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

RE: Docket No. FDA-2014-N-2244
Comments on the Draft Environmental Impact Statement for the Proposed Rule, Standards for the Packing and Holding of Produce for Human Consumption

To Those at the Food and Drug Administration:

On behalf of the Recirculating Farms Coalition ("RFC")[1] and our members, please accept this letter as formal comments on the Draft Environmental Impact Statement ("DEIS") for the Food and Drug Administration's ("FDA") proposed rule for "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Produce Rule" ("Produce Rule").

In addition to these comments, RFC incorporates by reference all of the comments that it has already submitted on the Produce Rule, and the Proposed Amendments to the Produce Rule.

Specifically, RFC offers comments that urge the final EIS account for the environmental impacts this rule can have on emerging agricultural sectors. We ask that the FDA become more familiar with the urban agriculture and recirculating farming industries, as they are growing nationwide and contribute to the overall sustainability of our country's food system. As such, it is not effective or appropriate to simply exclude them from the requisite environmental impact assessment that must be done prior to the final implementation of the Produce Rule.

Further, RFC requests that the FDA's final EIS specifically state that its environmental assessment of the Produce Rule's Agricultural Water and Soil provisions excludes recirculating farms because the nature of these operations does not make them subject to compliance with these sections of the proposed Produce Rule.

[1] The Recirculating Farms Coalition is a national non-profit collaborative group of farmers, educators, non-profit organizations and many others committed to building local sources of healthy, accessible food,

I. Background

The Recirculating Farms Coalition works with growers throughout the United States who use nutrient rich, naturally cleaned and constantly recycled water in place of soil as the basis to grow food and other agricultural products. These "recirculating" farmers employ "hydroponics" – growing plants in recirculating nutrient rich water, "aquaculture" – raising fish on land, in tanks with recirculating water (similar to an aquarium type design) and "aquaponics" a combination of hydroponics and aquaculture where fish and plants are raised together in one closed-loop symbiotic recirculating system.

Recirculating farms are currently operating successfully throughout the United States and in many other countries. In fact, recirculating technology has been developing for over 35 years in the United States. Researchers, scientists and farmers are continually refining techniques and methods to increase production, profitability and environmental sustainability. Facilities across the country, and around the world are conducting research and implementing new ways to further improve and expand these farms.

Recirculating farms may be indoors, like in a greenhouse or other structure, or outside, depending on the climate. Their main feature is that the water used is continuously filtered and recycled, then circulated throughout the farm.

These farms are mostly closed-loop operations. Their contained nature makes it more difficult for pests and contaminants from outside the farm to get in, so often these systems can operate without antibiotics, and other drugs or chemicals.

Recirculating hydroponics, aquaculture and aquaponic farms also need not be connected to natural waters to source or drain water. Being closed-loop means that whatever is in the farm system is unlikely to escape.

These farms can also rely largely on renewable energy, like solar, wind and geothermal power, or repurposed energy like methane gas generated from waste and previously used vegetable oil, to heat, light or otherwise power the farm.

Recirculating farms can be completely contained systems that re-use most of their water. There are a number of filtration methods to remove waste; the filtered water is then recycled back throughout the system. Ideally, farms only replace very small percentages of the total water volume, due to some loss during waste removal and/or evaporation

Researchers and industry experts are developing a variety of resourceful ways to deal with farm by-products, such as creating feed ingredients for other fish or shellfish (which would naturally consume such products in the wild). Some farms re-purpose waste into fertilizer for soil-based plants.

These farms are scalable too — they can be as compact as a desktop, for personal use, or larger, for a commercial operation. Being versatile in shape and size and self-contained

allows these farms to be located within the communities that will use the products. This cuts down on use of fuel for transport and gives consumers fresher food.

New recirculating farms are popping up all around the United States, and these farms are continuously working to increase their safety, efficiency, and environmental sustainability. The industry should not be penalized for their unique and innovative practices by being grouped in with other farming techniques with different inherent risks. However, in yet another step in the development and implementation of the food safety modernization act, the FDA has not accounted for the important ecologic, social and economic role of recirculating farms in the United States

As the FDA is surely aware, the National Environmental Policy ACT ("NEPA") requires it to issue an Environmental Impact Statement ("EIS"), which is a "detailed statement . . . on the environmental impact of the proposed action, any adverse environmental effects which cannot be avoided should the proposal be implemented, [and] alternatives to the proposed action . . . [,]" among other disclosures.[2] These sweeping policy goals are realized through a set of "action forcing" procedures that require agencies to take a "hard look" at the environmental consequences of their actions.[3] Under NEPA, if a draft EIS "is so inadequate as to preclude meaningful analysis, the agency *shall* prepare and circulate a revised drafted of the appropriate action."[4]

In light of NEPA's statutory requirements, please find RFC's comments below on the deficiencies of the proposed DEIS for the Produce Rule in its current form.

