules make no such provision, requiring weekly testing forever, with no end.

The proposed rules require that the farmer "immediately discontinue" the use of a source of water for certain uses – including washing produce, handwashing, or making compost teas -- if there is any detectable generic *E. coli.* While generic *E. coli* may be the appropriate test to use for screening purposes, it does not reflect the presence of pathogens. Given the difficulty farmers are likely to have in finding an alternative water source, the requirement to immediately discontinue use based on the generic *E. coli* test is neither scientifically nor economically sound.

Westphal et al. 2011. *General suppression of Eschericia coli O157:H7 in sand-based dairy livestock bedding.* Applied and Environmental Microbiology, March 2011, p 2113 – 2121; Mary L. Droffner and William F. Brinton, 1995. *Survival of E. coli and Salmonella populations in aerobic thermophile composts as measured with DNA gene probes.* Zbl. Hyg. 197, pp 387 – 397.

Indeed, the FDA recognizes that it is very unlikely that any untreated surface water could meet this standard, forcing farmers to either treat the water or find another source. *See* RIA at p.141.

We urge the FDA to amend the water testing requirements to:

1) Require testing no more than three times per growing season; or
2) If monthly testing is required, to reduce the frequency of testing after a farmer has established the safety of their water source through three consecutive negative tests.
3) Provide farmers with the option to test for pathogens if a water source has exceeded the standards for generic e. coli, rather than having to treat or stop using the water.

IV. The proposed rule creates significant ambiguity as to what farmers will have to do with both domestic animals and wildlife

Subpart I, the standards for domestic and wild animals, provides extreme discretion to FDA inspectors and officials. There are no clear or explicit provisions at all.

For example, if there is a reasonable probability that domesticated animals that graze in fields will contaminate covered produce, then the proposed standards require an "adequate waiting period" between grazing and harvest. The regulations do not specify a length of time that FDA considers an adequate waiting period, but the preamble to the regulations states that FDA "would not expect" the waiting period to exceed nine months;[2] this is the same interval that FDA proposes between the application of raw manure and harvest, and it effectively forces a farmer to abandon using that section of his property for the growing season..

Similarly, if there is a reasonable probability that working animals will contaminate covered produce, then FDA requires a farmer to take "measures" to prevent the introduction of foreseeable hazards such as animal feces, but the agency does not specify what those measures are.

The FDA is clearly trying to avoid the criticisms that have been leveled at the Leafy Green Marketing Agreement. In the preamble, the agency states that it does "not intend for proposed §112.11 to suggest that you would need to take measures to exclude animals from outdoor growing areas, to destroy animal habitats near your outdoor growing areas, to clear farm borders around outdoor growing areas or drainages, or to take any action that would violate applicable environmental laws or regulations."[3] Yet nowhere does FDA explain what measures the farmers should take to meet the vague standards in the proposed rule, and it would be difficult to comply with a strict interpretation of those standards without taking at least some such measures.

The rules fail to recognize a critical distinction between machine harvesting crops and hand harvesting them. A machine cannot discriminate between a live animal, animal feces, and a vegetable plant; as a result, the presence of livestock or wildlife on large-scale farms that use

[2] *See* 78 Fed. Reg. 3504, 3587.

[3] *See* 78 Fed. Reg. at 3552.

machine harvesting poses a significantly different level of risk than on a small-scale farm that uses hand labor.

Combined with the proposed rule on animal-based soil amendments, this section poses significant problems particularly for diversified farms that integrate produce and animal production, a key part of which is adding animal excreta to the soil. These diversified farms are efficient, both biologically and economically, yet would be hard-pressed to comply with the proposed rules; even ignoring expense, many of their methods simply could not be brought into compliance. These farms have not been shown to pose a high risk of foodborne illnesses in practice, and are being penalized based on fear-based assumptions rather than data.

We urge the FDA to clarify the provisions on wildlife and domestic livestock to protect farmers who use biologically diverse farming from field inspectors using their discretion to require measures such as fencing or destruction of habitat. We further urge the agency to provide for less stringent measures on farms using hand harvesting.

V. The FDA significantly overestimates the benefits of the proposed rule

FDA estimated that the benefits from the produce safety rule would be over $1 billion. *See* Regulatory Impact Analysis (RIA) at p.52. However, to reach this figure, FDA made several unjustified leaps of logic.

First, the FDA significantly overestimated the number of foodborne illnesses attributed to produce. The FDA relies heavily on a single study by Scallan et al, which looked at the number of foodborne illnesses that are reported and developed a multiplier to try to account for the illnesses that are not reported.

The FDA took Scallan's multiplier and applied it to the number of foodborne illneses from identified causes in raw agricultural commodities other than sprouts. The FDA then ***also*** used the multiplier on the number of foodborne illnesses from *unidentified* causes in raw agricultural commodities. *See* RIA at p.62. Yet FDA acknowledges that Scallan's own estimates of the number of foodborne illnesses from unidentified causes was significantly lower. *See* RIA at p.63. In other words, the FDA chose to use one study to estimate the number of illnesses and, without any justification, expand on its results to significantly increase its estimates.

This single, unjustified step has significant consequences. Using Scallan's methodology in a consistent manner leads to an estimated 996,390 illnesses from raw agricultural products, less than one third the FDA's estimate. *See* RIA at p.63.

