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

Submitted electronically via regulations.gov

Docket No. FDA-2011-N-0921-0973

RE: Comments on the Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

To Whom It May Concern:

The National Young Farmers Coalition is a nation-wide network of young and beginning farmers and ranchers dedicated to representing the interests of the next generation of American growers through education, advocacy and grassroots mobilization. NYFC has 24 local chapters across the country and represents a network of 54,000 supporters and almost 1,000 dues-paying members.

NYFC's explicit goal is to promote independent family farms, to encourage sustainable farming practices and to address the barriers that beginning farmers face. The coalition's farmer-members represent a diverse range of agricultural industries, from vegetables to animal-husbandry to value-added production.

We submit this comment because we are concerned that certain aspects of these proposed rules may cause undue hardships for beginning farmers without adding to the food safety value of the rules as a whole. Having submitted last year, we are pleased to see great improvement between the original proposed regulations and this second draft. Moving forward, we urge the FDA to maintain these necessary

revisions. In addition, we would like to call attention to a few improvements that support both the safety of the American consumer and the viability of the American producer. As farmers, we recognize that food safety is paramount in our work; our goal is to ensure the FDA's regulations are efficient and pragmatic in providing the oversight required.

Comments on the Proposed Produce Rule

A. An Integrated Approach to the Produce Rule is Required

In the newly proposed Produce Rule, the FDA has implemented part of the requirement from the Food Safety Modernization Act (FSMA) to "minimize, as appropriate, the number of separate standards that apply to separate foods" Specifically, the FDA has taken an "integrated approach" and has not set forth separate standards for separate foods (with the sole exception of sprouts) in the proposed Produce Rule.

The FDA is tentative in its determination to use an integrated approach rather than a commodity-specific approach, and the agency specifically requests additional comment on this approach. It is our view that an integrated approach is a critical component of making the produce regulations work for diversified farmers, and the regulations would be extremely burdensome for farmers with highly diversified operations if FDA decided to set separate standards for different agricultural products.

We understand that many of the operators and advocacy groups that the FDA will be hearing from represent monoculture or near-monoculture agriculture, and those groups would not be overly burdened by commodity-by-commodity standards. However, we want to make sure that farmers who pursue diversification in their operations are not over-burdened to the point of inability to abide by regulation.

Many of the beginning farmers in the National Young Farmer Coalition network choose to operate diversified operations for social, financial and environmental reasons. Many farmers have found that economic viability for their operations comes through the spreading of risk through many crops and through widening their market potential by growing many crops. In fact, with access to land and access to capital being two of the largest obstacles new farmers face, diversified vegetable operations have been repeatedly demonstrated to be low-cost ways to enter agriculture without needing large amounts of land.

Commodity-by-commodity regulations would make that diversification near impossible. Many of those diversified operations – some of which exist as Community Supported Agriculture (CSA) programs that by design require a great deal of diversification – grow dozens of types of vegetables. Filing separate paperwork for each would be an overwhelming burden, especially since many CSA operators grow only fractions of an acre of each crop.

This issue is not specific just to NYFC members: according to the last Census of Agriculture, there are well over 10,000 CSA farms in the country, and the trend is growing. As the USDA has stated, the

regulations stand to place a sizable cost already on small farms; forcing farmers to multiply their abidance for each crop would create a staggering additional burden.

Our Recommendation: The FDA should retain its "integrated approach" in the final Produce Rule and should not take a commodity-specific approach.

B. The Gross Sales Exemption and Modified Requirements Must be Fixed to Apply Solely to Covered Produce as Provided by FSMA

In the new Produce Rule, FDA proposes to exempt farms with an average annual monetary value of produce sold during a previous three-year period of $25,000 or less, and to use modified requirements for farms under a $500,000 threshold in annual sales, averaged over the past three years.

It is apparent that the exemption and modified requirements should logically only focus on covered produce in calculating a farm's annual revenue, not the business's entire gross sales of all food. The intent of the regulation is to ensure the safe production of covered produce, not to regulate the entire farm operation. We feel that the size of the overall operation does not have an impact on the safe handling practices of the actual produce that the regulations are concerned with. Given that many 21st century farms grow a variety of both covered and non-covered produce, there is a great risk that operators of small produce farms will be unfairly regulated.