II. The DEIS does not evaluate how the produce rule will impact the United States' growing urban agriculture sector.

The DEIS's NEPA analysis is completely void of addressing how the Produce Rule will impact urban farms and their surrounding cultural, socioeconomic and ecological environment. Without doubt, in the spirit of U.S. entrepreneurism, diverse forms of urban agriculture operations continue to emerge in cities across the United States. Many of these businesses employ some form of hydroponic, aquaponic and aquaculture growing techniques.[5]

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[2] 43 U.S.C. § 4332(2)(C) (2006).
[3] *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989).
[4] 40 C.F.R. § 1502.9(a)(emphasis added).
[5] *See e.g. Study to examine trends in urban agriculture*, PENN STATE NEWS, (Aug. 17, 2012), http://news.psu.edu/story/147385/2012/08/17/study-examine-trends-urban-agriculture (recognizing that "[u]rban agriculture also is diverse in production methods. For example, crops may be grown in vacant lots, on rooftops, by hydroponic methods (growing plants without soil) or in high tunnels (a type of greenhouse; also known as hoop houses), among others."); *see Board of Health Policy Regulations for Urban Agriculture in Somerville*, http://www.somervillema.gov/sites/default/files/All-Three.pdf (last visited Mar. 13, 2015)(including hydroponic and aquaponic farms in the definition of farming in municipal regulations); *A Summary of Urban Agriculture Amendments to Detroit's Zoning Ordinance*, http://www.law.msu.edu/clinics/food/busdickerfact.pdf (last visited Mar. 13, 2015)(including specific definitions for hydroponic, aquaponic and aquaculture urban agriculture initiatives in Detroit).

The North American Urban Agriculture Committee defines urban agriculture as "the production, distribution and marketing [and disposal] of food and other products within the cores and edges of metropolitan areas. Urban agriculture is a complex activity, addressing issues of food security, neighborhood development, environmental sustainability, land use planning, agricultural and food systems, farmland preservation, and other concerns."[6] It has becoming increasingly accepted that urban farms can improve the environment, reduce greenhouse emissions, and improve access to healthy, locally grown food.[7] The U.S. Environmental Protection Agency ("EPA") also recognizes that "other possible benefits include promoting health and physical activity, increasing community connections, and attracting economic activity."[8] Furthermore, the Food and Agriculture Organization of the United Nations ("FAO") has identified these additional contributions of urban agriculture to a region's overall food security:

- Locally produced food requires less transportation and refrigeration, it can supply nearby markets with fresher and more nutritious products at competitive prices.
- Consumers - especially low-income residents - enjoy easier access to fresh produce, greater choice and better prices.
- Vegetables have a short production cycle; some can be harvested within 60 days of planting, so are well suited for urban farming.
- Garden plots can be up to 15 times more productive than rural holdings. An area of just one square metre can provide 20 kg of food a year.
- Urban vegetable growers spend less on transport, packaging and storage, and can sell directly through street food stands and market stalls. More income goes to them instead of middlemen.
- Urban agriculture provides employment and incomes for poor women and other disadvantaged groups.
- Horticulture can generate one job every 100 square meter garden in production, input supply, marketing and value-addition from producer to consumer.[9]

Neither the Produce Rule, nor its DEIS, distinguish or recognize that a growing and significant quantity of food is being cultivated by urban entities that will likely be covered by the Produce Rule.

RFC recognizes that currently little data exists that quantifies the social, environmental and economic impact of urban agriculture within the United States. In fact, the United States Department of Agriculture's National Institute of Food and Agriculture recently awarded a nearly half million-dollar research grant to examine the trends in urban farming.[10] Nevertheless, it is incumbent upon the FDA to recognize the growing

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[6] *Frequent Questions*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, http://www.epa.gov/brownfields/urbanag/frequent.htm (last visited Mar. 13, 2015).