It is important to recognize how speculative all of these multipliers are in the first place. In the time period examined by FDA, there were only 4,293 illnesses actually reported from raw agricultural commodities other than sprouts. *See* RIA at p.59. FDA's series of assumptions led to an estimate of 2,314,715 illnesses from such products; ion other words, FDA estimated that there were more than five hundred times as many unreported illnesses as there are reported.

Even using Scallan's estimates would still lead to the conclusion that there are over two hundred times as many unreported illnesses as there are reported.

Second, the FDA's estimate that the proposed rule would prevent about 65% of these illnesses from happening (p.51) was based on a shaky survey. The effectiveness of the proposed rule was based on interviews with "industry experts", based solely on the leafy green and tomato industries and based on practices used more than three years ago. *See* RIA at p.75. Particularly since tomatoes and leafy greens have been linked to by far the greatest number of outbreaks (p.60), even if the industry experts' responses were accurate, it would be difficult to justify extrapolating those results to all produce.

The combination of unjustified assumptions about the number of illnesses that occur and about the number of illnesses that would be prevented means that FDA's estimate of the benefits of the rule are unjustified and likely overstated by a significant amount.

We therefore urge the FDA to re-analyze the alleged benefits of the rule.

VI. The costs of the proposed rule would be crippling to many farms

In contrast to the speculative and overstated benefits from the proposed rule, FAD's estimates of the costs are extremely conservative.

According to FDA's own analysis, the **annual** costs of compliance would be:

- $4,697 for very small farms (average annual food sales under $250,000)
- $12, 972 for small farms (average annual food sales under $500,000)
- $30,566 for large farms (average annual food sales over $500,000)

The actual costs are likely to be much greater, particularly with respect to farmers' ability to source biological soil amendments that meet FDA's standards and the costs associated with water testing.

The FDA disguises the first-year costs of the regulations by annualizing them over 7 years for depreciation. *See* RIA at p.8. This ignores the issue of whether the farmer has the money to comply in the first year to begin with, as well as the fact that many small farmers do not have sufficient income to make depreciation cycles relevant.

The FDA severely underestimates the costs of the rule by assuming that small and very small farms (under $500,000 per year) only operate for 3 months per year, and only harvest, pack, or hold produce for 45 days out of the year; the agency estimates that large farms (over $500,000 per year) operate only 6 months per year and harvest, pack, or hold produce only 90 days. *See* RIA at p.10 & 163. While that may be true for monoculture farms that grow only one or two crops per year, it is **absolutely false** for diversified farms. For example, in Texas, many diversified produce farms operate for at least 9 months each year, with some growing produce year-round, with harvesting, packing, or holding activities occurring multiple days every single week.

With respect to the costs of the new limitations on the use of manure, compost teas, and composts, the FDA assumes that the cost is nothing more than switching to purchasing treated compost, since that is the "minimum cost alternative." *See* RIA at p.189. Yet what if the treated compost that is available in the area is of poor quality? What if the farmer uses compost teas for foliar applications, which is impossible to do with compost? The costs that are imposed by these new requirements are far more complex and far-reaching than is reflected by FDA's analysis.

In estimating the costs of the 9-month rule, FDA uses the rental value per acre of the property, estimating that it is $359 for a full year. *See* RIA at p.185. But small farms raising produce make far more than that per acre. Indeed, consider the implications of FDA's numbers: if an acre is only worth $359 in production per year, it would take almost 700 acres to produce a gross income of only $250,000, which is FDA's cut-off for very small farms. This is absurd. Obviously, use of the acreage is far more valuable than just $359 per year – and thus the costs of leaving such acreage unused for 9 months of the year is orders of magnitude greater than FDA's estimate.

In fact, these numbers contradict FDA's own estimates. The FDA assumes that "the midpoint of the acreage" for 112.5 acres for very small farms. *See* RIA at p.203. Even that is a gross overestimate of the likely acreage of such farms, and it still would mean an average production of over $2,000 per acre.

With respect to the provisions for agricultural water, the FDA's cost estimates appear to be based on wishful thinking. The agency states that "there are currently no EPA-approved water treatments that are available to consumers." *See* RIA at p.152. In other words, it would be impossible for farmers to treat their irrigation water currently in a way that complies with the regulations. The FDA is simply assuming that there will be safe treatment options developed and approved by EPA before the rules go into effect. If not, the FDA acknowledges that farmers who rely on water that does not meet the standards will have to stop irrigating or buy water from public water supplies, although the agency's cost estimates do not address the high cost of these outcomes. *See* RIA at p.153. Remember that the water might fail the standards even if it contains **no** pathogens.

FDA's over-estimate of the benefits and under-estimate of the costs of the proposed rules means that the costs of the rule will **exceed** any benefits. Moreover, there will be indirect costs, in the form of discouraging new farmers, as well as favoring chemical methods of agriculture over sustainable methods. The costs attributable to these effects need to be addressed before FDA moves forward with regulations under FSMA.

We therefore urge the FDA to re-analyze the alleged costs of the rule.

VII. Conclusion and request for second comment period

The undersigned organizations urge FDA to address the comments above, along with the many other comments that have been submitted by individuals and organizations, and to then publish a revised proposed rule.

Given the complexity of the proposed rule and the need for extensive, substantive changes, it is vital to allow time for a second public review. Rushing to implementation could have irreversible negative consequences.

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