For example, many of NYFC's members are returning to family farms to start their own enterprises. It would be an unfortunate negative impact of the rules if an aspiring new farmer's small CSA were to be severely restricted by regulation just because it was unwittingly linked to the parents' pick-your-own pumpkin patch or dairy operation. It is clear that that quarter-acre CSA operation should not be regulated the same as a thousand-acre vegetable operation just because of its physical and legal proximity to another operation outside the bounds of the covered produce list.

Finally, we fear that the proposed system for calculating revenue for the exemption would unduly hinder farm entrepreneurialism by needlessly limiting farms from expanding into multiple revenue-generation enterprises – adding a small (covered) vegetable operation to an existing farm. Our country needs to focus on ways that it can strengthen our nation's food system – this regulation, as proposed, would only weaken it without adding any additional protection for consumers.

Recommendation: FDA should base the threshold for modified requirements and for the exemption on produce covered by the Produce Rule.

C. Standards Directed to Agricultural Water Still Fail to Meet the Requirements of FSMA for a Science- and Risk-Based Approach.

We applaud the FDA for taking steps to revise its standards on agricultural water and feel that progress was made in both strengthening the rules and also making them more manageable for our national agricultural system. However, we feel that the standards need to be revised further so that they are flexible enough to ensure safety while also being workable for new farmers and small operations.

We fully support the switch to using baseline data analysis instead of regular frequent testing once a safe track record is established, but we feel that the requirements for establishing that baseline are far too high for the average small to mid-size farm. Requiring twenty tests for surface water over the course of two years is a huge amount of time and money for the operator, and is much more than is needed. This is especially true for farms with shorter growing seasons, where ten tests per year could mean tests less than a month apart!

It seems most logical to require fewer tests (four to six) and then just to be more deliberate in what is acceptable to establish a baseline. For example, six tests all showing near-identical numbers all within a safe range indicate a strong likelihood that further testing would only return the same results. On the other hand, large divergence within those six tests could indicate more tests are needed before a baseline is set. Through this method, safe and stable sources are established at low cost and unstable and potentially dangerous tests are subject to more rigorous testing.

Our concern is that these rules are being written with large farms – and large water sources – in mind. Many of our member farms irrigate between two and twenty acres and yet will often use multiple water sources. We have surveyed many of our members as to the cost of these additional testing requirements and are astounded at the additional burden they will present. Farms in different regions reported different testing costs, but the average came to approximately $46 per test, not including shipping and labor costs.

As an example, a commonplace set-up for a small farm is to use two land sites (because of the unavailability of large tracts of contiguous and affordable land in many regions of the country). That example farm is just over the $500,000 threshold and uses surface water (from on-site ponds) for irrigation. When the operation first began on those two sites, the irrigation ponds were testing multiple times and found to be well within the safety levels. If the new rules were in place, the testing burden for that small farm to establish a baseline would be:

> Testing surface water ponds:
> Testing 2 ponds, 10x per year, for 2 years = 40 tests
>
> Test costs $40
> Overnight shipping: $29 (sample would have to be overnighted to lab (or driven in person) so as to arrive within 24 hours)

Total= 40 x ($40 + $29) = $2760

That number, which is a significant cost for this one section of the overall proposed food safety regulation, does not include time spent on collecting samples. In short, this would be a huge burden on a farm that has no need to test so frequently, given the safe track record the water supply has.

Recommendation: In the final Produce Rule, FDA should adjust requirements to establish a baseline for water testing of surface water sources to be more flexible and to account for demonstrated reliability in initial testing.

D. FDA Must Further Define Material Conditions Clause and Strengthen Protections for Farmers

The newly proposed regulations contain clear improvements in the material conditions clause that determines when a farm can lose its exemption and by what process the FDA goes about removing that qualified exemption status. We are happy that the FDA has made those positive changes, but feel that further explication is needed so that farmers understand the process and can better follow the regulations.

The FDA has requested input on is how long a farmer would have to come into compliance when an issue is raised in the withdrawal process. We feel that farms should be given the same 120 days that facilities are given to come into compliance, unless the issue is so great a threat that greater timeliness is required. Very often a farm will strive to come into compliance as quickly as possible, but systemic change can require lengthy adjustment – an operation should not be unfairly penalized when they are actively working to rectify a problem.

