National Sustainable Agriculture Coalition

April 18, 2014

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Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

Docket No. FDA-2011-N-0921
RIN 0910-AG35

Submitted electronically via http://www.regulations.gov

Re: Supplemental Comments on the Scoping Process for the Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

On behalf of the represented member organizations[1] of the National Sustainable Agriculture Coalition (NSAC), we submit the following supplemental comments on the scoping process for the Environmental Impact Statement (EIS) for the proposed rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. NSAC submitted initial comments on the scoping process on November 15, 2013, and we welcome the opportunity to submit supplemental comments.

NSAC's work on the EIS process occurs through a subcommittee of NSAC members. The NSAC members that contributed to these comments include Jo Ann Baumgartner of Wild Farm Alliance, Roger Noonan of New England Farmers Union, Dave Runsten and Daniel Cohen of Community Alliance with Family Farmers, and Patricia Stansbury of Virginia Association for Biological Farming. NSAC partners Mindy Goldstein and Jordan Hansbrough from the Turner Environmental Law Clinic at Emory University School of Law contributed significantly to these comments.

[1] Agriculture and Land-Based Training Association - Salinas, CA; Alternative Energy Resources Organization - Helena, MT; California Certified Organic Farmers - Santa Cruz, CA; California FarmLink - Santa Cruz, CA; C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture) - Hereford, TX; Center for Rural Affairs - Lyons, NE; Clagett Farm/Chesapeake Bay Foundation - Upper Marlboro, MD; Community Alliance with Family Farmers - Davis, CA; Dakota Rural Action - Brookings, SD; Delta Land and Community, Inc. - Almyra, AR; Ecological Farming Association -Soquel, CA; Farmer-Veteran Coalition - Davis, CA; Fay-Penn Economic Development Council - Lemont Furnace, PA; Flats Mentor Farm - Lancaster, MA; Florida Organic Growers - Gainesville, FL; GrassWorks - New Holstein, WI; Hmong National Development, Inc. - St. Paul, MN and Washington, DC; Illinois Stewardship Alliance - Springfield, IL; Institute for Agriculture and Trade Policy - Minneapolis, MN; Iowa Natural Heritage Foundation - Des Moines, IA; Izaak Walton League of America - St. Paul, MN/Gaithersburg, MD; Kansas Rural Center - Whiting, KS; The Kerr Center for Sustainable Agriculture - Poteau, OK; Land Stewardship Project - Minneapolis, MN; Michael Fields Agricultural Institute - East Troy, WI; Michigan Food & Farming Systems (MIFFS) - East Lansing, MI; Michigan Organic Food and Farm Alliance - Lansing, MI; Midwest Organic and Sustainable Education Service - Spring Valley, WI; National Catholic Rural Life Conference - Des Moines, IA; The National Center for Appropriate Technology - Butte, MT; Nebraska Sustainable Agriculture Society - Ceresco, NE; Northeast Organic Dairy Producers Alliance -Deerfield, MA; Northern Plains Sustainable Agriculture Society - LaMoure, ND; Northwest Center for Alternatives to Pesticides - Eugene, OR; Ohio Ecological Food & Farm Association - Columbus, OH; Organic Farming Research Foundation - Santa Cruz, CA; Rural Advancement Foundation International – USA - Pittsboro, NC; Union of Concerned Scientists Food and Environment Program - Cambridge, MA; Virginia Association for Biological Farming - Lexington, VA; Wild Farm Alliance -Watsonville, CA.

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NSAC looks forward to continuing to work with the Food and Drug Administration to ensure that the Food Safety Modernization Act regulations and their implementation are successful and supportive of sustainable agriculture and food systems.

Sincerely,

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Supplemental Scoping Comments

on

FDA Produce Rule

Submitted by

National Sustainable Agriculture Coaltion

Docket No. FDA-2011-N-0921
RIN 0910-AG35

April 18, 2014

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SUPPLEMENTAL SCOPING COMMENTS ON FDA'S PRODUCE RULE ENVIRONMENTAL IMPACT STATEMENT
Docket No. FDA-2011-N-0921
RIN 0910-AG35

Submitted on April 18, 2014

The National Sustainable Agriculture Coalition (NSAC) – an alliance of grassroots organizations that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities – submits these supplemental comments regarding the scope of the Environmental Impact Statement (EIS) for the Food and Drug Administration's (FDA) proposed rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the Produce Rule).[1] On November 15, 2013, NSAC submitted comments on the scope of the Produce Rule EIS (Initial Scoping Comments)[2] and comments on the Produce Rule itself (Rulemaking Comments),[3] both of which are incorporated herein by reference. The comments below supplement the Initial Scoping Comments and Rulemaking Comments, and primarily address the proposed actions and alternatives set forth in FDA's recent scoping notice published in the Federal Register on March 11, 2014 (FR Notice).[4]

I. Background

President Obama signed the Food Safety Modernization Act (FSMA) on January 4, 2011 to help ensure the safety and security of the United States' food supply.[5] On January 16, 2013, FDA published the Produce Rule as part of the implementation of FSMA's requirements to regulate the production of produce.[6] Seven months after publication of the proposed Produce Rule, on August 19, 2013, FDA determined that its implementation may significantly affect the quality of the human environment, and accordingly filed a notice of intent to prepare an EIS (the

[1] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3,504 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. pts. 16, 112) (Produce Rule). The docket number for the Produce Rule is FDA-2011-N-0921 and the Regulatory Information Number (RIN) is 0910-AG35.
[2] NSAC, *Scoping Notice Comments on FDA Produce Rule*, submitted in Docket No. FDA-2011-N-0921, RIN 0910-AG35, on Nov. 15, 2013 (Initial Scoping Comments).
[3] NSAC, *Comments on the Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, submitted in Docket No. FDA-2011-N-0921, RIN 0910-AG35, on Nov. 15, 2013 (Rulemaking Comments).
[4] Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption; Public Meeting on Scoping of EIS and Extension of Comment Period for EIS, 79 Fed. Reg. 13,593 (March 11, 2014) (FR Notice).
[5] 21 U.S.C.A. §350h (2013).
[6] 78 Fed. Reg. 3,504.

Scoping Notice) pursuant to the National Environmental Policy Act (NEPA).[7] Unfortunately, this Scoping Notice provided very little information about the EIS.