[7] *See e.g. Urban Agriculture & Improving Local, Sustainable Food Systems*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, http://www.epa.gov/brownfields/urbanag/ (last visited Mar. 13, 2015).

[8] *Id.*

[9] *Urban Agriculture*, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, http://www.fao.org/urban-agriculture/en/ (last visited Mar. 13, 2015).

[10] *Study to examine trends in urban agriculture*, *supra* note 5.

importance of urban agriculture in its EIS because the implementation of the Produce Rule could have significant environmental impacts on the longevity of this important sector in U.S. agriculture.

Urban agriculture operations face distinct challenges and opportunities compared to their rural counterparts, none of which are accounted for within the Produce Rule's DEIS. They have unique food safety concerns, and their relationship to water, biological, ecological and soil resources differ significantly from rural operations. Urban farms contribute significantly to the reduction of cities' waste, greenhouse gas emissions, and health disparities. The potential loss of urban farming enterprises because of produce rule's impact could have serious and detrimental environmental ramifications on the communities who depend on these local food sources. Consequently, the final EIS must address this deficiency in order to fully comply with NEPA.

III. The DEIS Fails to Address Aquaponic and Hydroponic Farms.

A. Summary of Differences

As RFC explained in previous 2013 and 2014 comments on the Produce Rule (developed from comments submitted by the Chicago Food Policy Council) recirculating farms are distinctly different from soil-based growing operations. Produce grown via covered aquaponics and hydroponics or even those in more open systems, are not exposed to the same risk factors as produce grown in the ground of outdoor fields. Produce grown in fields can become contaminated from a variety of sources, including mammalian manure used as fertilizer, contaminated surface and ground water used to irrigate plants, in processing or from other sources, and contact with birds, insects, cats, dogs, deer, and livestock carrying human pathogens, and previously-contaminated soil, among other concerns.[11] In contrast to conventional field farming, recirculating farming minimizes the risk of human pathogen transmission because (1) fish are inherently different than mammalian or avian species and do not carry the suite of pathogens responsible for the majority of foodborne illness, and (2) operation of recirculating systems involves numerous safeguards within in a closed loop system.[12] Additionally, these farms are raised from the ground and often protected by various methods of enclosure and cover.

In recirculating aquaponics and hydroponics, water is not applied directly to the harvestable portion of the plants. Rather, the water directly contacts the roots of the plants, which act as biofiltration systems that filter the water before it is recirculated back to the rest of the system. Often, a barrier separating the harvestable portion of the plants from the water minimizes the likelihood that contamination will occur.[13] In fact, FDA has recognized that indirect methods of water application -- such as those used in aquaponic

[11] R.V. Tauxe, et. al., Evolving Public Health Approaches to the Global Challenge of Foodborne Infections, 139 INT'L J. OF FOOD MICROBIOLOGY S-16, S-20 (2010).
[12] *See id.* at S17-18
[13] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg.3504, 3523 (Jan. 16, 2013) (proposed for codification at 21 C.F.R. pts. 16 and 112).

and hydroponic systems -- are less likely to contaminate produce than water applied by direct methods.[14]

In aquaponics, water circulated through the system must be of good quality to maintain the health of the fish in the tanks.[15] Aquaponic systems also have natural biofiltration systems, in which fish waste metabolites are removed by nitrification and direct uptake of the plants. Water absorbed through plant roots eventually flows back to the fish tanks for reuse.[16] Water used in aquaponic systems most often comes from public drinking water systems, which "have the lowest relative likelihood of contamination due to existing standards and routine analytical testing."[17] An aquaponic system can fail if any of the various components become unbalanced: dissolved oxygen, carbon dioxide, ammonia, nitrate, nitrite, pH, chlorine, stocking density of the fish, growth rate of the fish, feeding rate and volume, and related environmental fluctuations.[18]

Additionally, and perhaps most notably, fish are not high-probability vectors of diseases to humans.[19] Human enteric pathogens responsible for the majority of foodborne illnesses survive primarily in warm-blooded mammals and not in cold-blooded animals such as fish. E. coli and Salmonella, the two human pathogens of greatest concern to FDA, are not present in fish manure.[20] E. coli is transmitted only by mammals, with cattle serving as carriers of the O157:H7 serotype and other mammals such as pigs, dogs, cats, rabbits, goats, and sheep carrying various other serotypes.[21] Primarily mammals such as poultry, cattle, sheep, and pigs carry salmonella.[22] Fish tissue may become contaminated with Salmonella if they are exposed to water containing bird or mammal manure containing Salmonella, yet fish do not carry Salmonella or E. coli in their gut as mammals do.[23] FDA itself has recognized that the best indicator human pathogen risk is testing for "non-pathogenic microorganisms that are commonly found in the intestines of warm-blooded animals."[24]