Further, we feel that in any interaction with a farm regarding a withdrawal – whether it be a warning letter or the actual withdrawal - the FDA needs to include facts specific to the business that holds the qualified exemption, to ensure that each withdrawal is made on an individualized basis and that the farmer or facility has a real opportunity to rectify the problem. Our concern is that if a potential food safety concern arises (ie, a pathogen outbreak in spinach sold at a major retailer), all farms across the country that happen to grow spinach will have their exemptions or modified requirements taken away. This sort of over-reaction is completely unnecessary and has the potential of destabilizing the nation's food system. To control for that, we need the FDA to respond to such occurrences in a safe and moderate manner, including only withdrawing exemptions or modified requirements for farms that are directly related to the outbreak.
Furthermore, FDA should retain the exemption and modified requirement reinstatement process, and the final rules should clarify that FDA will reinstate an exemption within a reasonable period of time.

Recommendation: In the final Produce Rule, FDA must clarify the Material Conditions clause. It should provide farmers with the 120-day period for coming into compliance with the rules, require that a specific

farm demonstrate the need for withdrawal (rather than targeting farms based on general characteristics, such as what they grow), and clarify the reinstatement process.

E. The Produce Rule Still Fails to Comply with FSMA By Not Adequately Supporting Conservation Practices and Co-Management of Conservation, Environmental, and Public Health Considerations

The FDA has made great strides to address conservation in the new proposal. However, we remain concerned about the role of co-management practices in the re-proposed regulations.

Co-management is the idea that the farm is managed to sustain the natural ecosystem, biodiversity and soil and water health while also being managed to reduce risk of danger to consumers. Examples of practices that support conservation and food safety include stream-side vegetation, buffer strips, hedgerows, and cover crops.

Although FDA mentions its support for practices that support food safety, conservation, and environmental protection, FDA does not include a definition of co-management in the proposed rule. Furthermore, it does not build those important considerations into other aspects of its regulations.

The importance of co-management in order to sustain the farm and environment are clear. Further, it is our belief that public health, plant health and ecological health are all intertwined; when farms put focus on the larger ecological considerations, the value and safety of the food produced increases. A survey conducted in 2011 of thousands of farmer-members shows that nearly 77% self-identify as using some form of conservation practice on the farm, either for ecological or monetary reasons. Of those who do use those practices, 93% of farmers provide pollinator habitat, 81% provide beneficial insect habitat, 48% use buffer strips to reduce erosion and 21% work to consciously protect riparian herbaceous cover to maintain water quality. Those numbers reflect a growing trend in recognizing the importance of conservation, and should not be ignored by FDA rules.

The FDA needs to be explicit in permitting co-management practices and making clear that farmers will not have to choose between obeying the regulations and following proper ecological farming practices. While we understand, based on the rules preamble, that the FDA is supportive of comanagement right now, this support needs to be codified in the regulatory language itself to protect sustainable farmers and their practices from regulatory overreach in the future.

Recommendation: In the final Produce Rule, FDA must be proactive about on-farm conservation and natural resource conservation to fulfill FSMA requirements and protect against unfounded buyer-driven food safety requirements to remove conservation practices.

F. The Produce Rule must support diversified crop-livestock farming systems and clarify grazing.

The FDA has made great strides to address conservation in the new proposal. We are pleased to see improvement in the new proposed regulations, but still want to stress the importance of recognizing the requirements of diversified operations that raise both vegetables and animals, and of recognizing the value of supporting conservation efforts on farmland.

With regard to diversified operations, we continue to stress that the nine-month waiting period between the time when animals are grazing a specific field and the harvest period for crops is far too long. Throughout our membership, domesticated animals or poultry are often allowed to graze produce fields after harvest of one crop and before planting the next, for the purposes of weed, pest, and crop disease management. This timeless practice also allows for better parasite control and enhanced biological diversity.

We realize that the FDA has not yet stated that nine months will be the required period, but the preamble states that the period will be "no more than nine months," and we are concerned this maximum period may be exercised. Given the need stated in the re-proposed regulations to conduct further research into the safety and practicality of that nine month period for raw manure application, we want to ensure that the period between grazing and harvest similarly reflects the best proven-safe systems that do not needlessly impede farm diversification.