On September 14, 2013, NSAC filed a letter with FDA, requesting the agency withdraw the Scoping Notice and republish a more complete one.[8] FDA did not respond to this request. Thus, notwithstanding the deficiencies in the Scoping Notice, on November 15, 2013, NSAC filed its Initial Scoping Comments on the Produce Rule EIS. At the same time, NSAC also filed its Rulemaking Comments on the Produce Rule itself. Shortly thereafter, the deadline for submitting scoping comments on the EIS was extended until March 15, 2014.[9]

Then, on December 19, 2013, Michael R. Taylor, FDA's Deputy Commissioner for Foods and Veterinary Medicine, announced the agency's plan to make "significant changes" to the proposed Produce Rule. As part of these changes, FDA committed to revising "sections covering water quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities (such as a farm that has a food-processing operation), and procedures used to withdraw the qualified exemption to these requirements for certain farms."[10] According to Mr. Taylor, FDA will publish the revisions to the Produce Rule in the Federal Register for public comment by early summer 2014.

On March 4, 2014, NSAC, along with several other parties, sent a letter to Margaret A. Hamburg, Commissioner of the FDA, requesting that the deadline for submitting scoping comments be extended to a minimum of 60 days *after* the date FDA issues the revisions to the Produce Rule.[11]

FDA then published the FR Notice on March 11, 2014, only extending the deadline for the current public comment period on scoping to April 18, 2014.[12] The FR Notice did, however, correct certain deficiencies in the original Scoping Notice that NSAC first brought to FDA's attention in its September 14, 2013 letter. And, for the first time, the FR Notice listed the scope of significant issues and potential alternatives of the Produce Rule that FDA may consider in the EIS. NSAC's detailed comments regarding these issues and alternatives are set forth in Sections III and IV below.

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[7] Notice of Intent to Prepare an EIS for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 50,358 (Aug. 19, 2013).
[8] Letter from Mindy Goldstein and Helen Jubran to Leslie Kux, Docket ID No. FDA-2011-N-0921-0216 (Sept. 4, 2013).
[9] 78 Fed Reg. 69,006 (Nov. 18, 2013).
[10] Michael Taylor, *Your Input is Bringing Change to Food Safety Rules*, FDA VOICE (Dec. 19, 2013), http://blogs.fda.gov/fdavoice/index/php/2013/12/your-input-is-bringing-change-to-food-safety-rules/
[11] Letter from NSAC and several other parties to Commissioner Hamburg, Request for Extension of Time for Comments, FDA Food Safety Modernization Act Proposed Rules, Docket No. FDA-2011-N-0921-0321, RIN 0190-AG35 (Mar. 4, 2014).
[12] 79 Fed. Reg. 13,593 (Mar. 11, 2014).

II. FDA May Need to Rescope after Publication of the Revisions to the Rule

In our March 4, 2014 letter to FDA discussed in Section I above, NSAC and other parties asked the agency to extend the scoping comment deadline until after the revisions to the Produce Rule are published. As stated in that letter:

> A comment extension is necessary because FDA announced it is revising significant portions of the proposed [Produce Rule]. Comments submitted before the proposed rule is revised can neither sufficiently, nor reasonably, alert FDA to those issues that it needs to address in its environmental review. As a result, the public will not have the required meaningful opportunity to comment on the EIS scoping process.

NSAC once again respectfully requests that FDA extend the scoping comment deadline to a minimum of 60 days after the revisions to the Produce Rule are released in order to afford the public a meaningful opportunity to comment on the scope of the environmental impact of the Produce Rule, as revised. In the FR Notice, FDA states that, "this EIS process is required under NEPA and is distinct from and in addition to the process FDA has announced to revise parts of the [Produce Rule]."[13] We disagree. The EIS process and rulemaking process are interrelated and codependent. Indeed, the primary purpose of the EIS process is to determine the relevant issues and alternatives related to the proposed action.[14] Without understanding the provisions of the Produce Rule, it is nearly impossible to formulate relevant comments on the rule's environmental impacts. As a matter of law and logic, the revisions to the Produce Rule should be released before requiring submission of scoping comments.

With that said, we understand the need for FDA to move forward under tight, court-ordered deadlines. These deadlines, of course, do not excuse the agency from adhering to the NEPA process. In accordance with that process, NSAC has prepared its comments concerning the proposed action and alternatives addressed in the FR Notice. The comments touch upon multiple issues we believe FDA must consider in the EIS, two of which are in sections of the rule that FDA has explicitly committed to revise – microbial standards for agricultural water and minimum application intervals for biological soil amendments of animal origin. Additionally, FDA may also change the definition of "farm" and the supporting definition of "facility" in the revisions to the rule, which will affect the number of farms covered by the rule and the overall magnitude of the rule's environmental impacts.[15] If the revisions to the Produce Rule fall outside of the proposed actions and alternatives set forth in the FR Notice, NSAC requests that FDA "rescope" after publication of the revisions.[16] Regardless of external deadlines for finalizing the Produce Rule, this is what NEPA demands.

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[13] *See* 79 Fed. Reg. 13,594 (Mar. 11, 2014).
[14] 40 C.F.R. § 1501.7.
[15] *See Rulemaking Comments*, *supra* note 3, at 27–44.
[16] 40 C.F.R. § 1501.7(c).

III. FDA Must Address Certain Issues Not Set Forth in the FR Notice

On November 15, 2013, NSAC submitted its Initial Scoping Comments and Rulemaking Comments. As stated in those comments, when a federal agency proposes regulations that will "significantly affect the quality of the human environment," NEPA requires the agency to consider all of the environmental impacts in an EIS.[17] Pursuant to NEPA, FDA must therefore take a hard look at the direct, indirect, and cumulative impacts to the environment of the Produce Rule.[18] Additionally, FDA must consider all reasonable alternatives to the rule as proposed, including the no-action alternative.[19]

FDA concedes that the FR Notice was not intended to provide a comprehensive list of actions and alternatives that it will consider in its EIS, and invited comments on other issues it should consider for in-depth analysis.[20] Thus, while the agency identified a number of issues that may impact the environment, NSAC has identified several additional issues below. Most of these were also discussed in NSAC's Initial Scoping Comments and Rulemaking Comments. We do not intend to restate everything set forth in those comments, but instead incorporate them herein by reference.

A. FDA Must Consider Impacts Created by the Preference for Use of Municipal Water and Public Supplies

The Produce Rule creates a preference for farmers to use municipal water and public water supplies because it exempts the use of water from these sources from burdensome testing and chemical treatment requirements.[21] However, the FR Notice does not consider the impacts created by this preference. Instead, it speaks only of: (1) impacts created by the preference for use of groundwater, and (2) impacts from the chemical treatment of surface water.[22] As NSAC explained in our Initial Scoping Comments, preference for use of municipal water and public water supplies causes impacts to water and animals.[23] FDA must take a hard look at these impacts in the Produce Rule EIS.