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[14] *See id.* at 3523.
[15] Steve Diver and Lee Rinehart, Aquaponics – Integration of Hydroponics with Aquaculture, ATTRA (NCAT/Nat'l Sustainable Agric. Info. Service) 2006, updated 2010, at 1.
[16] James Rakocy, Donald Bailey, R. Charlie Schultz, Eric Thoman, Update on Tilapia and Vegetable Production in the UVI Aquaponic System, 676-690, New Dimensions on Farmed Tilapia: Proceedings of the Sixth International Symposium on Tilapia in Aquaculture (2004).
[17] 78 Fed. Reg. at 3523.
[18] Diver, *supra* note 15, at 3.
[19] J. Hollyer, et al., On-Farm Food Safety: Aquaponics, 38 FOOD SAFETY AND TECH. J. 1 (July 2009).
[20] *See* R.V. Tauxe, supra note 11, at S17
[21] M.D. Sobsey., L.A. Khatib, V.R. Hill, E. Alocilja, S. Pillai, Pathogens in Animal Wastes and the Impacts of Waste Management Practices on their Survival, Transport, and Fate. NATIONAL CENTER FOR MANURE AND ANIMAL WASTE MANAGEMENT PUB. NO. 913C0306 (USDA NIFA Fund for Rural America Grant) 2006 at 620.
[22] *Id.* at 623.
[23] İlkan Ali Olgunoğlu, Salmonella in Fish and Fishery Products, in SALMONELLA -A DANGEROUS FOODBORNE PATHOGEN (Dr. Barakat S M Mahmoud, Ed., 2012).
[24] 78 Fed. Reg. at 3561.

Fresh leafy greens grown in fields have been responsible for many outbreaks of E. coli O157:H7 and Salmonella infections in the United States.[25] E. coli and Salmonella pathogens may be transferred to the harvested produce by field animals, mammalian manure application, or contaminated surface and ground waters. As none of these risk factors are present in aquaponic or hydroponic recirculating closed-loop systems, these methods of farming greatly minimize the risk of E. coli or Salmonella contamination of produce.

Recirculating farms are different, by their very nature, than other forms of field soil-based agriculture. Nevertheless, the DEIS completely fails to recognize the differences between soil and water based agriculture in its environmental impact assessment of the proposed agricultural water rule. By failing to incorporate these differences into the overall framework of the DEIS, it is deficient in meeting its legal requirements of NEPA, which mandate a full environmental review of the potential impacts of the Produce Rule.

RFC recognizes that little data that quantifies the social, environmental and economic impact of recirculating farms within the United States. Our organization is currently working to compile a map of the many recirculating farms throughout the country, and would be willing to share our research should it be helpful to the FDA to fulfill its NEPA obligations.

Nevertheless, RFC suggests that the finalization of the FDA's EIS must incorporate recirculating farming into its understanding of agricultural production in the United States. Excluding these operations creates and flawed assessment of the Produce Rule's potential environmental impacts.

B. The DEIS' assessment of the produce rule's "agricultural water" provision should specifically exclude aquaponic and hydroponic systems.

First, water containing fish waste fertilizer is not intended or likely to come into contact with the harvestable portion of the plants. Second, fish waste does not contain E. Coli, and therefore the microbial testing proposed by FDA is inapplicable to water used in aquaponic systems.