With regard to the importance of conservation efforts, the FDA has added a provision that specifically states that nothing in the Produce Rule requires covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainage areas.

It is vitally important that the final regulations support efforts to maintain conservation areas and support conservation efforts. It is important not only to beginning farmers, but for the viability of our nation's agricultural system, that regulation not precludes this important conservation work.

Recommendation: We are pleased that the FDA has expressed the need for conservation areas and we strongly recommend that that explicit language continue into the final draft. Further, we urge the FDA to harmonize the livestock grazing regulations with the re-drafted raw manure application interval.

G. The Produce Rule should not establish a list of "animals of concern."

In the preamble of the initial proposed Produce Rule, FDA tentatively concludes that "current scientific evidence on the extent to which specific animals present the greatest risk for pathogens is inadequate to

develop such a list." FDA's conclusion is correct; FSMA does not require such a list and to include one would be unscientific and, therefore, a violation of FSMA's requirement to establish science-based rules.

We feel strongly that to establish a list of animals – which would also then require preventative measures for each – would drag out and muddle actual farm planning for proper response. In short, any animal that leaves feces in a crop field or damages a crop might be a source of contamination. The type of animal does not matter and a list of animals of concern would result in certain animals being targeted over others. Deer, which were on the CALGMA list until recently, were no more of a food safety risk than rodents on some farms. Yet since deer were on the list, environmentally destructive measures that included fencing and destroying deer habitat were used to control them, even when they may have not been causing any food safety problems.

Recommendation*:* In the final Produce Rule, FDA should retain its current conclusion and should not develop a list of "animals of concern."

H. FDA Should Maintain its New Manure and Compost Regulations

We are pleased with the improvements that the FDA has made in the "manure and compost" section of the rule, and want to stress the importance of maintaining those changes in the final draft of these regulations. The practices of using raw manure and composted manure have been a part of agriculture for thousands of years and continue to be instrumental in our nation's agricultural system today. As an example of the widespread use of these amendments, USDA's National Agricultural Statistics Service 2008 Organic Production Survey (OPS) found that 65 percent of certified organic farms use green or animal manures, and that 51.3 percent of certified organic farmers use organic mulch or compost. These practices are fundamental and foundational aspects of sustainable and organic production systems.

Following the recommendations of NYFC and many other organizational and individual comments, FDA has changed the application-to-harvest interval of composted manure (using approved methods for composting) from 45 days to zero. As we stated in our original comment, for farmers who use compost, enactment of the proposed 45-day interval would severely limit crop rotations for short-season crops and significantly restrict the use of compost during the growing season for side-dressing. Mesclun and other salad mixes, spinach, radishes, arugula, and salad turnips are often harvested as soon as 20 to 45 days after planting; all of these crops are relatively heavy feeders that typically require compost during growth to provide satisfactory yield and quality. In addition, summer squash, zucchini, and cucumbers typically begin yielding within 40 days of being transplanted into the field or high tunnel. Finally, some producers side-dress with compost as a part of their integrated pest management plan, with the goal of enhancing soil biological activity and thereby improving nutrient availability and suppressing certain crop diseases.

The National Organic Program standards have already proven that no interval is required (and in fact, specifically contradicts the originally proposed FSMA rules). Given that use of composted manure – often with a short interval – is important to many vegetable producers, we would like to stress the importance of maintaining the zero day interval in the final rule.

With regards to the use of un-composted manure, we are pleased that the new regulations have eliminated the nine month interval between application and harvest in favor of further research.

As we stated in our original statement, a nine-month interval between application and harvest of covered produce means that, for farmers who use manure in produce production in certain areas of the country, *the interval between application and harvest will be longer than the growing season*. That means that the proposed intervals would effectively eliminate the use of untreated biological soil amendments of animal origin (including raw manure, aged manures, and cool-composted amendments with any ingredients of animal origin) in most production systems, and create significant barriers to the use of compost. The use of these types of biological soil amendments is a fundamental and foundational practice in sustainable production systems, and is a critical aspect of soil, nutrient, fertility, water-holding capacity, and pest management in sustainable and organic agriculture. To prevent their use would force many farmers into greater reliance on costly agrichemicals that serve as major contributors to agricultural pollution and run-off.