B. FDA Must Consider Impacts Created by the Preference for Domesticated Animal Confinement

The Produce Rule creates a preference for animal confinement because it places restrictions on animal grazing in produce fields and animal contact with agricultural water

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[17] National Environmental Policy Act of 1969, 42 U.S.C. § 4321 *et seq.* (1970).
[18] *Initial Scoping Comments*, *supra* note 2, at 8; 40 C.F.R. § 1508.25; 42 U.S.C.A. § 4332(C)(i); *Robertson v. Method Valley Citizens Council*, 490 U.S. 332, 350 (1989)(requiring agencies to take a "hard look" at environmental consequences in its EIS) (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21 (1976)).
[19] 40 C.F.R. § 1508.25.
[20] *See* 79 Fed. Reg. 13,595 (Mar. 11, 2014).
[21] *Initial Scoping Comments*, *supra* note 2, at 11.
[22] *FR Notice*, *supra* note 4, at 13594.
[23] *Initial Scoping* Comments, supra note 2, at 11–12.

sources, leading to the increased use of concentrated animal feeding operations (CAFOs).[24] Although the FR Notice discusses the issue of and alternatives to measures related to animal grazing and animal intrusion, there is no mention of CAFOs.[25] As NSAC explained in our Initial Scoping Comments, preference for animal confinement in CAFOs causes impacts to water, land, air, animals, and human health.[26] FDA must take a hard look at all of these impacts in the forthcoming EIS.

C. FDA Must Consider Impacts Created by Increased Use of Conventional Farming Methods

The Produce Rule's biological soil amendment standards, in aggregate, create a preference for farmers to grow produce using conventional methods, as opposed to using more sustainable or organic growing methods.[27] In our Initial Scoping Comments and Rulemaking Comments, we laid out how the Produce Rule's preference for conventional growing methods causes impacts to water, land, air, animals, and human health.[28] Surprisingly, the FR Notice fails to acknowledge that a shift from sustainable to conventional farming practices is likely. FDA must take a hard look at all of the impacts resulting from an increase in conventional growing methods (and a corresponding decrease in sustainable growing methods) in the forthcoming EIS.

D. FDA Must Consider Cumulative Impacts

Although the FR Notice addresses the impacts of several individual provisions of the Produce Rule that FDA intends to consider in the EIS, it fails to account for the wide-ranging cumulative impacts of these provisions. As we set forth in our Initial Scoping Comments and Rulemaking Comments, FDA must address these cumulative impacts in the Produce Rule EIS in order to comply with NEPA.[29]

First, FDA must take a hard look at the impacts of all the provisions of the Produce Rule, taken together.[30] The preferences created by these provisions will likely affect growing practices at farms of all sizes, and implementation of the Produce Rule may result in the closing of both small and large farms across the country, while simultaneously discouraging the entry of new farmers into production.[31] The impacts caused by this change in the farming landscape must be considered in the Produce Rule EIS.[32]

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[24] *Id.* at 25–26 *Rulemaking Comments*, *supra* note 3, at 98-100.
[25] *FR Notice*, *supra* note 4, at 13594–95.
[26] *Initial Scoping Comments*, *supra* note 2, at 25–28.
[27] *Id.* at 21–24; *See also Rulemaking Comments*, *supra* note 3, at 69–90 (for a detailed explanation of the Produce Rule's conflicts with soil amendment practices of organic methods), and 94–99 (for further explanation of the Produce Rule's conflicts with the conservation practices of organic production).
[28] *See Initial Scoping Comments*, *supra* note 2, at 21–24.
[29] 40 C.F.R. §§ 1508.7, 1508.25.
[30] *Initial Scoping Comments*, *supra* note 2, at 33.
[31] Although the rule impacts both small and large farms, in the FR Notice FDA only considers impacts of and alternatives to the rule for the smallest of farms (i.e., those eligible for the *de*

Second, FDA must take a hard look at the impacts of the Produce Rule to the environment, together with impacts to water, land, air, animals, and human health caused by other agencies' actions, FDA's other pending actions, and the actions of private individuals.[33] In conducting this analysis, FDA should specifically consider the cumulative impacts caused by the concurrent implementation of the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Foods Rule (Preventive Controls Rule)[34] and the Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.[35] Taken together, these three regulations could force numerous farms to close, leading to the loss of farmland and decreased access to fresh produce.[36] FDA must consider these consequences in its EIS.

And finally, FDA should consider the cumulative environmental impacts of foreign farms complying with the Produce Rule.[37]

The Council on Environmental Quality, the entity tasked with ensuring that federal agencies comply with NEPA, states in its handbook addressing cumulative impacts analyses that "the most devastating environmental effects may result not from the direct effects of a particular action, but from the combination of individually minor effects of multiple actions over time."[38] In light of this warning, FDA's consideration of the cumulative impacts is all the more

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minimus $25,000 exemption as proposed in the Produce Rule). *See FR Notice*, *supra* note 4, at 13595. Thus, this consideration is only in relation to those farms that should be entirely exempt from the Produce Rule. *Id.* The FR Notice fails to account for impacts to qualified exempt farms, mid-sized farms, and large farms that are not, and should not, be exempt from the rule.

[32] *Initial Scoping Comments*, *supra* note 2, at 33.

[33] *Id.* These include impacts of the Produce Rule, together with: impacts caused by pollution from point and nonpoint sources; impacts to 303(d) impaired waters; impacts to contaminated sites; impacts caused by groundwater depletion; impacts caused by climate change; and impacts to endangered species.

[34] *Id* at 33–34; *see also* Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3,646–01 (proposed Jan. 16, 2013) (to be codified at 21 CFR pts. 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211).

[35] *See* NSAC, *Comments on the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food and Animals*, submitted in Docket No. FDA-20110N-0922, on March 31, 2014.

[36] Of course, any change in the definition of "farm" and the supporting definitions of "facility" in in either the Produce Rule or the Preventive Controls Rule could change the magnitude of these cumulative impacts and the number of farms that would be forced to close.

[37] *See Initial Scoping Comments*, *supra* note 2, at 33–34.