The water used to irrigate the plant roots in aquaponic and hydroponic systems does not fall within FDA's definition of "agricultural water." FDA defines "agricultural water" as "water that is intended to, or likely to, contact the harvestable portion of covered produce" or food contact surfaces, including water used in growing activities and in harvesting, packing, and holding activities.[26] FDA's guidance indicates that agricultural water is intended to encompass water used for overhead spray irrigation but not water

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[25] *See e.g. Leafy Greens Safety Initiative Continues* (2nd Year), FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/Food/FoodborneIllnessContaminants/BuyStoreServeSafeFood/ucm115898.htm (last modified 2013) (last accessed Mar. 13, 2015); *see also* R.V. Tauxe, supra note 11, at S19 (explaining that salad greens, lettuce, sprouts, and melons were the types of produce most often associated with norovirus, Salmonella, and E. coli
O157:H7)

[26] *See* 78 Fed. Reg. at 3630 (proposed 21 C.F.R. § 112.3(c)).

used for root irrigation.[27] In fact, FDA states that "indirect water application methods would not be subject" to the Produce Rule.[28]

Aquaponic and hydroponic systems are designed such that the nutrient-rich water targets only the roots of the plants and not the edible portions of the produce. In addition, water containing fish and fish waste is never used for washing or cooling harvested produce in these systems. Instead, a large number of aquaponic and hydroponic farmers use water from Public Water Systems, as defined under the Safe Drinking Water Act regulations, 40 CFR Part 141, to spray on and wash produce after harvest. FDA has provided an exemption to the agricultural water testing requirements for use of public drinking water supplies.[29] For these reasons, water used in aquaponics or hydroponics is not "agricultural water."

Additionally, FDA has proposed to require regular microbial testing for generic E. coli of all agricultural waters at a frequency that reflects the risk of contamination.[30] FDA has concluded that generic E. coli is the best microbial indicator of water quality for the purpose of pathogen testing of agricultural water. As established in above, E. coli and human pathogens are unlikely to be present in water circulated through aquaponic and hydroponic systems. Because it is highly unlikely that water circulated through aquaponic and hydroponic systems would be contaminated with E. Coli, there is not any science-based or risk-based justification for applying the Agricultural Water Standards to aquaponic or hydroponic recirculating farming.

However, the DEIS does not acknowledge the differences amongst soil and water based growing when it assesses the affected environment, environmental impacts, cumulative impacts, and potential irretrievable and irreversible impacts of the agricultural water provision. RFC suggests the final EIS **specifically state that its analysis of the environmental impact from the Produce Rule's agricultural water provision excludes water based growing operations because these operations do not fall under the agricultural water provision.**

C. Recirculating farms should not be subject to the Biological Soil Amendments.

The amendments for the Produce Rule, Subpart F – Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste ("Soil Standards") do not contemplate the nature of aquaponic or hydroponic farming and, as written, is inapplicable to recirculating farming systems. RFC requests that final EIS specifically recognize that its environmental assessment of the Produce Rule's Soil Standard Provision does not include aquaponic and hydroponic systems.

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[27] *See id.* at 3563. FDA explains that "water used for drip or furrow irrigation in apple orchards would not be considered agricultural water because the water is unlikely to contact the harvestable portion of the crop." *Id.* Drip or furrow irrigation used in apple orchards involves application of water to the root zones only.
[28] *Id.*
[29] *See* 78 Fed. Reg. at 3570 (proposed 21 C.F.R. § 112.45).
[30] *Id.* at 3560 (proposed 21 C.F.R. § 112.45(a)).

It seems that FDA did not intend to regulate aquaponic and hydroponic farming via the Soil Standards. FDA defines "soil amendment" as "any chemical, biological, or physical material (such as elemental fertilizers, humus, manure, non-fecal animal products, peat moss, perlite, pre-consumer vegetative waste, agricultural tea and yard trimmings) intentionally added to the soil [emphasis added] to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water."[31]

Aquaponic and hydroponic systems do not utilize soil at all and therefore should be specifically exempted from the proposed regulations. While the Soil Amendments would not apply to aquaponic and hydroponic growing methods, we request that the final EIS be extremely clear by stating aquaponics and hydroponics are exempted from the Soil Standards, and therefore not subject to environmental review under NEPA.

IV. Conclusion

The Recirculating Farms Coalition and its members share FDA's goal in making informed environmental decisions in its effort to minimize instances of foodborne illness related to the growing, harvesting, packing, and holding of produce.

For the reasons set forth above, we respectfully request that FDA to develop a more robust EIS before finalization that addresses the produce rule's environmental impact on urban environments, urban agriculture operations and recirculating farms.

We appreciate your review of our comments and look forward to working with FDA in promoting a safe, sustainable food production system in the U.S.

Sincerely,

Marianne Cufone, Executive Director
Emily Posner, Policy and Legislative Counsel

[31] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3504, 3548 (Jan. 6, 2013) (proposed for codification at 21 C.F.R. pts. 16 and 112).