We are glad that the FDA recognizes the need to conduct further research into use of raw manure before implementing any specific requirements on application intervals. As we stated before, there is a significant lack of research into the area and it behooves the FDA to ensure it has adequate information in hand before introducing a major disruption to farming practices. It is important that the FDA will consider such specific parameters as:

- Type of manure
- Method of application
- Specific regional climate
- Soil characteristics
- Specific vegetable being grown and how it is in contact with manure

Until this research is done, we strongly urge the FDA to not implement untested limitations on farmers in blind pursuit of safety.

Regarding both use of composted and uncomposted manure, it might be useful to know some of the reactions of our membership in considering the originally proposed restrictions. In surveying our membership on their compost and manure usage and how the 45 day and nine month intervals would impact their operations, these are a sampling of some responses:

"We would have to eliminate early spring crops that are harvested in less than 45 days. We would probably eliminate any application of uncomposted manure."

"Fields are amended with composted manure in spring and early greens are harvested before 45 days. I also plan to use uncomposted animal manure in the future. If I apply in the fall, I would not be able to harvest until summer of the following year, potentially losing 2 months of sales when vegetables could be harvested."

"I run the chickens over the tomato patch every spring. Of course this poses no food Safety issues since the tomatoes are harvested 80 days after transplant and they are so high off the ground."

"My vegetable fields are used continuously (with short stints of cover-cropping during the season and over the winter), and lightly composted manure is my main source of nutrients. As it is, I only apply once a year, in late fall, but the 9 month rule would make it impossible to use that system."

"We would not be able to use chicken tractors to clean up/fertilize land."

"These restriction would lessen our farm fertility since we would be very limited in when we could add manure. We would probably stop rotating our chickens through the farm."

Recommendation*:* In the final Produce Rule, FDA should retain its current conclusion and not require any interval between composted manure and harvest, and should conduct in-depth, risk-based assessments before requiring a specific interval between application of raw manure and harvest. Ideally, this standard would match the proven standard used by the National Organic Program.

I. The proposed foundational definitions applicable to both Produce Rule and the Preventative Controls Rule are still insufficient and must be improved so that farms are not inappropriately regulated as "facilities."

The FDA's regulations need to be careful in differentiating between farms and facilities, as it will have a huge impact on the way our food system will function. We encourage the FDA needs to take a nuanced approach to deciding which post-harvest handling are facilities-level processing and what are common on-farm practices. We also encourage the FDA to consider than many modern farms utilize off-site resources – whether it be other farms or storage facilities – to aggregate their product. Additionally, a large percentage of farms operate on multiple sites that are not geographically linked. In many cases, these also should not be considered worthy of triggering the "facilities" definition.

Specifically, these issues include:

- Washing freshly-harvested produce in an on-farm packing area.

- Washing, cooling or packing at an off-farm location, dependent on the definition of off-farm. Many farmers are operating on multiple locations and there is a risk that when harvest and post-harvest handling occur on different locations, this could unfairly trigger a "facilities" definition. Similarly, many beginning farmers may rent land and share the processing facilities of the farmer from whom they rent. That processing should also not trigger the "facilities" definition.
- Finally, a strict reading of the regulations indicate that if a farmer sends their produce to another farm for aggregation purposes (which could include sorting and storage) then that would be considered "facilities"-worthy. Our concern with that is that many farms share either transportation to markets or operate shared-CSA businesses. The final rules need to be explicit that such situations would not trigger the "facilities" definition.

We feel that to otherwise institute artificial restrictions on the way a small farm can handle food will hugely impact the types of vegetables that can be grown on that scale and the types of marketing and distribution systems that can be employed.

***Recommendation**:* In the final Produce Rule, FDA should ensure that its "facilities" definition does not unnecessarily target modern forms of farming operations. This means widening the definition of what are acceptable "farm" activities and removing the phrase "in one general physical location" from the farm definition.

We commend the work that the FDA has done already to make this proposed rule work for small, beginning, and diversified farmers. We appreciate this second opportunity to submit comments and we stand ready to continue to help make these rules meet the needs of our members.

Sincerely,

Lindsey Lusher Shute
Executive Director

Eric Hansen
Policy Analyst

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