[38] Council on Environmental Quality, Considering Cumulative Effects Under the National Environmental Policy Act at 1 (Jan. 1997), http://energy.gov/sites/prod/files/nepapub/nepa_documents/RedDont/G-CEQ-ConsidCumulEffects.pdf.

important. NEPA requires a complete and in-depth consideration of the full range of consequences of implementation of the Produce Rule.[39]

E. FDA Must Consider Environmental Justice and Tribal Impacts

The Produce Rule's exacting provisions, in aggregate, may have a disproportionate impact on minority, Tribal, low-income, socially disadvantaged, and historically underserved farmers. These farmers, more than others, may not be able to bear the costs associated with Produce Rule compliance,[40] and they could be forced to shut down their farms. NEPA requires FDA to consider the environmental justice and Tribal impacts associated with the closing of these farms.[41]

Moreover, the closing of these farms, together with other farms across the country, will reduce the availability of fresh produce to consumers, especially those with low income and senior citizens, and those who live in historically underserved areas (e.g. food deserts). As we stated in our Initial Scoping Comments, these impacts must also be considered.[42]

IV. FDA Must Address the Impacts of the Proposed Actions and Alternatives Set Forth in the FR Notice

While failing to discuss the issues listed above, the FR Notice does account for four provisions of the Produce Rule that may significantly affect the quality of the environment and sets forth several alternatives to each of these provisions. NEPA requires FDA to take a hard look at the impact of these provisions and alternatives.

NSAC's comments on many of the impacts and alternatives were previously discussed in NSAC's Initial Scoping Comments and Rulemaking Comments. We do not intend to restate everything set forth in those comments, but instead incorporate them herein by reference.

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[39] *Id.* at 3.

[40] These costs include, but are not limited to: (1) costs associated with the purchase of chemicals to treat surface water, or the purchase of expensive groundwater and municipal water, (2) costs associated with the purchase of synthetic fertilizers, (3) costs associated with administering inspection, monitoring, and testing requirements related to water and biological soil amendments, and (4) costs associated with relocating farms. Each of these is discussed in more detail throughout these supplemental comments.

[41] For consideration of environmental justice impacts, *see generally* Exec. Order No. 12898, 59 Fed. Reg. 7629 (1994) and CEQ Guidance Document on Environmental Justice under NEPA (1997) (http://ceq.hss.doe.gov/nepa/regs/ej/justice.pdf). For consideration of Tribal impacts, *see generally* 40 C.F.R. § 1508.8 (providing that impacts covered by NEPA include impacts to historic and cultural resources); for consultation requirements, *see* Exec. Order No. 13175, 65 Fed. Reg. 67249 (2000).

[42] *Initial Scoping Comments*, *supra* note 2, at 32.

A. Microbial Standard for Agriculture Water Used During Growing Activities for Covered Produce

The FR Notice provides that the Produce Rule provision addressing microbial standards for agricultural water may significantly affect the environment. We agree. In our Initial Scoping Comments and Rulemaking Comments, we discussed at length how the Produce Rule creates a preference for farmers to chemically treat their water, increase their use of municipal and public water supplies, and increase their use of groundwater supplies.[43] FDA must take a hard look at all of the environmental impacts of these expensive preferences in its EIS, which could force some farms to close.[44]

NSAC understands and appreciates that FDA is revising the microbial standard for agriculture water, and the agency could issue a revised standard that changes the impacts previously mentioned in our comments and set forth below. As currently proposed, however, the rule has significant environmental impacts that must be considered.

i. FDA must consider the impacts of the Produce Rule's microbial water standard on water, land, air, animals, and human health

The proposed microbial standard for agricultural water is unnecessarily stringent and is neither science-based nor risk-based.[45] This standard will force farmers to either chemically treat their water or rely upon limited and expensive municipal and groundwater supplies.[46] FDA must consider the impacts of the proposed microbial water standard on water, land, air, animals, and human health.

Impacts from Preference for Municipal and Public Water Supplies: The FR Notice acknowledges that the Produce Rule could significantly impact the environment by increasing the use of groundwater and increasing chemical treatment of water.[47] As noted in Section III.A above, the FR Notice never acknowledges the possibility that farmers' use of municipal water may also increase under the rule. Preference for municipal and public water supplies creates environmental impacts by placing an increased demand on already-stressed municipal waters, requiring construction of new water treatment facilities, and requiring construction of new water supply reservoirs to accommodate the increased water supply need.[48] FDA must consider all of these impacts in its forthcoming EIS.

Impacts from Preference for Groundwater: As we emphasized in our Initial Scoping Comments and Rulemaking Comments, the Produce Rule likely encourages farmers to use groundwater

[43] *Id.* at 9–13.
[44] These impacts include water, animal and human health impacts created the Produce Rule's preference for chemical water treatment. *See id.*
[45] *See Rulemaking Comments* at 61-68.
[46] *Id.*; *Initial Scoping Comments* at 9-13.
[47] *See FR Notice*, *supra* note 4, at 13594.
[48] *See Initial Scoping Comments*, *supra* note 2, at 11–12.

over surface water.[49] The proposed rule places costly testing and treatment requirements on surface water, which will deter farmers from using it for agricultural purposes. These farmers may be forced to look to groundwater as a replacement. The preference for groundwater will increase reliance on already-strained groundwater resources and will force farmers to relocate farming activities.[50] Additionally, forcing farmers to use groundwater is likely to exacerbate already competing demands for water resources, causing extreme drops in groundwater levels, reductions in stream flow, harm to terrestrial ecosystems, and destruction of wildlife habitat.[51] Competition for groundwater resources may also harm aquatic life.[52] As FDA acknowledges in the FR Notice, it must take a hard look at these impacts to water and animals in its EIS.[53]

Impacts from Preference for Chemical Treatment of Water: As we emphasized in our Initial Scoping Comments and Rulemaking Comments, the Produce Rule likely encourages farmers to use chemically treated water in two ways. First, the proposed rule prohibits farmers from applying water to covered produce containing 235 colony-forming units (CFU) of E. coli per 100 ml.[54] In many parts of the country, surface water cannot meet this criterion without chemical water treatment. Second, the Produce Rule imposes strict inspection, monitoring, modification, and testing requirements on farmers who use untreated surface water.[55] To avoid these requirements, farmers may choose to chemically treat their water. The increase in chemical treatment of water creates environmental impacts because these chemicals (including chlorine) may run off into streams, rivers, or lakes, causing detrimental water, land, air, animal, and human health effects (including health effects caused by the improper or frequent use of those chemicals on food).[56] As FDA acknowledges in the FR Notice, it must take a hard look at these impacts in its EIS.

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[49] *Id*. at 12–13.
[50] *Id.* at 13.
[51] *Id.*
[52] *Id.*
[53] *FR Notice*, *supra* note 4, at 13594.
[54] *See id.* at 9.
[55] *Id.*
[56] *Id.* at 10–11; *see also id.* at n. 56 ("FDA alleges that the Produce Rule's chemical water treatment requirements are dependent on EPA certification, and it may try to rely on this certification process to relieve it of its NEPA duties. Produce Rule, 78 Fed. Reg. 3,504 (§ 112.43(b) ("any chemicals used in the treatment of water would require EPA registration under the [FIFRA] before they can be lawfully used"). Any such reliance would be misplaced. First, no certification for chemical treatment of irrigation water currently exists. *Id.* at 3,566 (§ 112.43(b)). Additionally, and more importantly, encouraging farmers across the United States to use chemical water treatment will likely create substantial direct, indirect, and cumulative effects on water resources. FDA must consider these effects in its EIS now, regardless of what actions EPA may take in the future. Therefore, EPA's registration process under FIFRA simply does not excuse FDA from evaluating the impacts of chemical water treatment on water resources.").

ii. FDA must consider alternatives to the microbial water standard

NEPA also requires FDA to consider all reasonable alternatives to the microbial water standard, and the agency has set forth a list of alternatives in Table 1 of the FR Notice. As we indicated in our Rulemaking Comments, the Produce Rule should contain flexible, science-based water standards that account for major differences in farming practices across the country, including: the risk of E. coli contamination, climate, soil type and conditions, farm location, farming system, and water source.[57] Without a flexible approach that recognizes these differences, FDA may overreach – targeting farming practices that do not cause foodborne illnesses while unnecessarily harming the environment. We have identified the alternatives in the FR Notice which we believe most effectively allow FDA to achieve a targeted balance between protection against foodborne illness and protection of the environment.

FDA comes closest to adopting a science-based, flexible approach in *alternative iv*, listed in Table 1 of the FR Notice in the row designated for "Microbial standard for agricultural water." As stated, the alternative provides "[a] flexible water quality standard that allows for adjustment to a specified microbial quality standard based on mitigation steps that occur after application of agricultural water and prior to consumption."[58] NSAC supports this characterization. There is a problem, however, with the World Health Organization (WHO) standard used as an example.[59] The WHO standard suffers from the same rigidity as the originally proposed standard, and both fail to account for differences in farming practices.[60] This rigidity runs counter to FSMA's mandate that the water standard be flexible.[61]

Instead of using the WHO standard, NSAC suggests that:

- FDA adopt a flexible, reasonable, science- and risk-based approach to the microbial standard for agriculture water (like the standard set forth in the first sentence of *alternative iv*), which might vary according to the region, farming system, or other

[57] *Rulemaking Comments*, *supra* note 3, at 61–68.
[58] *FR Notice, supra* note 4, at 13595.
[59] WHO recommends a minimum microbial quality for water of 1,000 CFU generic E. coli per 100 mL for water used on root crops that are eaten raw, and 10,000 CFU generic E. coli per 100 mL for water used on leaf crops, which is dependent upon a 2-lod reduction due to die-off between last irrigation and consumption (includes die-off in the field and during distribution) and a 1-log reduction attributed to washing prior to consumption. *See id.* at 13595. While NSAC supports the more permissive E. coli limits, as explained above, the WHO standard is impermissibly rigid.
[60] *Rulemaking Comments*, *supra* note 3, at 63–64.
[61] When writing FSMA, Congress strongly rejected a "one-size-fits-all" approach, and provided FDA with flexibility to ensure the Produce Rule worked for a diversity of farms. FSMA emphasizes the importance of using a flexible approach by adding several overarching provisions to § 419 of the Federal Food, Drug, and Cosmetic Act (FD&CA). *See Rulemaking Comments*, *supra* note 3, at 52–53.

variables.[62] This will ensure that the Produce Rule sufficiently accounts for the diversity of farming practices throughout the country.

NSAC also recommends that:

- FDA reject the proposed action (i.e. *alternative ii*) because it is not science-based and does not account for the diversity of farms throughout the country. As we stated in our Rulemaking Comments, this standard is inappropriately based on studies where the type and intensity of exposure to E. coli was far greater and qualitatively different from E. coli exposure resulting from farmers' use of water during crop irrigation.[63] As a result, it is unnecessarily stringent, causing great environmental harm (through increased chemical treatment of water and increased use of groundwater and municipal water supplies) without the correlating public health benefit.

- FDA reject *alternative iii* because it also lacks science-based support and does not account for the diversity of farms throughout the country.[64] Although NSAC commends FDA for relaxing the E. coli standard from the proposed action (i.e. *alternative ii*), this alternative is still unnecessarily rigid.

- Regarding *alternative v*, FDA should adopt a modified alternative that is more flexible than the options provided.[65] Specifically, FDA should identify when the use of drip irrigation in the production of root crops that fit the definition of covered produce increases the risk of microbial pathogen contamination through water. Once those uses are identified (which may be crop-specific), FDA should then develop a strategy to minimize the risk through additional guidance for public comment. In the vast majority of uses, drip irrigation, and specifically buried drip irrigation, should not fall under the definition of "direct water application method." Additionally, many root crops do not fit the definition of covered produce because they are not usually consumed raw. NSAC does recognize, however, that there may be root crops that are covered produce, that are drip irrigated, and that are more likely to come into contact with agricultural water through drip irrigation than other root crops. In those instances, FDA should provide guidance for public comment that seeks to minimize the risk of contamination through agricultural water. NSAC believes that this modification to the alternative will appropriately narrow the proposed alternative to focus on uses that increase risk of contamination without causing unnecessary burden to farmers or harm to the environment.

[62] *See Rulemaking Comments*, *supra* note 3, at 61–66. Specifically, see NSAC's Recommendations 1-5, set forth on page 66 of the *Rulemaking Comments*.
[63] *Rulemaking Comments*, *supra* note 3, at 62–63.
[64] *See FR Notice*, *supra* note 4, at 13595.
[65] *See id.*

B. Minimum Application Intervals for Biological Soil Amendments of Animal Origin

In our Initial Scoping Comments and Rulemaking Comments, we discussed how the Produce Rule creates a preference for treating biological soil amendments of animal origin (as opposed to leaving the soil amendments untreated) due to the additional requirements imposed upon such soil amendments.[66] These additional requirements include restrictions on handling, conveying, storing, application intervals, and method of application. Indeed, the requirements greatly restrict the use of raw manure and composting altogether. The soil amendment provisions, in aggregate, also create a preference for farmers to grow produce using conventional growing methods.[67] And they create a preference for the use of synthetic fertilizers.[68] In the FR Notice, FDA acknowledges some of these preferences. Pursuant to NEPA, FDA must take a hard look at all of the environmental impacts of the biological soil amendment provisions.

NSAC understands and appreciates that FDA is revising the biological soil amendment standards, and the agency could issue revisions to the rule that change the impacts previously mentioned in our comments and set forth below. As currently proposed, however, the rule has significant environmental impacts that must be considered.

i. FDA must consider the impacts of the Produce Rule's minimum application intervals for biological soil amendments of animal origin on water, land, air, animals, and human health

In the FR Notice, FDA acknowledges that the biological soil amendment requirements in the Produce Rule "are expected to result in changes in the current use of treated and untreated biological soils amendments of animal origin or potentially greater use of synthetic fertilizers." And that, "changes in the type or handling of soil amendments, in response to the minimum application intervals, may significantly affect the quality of the human environment." NSAC agrees, and – as we stated in our Initial Scoping Comments and Rulemaking Comments – FDA must take a hard look at the impacts to water, land, air, animals, and human health created by these requirements.[69]

As noted in Section III.C above, the FR Notice fails to account for the fact that the soil amendment requirements of the Produce Rule, in aggregate, also create a preference for farmers to grow produce using conventional methods, as opposed to using more sustainable methods.[70] Specifically, the soil amendment preferences conflict with farmers' ability to grow produce

[66] *See Initial Scoping Comments*, *supra* note 2, at 13–24; *See also Rulemaking Comments*, *supra* note 3, at 69–90.
[67] *Id.* at 18-24.
[68] *Id*. *at* 13-17.
[69] *Id.* at 13-24; *Rulemaking Comments*, *supra* note 3, at 69–90.
[70] *Initial Scoping Comments*, *supra* note 2, at 21–24.

according to USDA National Organic Program (NOP) regulations.[71] FDA must consider the significant environmental impacts to water, land, air, animals, and human health caused by this preference for conventional growing methods.

ii. FDA must consider alternatives to the minimum application intervals for biological soil amendments

As set forth above, NEPA requires FDA to consider all reasonable alternatives to the proposed rule's minimum application intervals for biological soil amendments of animal origin. FDA has set forth a list of these alternatives in Table 1 of the FR Notice. NSAC understands that FDA is currently revising the minimum application intervals for biological soil amendments of animal origin, and after revision the list of relevant alternatives may change. But, for now, NSAC has identified the alternatives in the FR Notice which it believes most effectively allow FDA to reduce foodborne illnesses while avoiding or minimizing harmful impacts to the environment.

As we indicated in our Initial Scoping Comments and Rulemaking Comments, FDA should amend the Produce Rule's provisions regarding biological soil amendments to avoid conflict with NOP regulations. Conflict with NOP regulations may result in increased use of synthetic fertilizers and a decrease in sustainable farming practices – unnecessarily harming the environment without increasing protection in public health.

Thus, with regard to the alternatives listed in part A of "Proposed action 2," set forth in Table 1 of the FR Notice in the row designated "Minimum application intervals for biological soil amendments of animal origin," NSAC recommends:

- FDA adopt a combination of *alternative iii* and *alternative iv*, with some revision. As stated in the FR Notice, *alternative iii* provides for no application interval. *Alternative iv* provides "U.S. Department of Agriculture's National Organic Program (USDA/NOP) application intervals for the use of raw manure as a soil amendment, i.e., 90 days or 120 days before harvest, depending on whether or not the edible portion of the crop has direct contact with the soil (as specified in 7 CFR 205.203(c)(1))."[72] NSAC respectfully recommends that the alternatives be combined and revised to provide, "Minimum application intervals that *do not exceed* USDA/NOP application intervals for the use of raw manure as a soil amendment, i.e., 120 days before harvest if the edible portion of the crop has been in direct contact with the soil. An application interval of 0 days is appropriate if the edible portion has not been in direct contact with the soil."[73] This allows for adherence with NOP regulations for certified organic farmers, without requiring a 90-day interval for non-organic farmers who apply biological soil amendments of

[71] *Id*. at 21–23. Moreover, even on non-organic farms, farmers regularly use manure to fertilize their fields. The biological soil amendment requirements could therefore change practices at both organic and conventional farms, increasing the magnitude of environmental harm.
[72] *FR Notice*, *supra* note 4, at 13595.
[73] *See Rulemaking Comments*, *supra* note 3, at 85.

animal origin to covered produce that does not come into direct contact with the soil. This accommodates different types of production systems, without overreaching and imposing additional intervals for produce that is not certified organic and that does not come into contact with the soil and, therefore, soil amendments. Intervals for produce that does not contact the soil may cause unnecessary environmental harm without reducing the risk of foodborne illness.

Regarding part B of "Proposed action 2," set forth in Table 1 of the FR Notice in the row designated "Minimum application intervals for biological soil amendments of animal origin," NSAC recommends:

- FDA adopt *alternative iii*, which does not require an interval between the application of a biological soil amendment of animal origin that is treated by a composting process to covered produce. As explained in more detail in our Rulemaking Comments, FDA has failed to provide a scientific basis for the 45-day application interval set forth in the proposed rule (and *alternative ii*).[74] Unnecessarily restrictive interval standards may encourage the increased use of synthetic fertilizers and discourage sustainable growing practices, causing negative environmental and human health impacts. Given the lack of scientific support for application intervals and the harmful effect of such intervals, a standard that requires no application interval (i.e. *alternative iii*) should be adopted.

C. Measures Related to Animal Grazing and Animal Intrusion

In our Initial Scoping Comments and Rulemaking Comments, we discussed how the Produce Rule creates a preference for animal confinement by placing restrictions on animal grazing in produce fields and animal contact with agricultural water sources.[75] If animals are allowed to graze in produce fields and there is a reasonable probability that grazing will contaminate the produce, the Produce Rule requires farmers to use an adequate waiting period between grazing and harvest.[76] This requirement will likely pressure farmers to prevent (or at least reduce) farm animals from grazing. It will also compel farmers to find alternative ways to feed animals, including feeding these animals in CAFOs.[77] Additionally, the proposed rule requires farmers to keep all agricultural water sources free from contact with animals, and

[74] *Id.* at 69–82.
[75] *Initial Scoping Comments, supra* note 2, at 25-28; *Rulemaking Comments*, *supra* note 3, at 98-100.
[76] In the preamble of the proposed Produce Rule, FDA provides this adequate waiting period should not exceed nine months, which is the application interval proposed for use of raw manure as a soil amendment. *Initial Scoping Comments*, *supra* note 2, at 25–26. Therefore, FDA implies feces left from grazing domestic animals is of similar risk as manure applications, without providing scientific basis to support this conclusion. *See Rulemaking Comments*, *supra* note 3, at 99–102.
[77] *Initial Scoping Comments*, *supra* note 2, at 25-28.

farmers may confine animals to reduce the likelihood of such contact.[78] Pursuant to NEPA, FDA must take a hard look at all of the environmental impacts of the preference for animal confinement created by the Produce Rule's provisions related to animal grazing, including harm caused by the increased use of CAFOs.

In our previous comments, we also discussed how the Produce Rule creates a preference for farmers to exclude wild animals from outdoor growing areas (because farmers may be unable to harvest produce after wild animal intrusion) and fails to protect conservation practices.[79] The proposed rule requires farmers to monitor areas for animal intrusion and if intrusion occurs, evaluate whether produce can be harvested.[80] Because of these animal monitoring requirements, farmers are likely to take actions to prevent animal intrusion altogether, including destroying habitat and clearing farm borders.[81] Additionally, farmers experiencing significant intrusion of wild animals may take control measures that exclude or destroy all animals and their habitat, instead of excluding only those animals causing harm.[82] Pursuant to NEPA, FDA must take a hard look at all of the environmental impacts created by the Produce Rule's provisions related to wild animal intrusion.

i. FDA must consider the impacts of the Produce Rule's measures related to animal grazing and animal intrusion on water, land, air, animals, and human health

In the FR Notice, FDA acknowledges that the measures related to animal grazing and animal intrusion in the Produce Rule "could potentially result in changes in current practices that would not be consistent with wildlife conservation practices and thus, may adversely affect wildlife including endangered and threatened species."[83] NSAC agrees, and – as we stated in our Initial Scoping Comments and Rulemaking Comments – FDA must take a hard look at the impacts related to water, land, air, animals, and human health created by these requirements.[84]

As noted in Section III.B above, the FR Notice fails to account for the fact that the Produce Rule creates a preference for animal confinement, which also harms the environment by leading to the increased use of CAFOs. Confined animals living in CAFOs produce a large amount of concentrated waste, which in turn contaminates and degrades water resources, such as groundwater and surface water.[85] CAFOs also create air pollution impacts due to toxic releases of methane emissions, hydrogen sulfide, ammonia, and pathogen-laden dust.[86] Soil located near

[78] *Id.* at 25–26.
[79] *Id*. at 28-32; *Rulemaking Comments*, *supra* note 3, at 97-102.
[80] *Initial Scoping Comments*, *supra* note 2, at 28.
[81] Additionally, these measures are likely to conflict with conservation efforts and the USDA Natural Resource Conservation Service's (NRCS) Conservation Practice Standards. *Initial Scoping Comments*, *supra* note 2, at 28–29.
[82] *Id*.
[83] *FR Notice*, *supra* note 4, at 13595.
[84] *Initial Scoping Comments*, *supra* note 2, at 25-32.
[85] *Id.* at 26.
[86] *Id.* at 27.

CAFOs is likely to become contaminated by chemicals and pathogens.[87] Animals living in CAFOs are more likely to suffer from diseases compared to animals allowed to graze.[88] Moreover, CAFOs can lead to severe human health impacts, including respiratory problems and lung disease in farmers who inhale CAFO odors, as well as heart disease and diabetes in people who consume CAFO-raised meat.[89] Each of these impacts must be considered in the Produce Rule EIS.

In addition, if animals are confined, farms cannot benefit from an integrated biological system. The FR Notice also fails to consider the impacts that would result if animals are forced to remain separate from crops. FDA must consider these impacts.

ii. FDA must consider alternatives to the measures related to animal grazing and animal intrusion

As set forth above, NEPA requires FDA to consider all reasonable alternatives to the Produce Rule's measures related to animal grazing and animal intrusion. FDA has set forth a list of these alternatives in Table 1 of the FR Notice, and NSAC has identified those alternatives it believes most effectively allow FDA to reduce foodborne illnesses while avoiding or minimizing harmful impacts to animals, their habitats, and the environment. As we indicated in our Rulemaking Comments, FDA should adopt a flexible, science-based approach to animal grazing and animal intrusion requirements.[90]

Thus, with regard to the alternatives list in part A of "Proposed action 3," set forth in Table 1 of the FR Notice in the row designated, "Measures related to animal grazing and animal intrusion," NSAC recommends:

- FDA adopt *alternative ii*. As stated in the FR Notice, *alternative ii* provides "As proposed, i.e., an adequate waiting period between grazing and harvesting."[91] NSAC supports this flexible approach. As we stated in our Rulemaking Comments, however, we remain concerned with language in the preamble of the proposed rule that provides the agency, "would not expect it to be necessary for such time period to exceed 9 months, which is the application interval we propose for use of raw manure as a soil amendment."[92] FDA should not imply that an adequate waiting period is nine months because there is no scientific basis for that assumption.[93] Such a long waiting period may cause farmers to unnecessarily confine animals without reducing the risk of foodborne illness. NSAC respectfully recommends that FDA eliminate that language from the preamble.

[87] *Id.* at 26–27.
[88] *Id.* at 27.
[89] *Id.* at 27–28.
[90] *Rulemaking Comments*, supra note 3, at 99-100.
[91] *FR Notice*, *supra* note 3, at 13596.
[92] *Rulemaking Comments*, *supra* note 3, at 100.
[93] *See id.* at 99–100.

FDA should instead provide clarification through guidance for public comment on what constitutes an "adequate" waiting period.

- FDA reject *alternative iv*. As stated in the FR Notice, *alternative iv* provides, "A minimum waiting period of 90 days and 120 days consistent with the USDA/NOP specified application intervals for the use of raw manure as soil amendments."[94] This standard inappropriately suggests that the NOP interval for biological soil amendments can be applied to measures related to animal grazing. As we stated in our Rulemaking Comments, the parallel between feces dropping during grazing and raw manure applied as a fertilizer is weak at best, and certainly not strong enough to determine an appropriate waiting period between animal grazing and harvest.[95]

Regarding part B of "Proposed action 3," set forth in Table 1 of the FR Notice in the row designated "Measures related to animal grazing and animal intrusion," NSAC recommends:

- FDA adopt *alternative ii*. As stated in the FR Notice, *alternative ii* provides "As proposed, i.e., if animal intrusion occurs, you must evaluate whether the covered produce can be harvested, and you must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated."[96] This provides the necessary flexible approach, which allows for reduction in foodborne illness without causing undue harm to wildlife and the environment.

- In addition, the Produce Rule should contain strong language discouraging the destruction of habitat and increasing protection of wildlife species. As we stated in our Rulemaking Comments,[97] § 112.83 of the Produce Rule should contain new subsections (c) and (d) regarding animal intrusion as follows:

> (c) If significant wild animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction occurs, you should focus on very targeted measures to exclude only those specific animals and not all animals. You should avoid:
>
> (1) Destroying wild animal habitat;
>
> (2) Clearing farm borders around outdoor growing areas, ponds, or drainages, particularly where such action would contribute to increased nutrient flow into waterways or increased soil erosion;
>
> (3) Harming migratory birds; and
>
> (4) Taking an endangered species.

[94] *FR Notice*, *supra* note 3, at 13596.
[95] *Rulemaking Comments*, *supra* note 3, at 99–100.
[96] *FR Notice*, *supra* note 4, at 13596.
[97] *Rulemaking Comments*, *supra* note 3, at 99.

(d) To the maximum extent practicable, you should use co-management and sustainable conservation practices that can enhance food safety.

D. Scope of Proposed Rule and Implications to Land Use

In our Initial Scoping Comments and Rulemaking Comments, we discussed how FDA must take a hard look at the impacts associated with altering the scope of the Produce Rule.[98] As currently drafted, the proposed rule does not apply to farms with an average annual monetary value of all food sold during a previous three-year period of $25,000 or less.[99] NSAC recommended that FDA consider excluding farms from the Produce Rule's requirements based upon calculation of sales of only those foods covered by the proposed rule (i.e., covered produce), rather than calculating sales based on all food sold.[100] The number of farms subject to the Produce Rule relates directly to the magnitude of all environmental impacts (including impacts to water, land, air, animals, and human health), and thus excluding more farms from the proposed rule will result in decreased environmental impacts.[101]

We also discussed how FDA must take a hard look at the impacts associated with expanding the number of farms with qualified exemptions to the proposed rule.[102] The Produce Rule exempts certain farms from the scope of most of the rule's provisions if they meet a two-prong eligibility test: during the previous three-year period preceding the applicable calendar year, the average annual monetary value of food sold directly to qualified end-users exceeded the average annual monetary value of food sold to all other buyers; and the average annual monetary value of all food sold during that three-year period was less than $500,000.[103] We suggested an alternative approach that loosens the restrictions of the eligibility test (applying the $500,000 threshold only to sales of produce covered by the Produce Rule, rather than sales of all food sold), thereby expanding the number of farms with qualified exemptions to the proposed rule.[104] Surprisingly, the FR Notice does not address these qualified exemptions. But, the scope of the qualified exemptions relates directly to the number of farming operations that will be subject to the majority of the Produce Rule's provisions, and an expanded scope of exemptions would decrease the magnitude of all environmental impacts.

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[98] *Initial Scoping Comments*, *supra* note 2, at 4–5; *Rulemaking Comments*, *supra* note 3, at 45–60.
[99] *Id.*
[100] *Initial Scoping Comments*, *supra* note 2, at 4; *Rulemaking Comments*, *supra* note 3, at 45–46.
[101] *Initial Scoping Comments*, *supra* note 2, at 4.
[102] *Id*. at 5.
[103] Farms qualify for the exemption if, during the previous three-year period preceding the applicable calendar year, the average annual monetary value of food sold directly to qualified end-users exceeded the average annual monetary value of food sold to all other buys; and the average annual monetary value of all food sold during that three-year period was less than $500,000. *Id.*
[104] Specifically, the alternative approach would apply the $500,000 threshold only to sales of produce covered by the Produce Rule, rather than the sales of all food sold. *Id.*

i. FDA must consider the impacts of the scope of the Produce Rule on water, land, air, animals, and human health

In the FR Notice, FDA acknowledges that "the Produce Safety rule, if finalized as proposed, would cause small farmers to go out of business and potentially result in negative environmental impacts due to changes in land use or land management."[105] NSAC agrees, and – as we state in our Initial Scoping Comments and Rulemaking Comments – FDA must take a hard look at these impacts in its EIS. However, the closing of farms will likely impact far more than just land use and land management. FDA must assess other impacts related to small farms going out of business, including reducing the availability of fresh produce to consumers, especially those with low income and senior citizens, and those who live in historically underserved areas (e.g. food deserts). Additionally, impacts to water, air, animals, and human health must also be considered.

ii. FDA must consider alternatives of the scope of the proposed rule and its implications to land use

As set forth above, NEPA requires FDA to consider all reasonable alternatives to the scope of the proposed rule, as well as alternatives to the provisions related to the number of farms with qualified exemptions. FDA has set forth a list of those alternatives in Table 1 of the FR Notice, and NSAC has identified the alternative it believes most effectively allows FDA to reduce foodborne illnesses in order to protect human health while avoiding or minimizing harmful impacts to the environment.

Thus, with regard to the alternatives listed in part A of "Proposed action 4," set forth in Table 1 of the FR Notice in the row designated "Scope of proposed rule and implications to land use," NSAC recommends:

- FDA adopt *alternative v* (or a similar alternative that exempts farms with even higher annual sales of covered produce, e.g. $50,000 or $100,000). As stated in the FR Notice, *alternative v* provides "Farms with $25,000 or less of annual value of covered produce sold are excluded from coverage of the rule."[106] Focusing solely on the value of covered produce will provide some flexibility to beginning farmers, non-produce farmers who are trying to diversify their production, and family farmers who have diversified operations.[107] Moreover, this alternative is the most logical, simply because the Produce Rule deals with the regulation of produce, as opposed to other business activities that farmers engage in.[108]

- FDA should also revise the eligibility threshold for a qualified exemption so that famers with annual sales of less than $500,000 of covered produce, as opposed to

[105] *FR Notice*, *supra* note 4, at 13595.
[106] *Id.* at 13596.
[107] *Rulemaking Comments*, *supra* note 3, at 45–46.
[108] *See id.*

$500,000 of all food, and who sell the majority of their food to qualified end-users, can qualify for the modified requirements.

V. Conclusion

The Produce Rule will significantly change farming practices across the United States, impacting farmers' livelihoods and creating significant environmental impacts. FDA has acknowledged the breadth of these impacts, and it has committed to revising the Produce Rule to address some environmental concerns. Whatever the revisions to the rule look like, FDA must consider its direct, indirect, and cumulative impacts, as required by NEPA. Additionally, FDA must take a hard look at alternatives and mitigation measures to the rule.

While the FR Notice identifies several important impacts and alternatives of the Produce Rule that FDA will consider in its EIS, FDA should also consider the other impacts and alternatives discussed in our Initial Scoping Comments, Rulemaking Comments, and the comments above. In doing so, FDA may be able to achieve its goal of reducing foodborne illness without unnecessarily harming the environment.