National Sustainable Agriculture Coalition

November 15, 2013

Division of Dockets Management (HFA-305)
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: Comments on Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for the 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), I submit the following comments on the Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. NSAC welcomes the opportunity to submit comments, and looks forward to working with the Food and Drug Administration to ensure that the regulations and their implementation are successful and supportive of sustainable agriculture and food systems. NSAC recognizes that the comment period has just been extended to March 15, 2014, and we may file supplemental comments at that time.

Sincerely,

Ariane Lotti

Ariane Lotti, Assistant Policy Director
National Sustainable Agriculture Coalition

[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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ACKNOWLEDGEMENTS

The National Sustainable Agriculture Coalition's (NSAC) comments on the proposed rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption are the result of months of analysis by, discussion by, and feedback from NSAC's Food System Integrity (FSI) Committee, NSAC's committee charged with working on the Food Safety Modernization Act. To develop the recommendations on the proposed rules, the FSI Committee met weekly by phone and twice in person between early January when the proposed rules were released and the mid-November public comment deadline. Several subcommittees were formed to work in detain on specific issues, including on the FDA's Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

The following people were part of the EIS subcommittee:

NSAC members:

Jo Ann Baumgartner, Wild Farm Alliance
Roger Noonan, New England Farmers Union
Dave Runsten, Community Alliance with Family Farmers
Mark Schonbeck, Virginia Association for Biological Farming

NSAC partners:

Mindy Goldstein, Edward Ezekiel, and Helen Jubran, Turner Environmental Law Clinic at Emory University School of Law

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Scoping Notice Comments

on

FDA Produce Rule

Submitted by

National Sustainable Agriculture Coalition

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

November 15, 2013

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I. INTRODUCTION

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 comments on 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 or Rule).[1] NSAC has also concurrently submitted comments on the Rule itself (the NSAC Rulemaking Comments),[2] which support and explain the comments set forth in this document. Those comments are incorporated herein by reference.

A. FACTUAL BACKGROUND

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act (FSMA).[3] Among other requirements, FSMA requires the FDA to regulate the production of produce.[4] Specifically, it requires the agency to "establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death."[5] FDA proposed such standards—the Produce Rule—on January 16, 2013.[6]

After publication of the Produce Rule, FDA determined that its implementation may significantly affect the quality of the human environment, and accordingly the National Environmental Policy Act (NEPA) required the agency to conduct an environmental analysis (EIS) before issuing the final rule.[7] FDA published a notice of intent to prepare an EIS (the Scoping Notice or Notice) in the Federal Register on August 19, 2013, and it sought comments on the issues, alternatives, mitigation measures, and other information FDA should include in the EIS.[8] NSAC's detailed comments are set forth below.

The Scoping Notice gives very little information regarding FDA's current thinking about the appropriate scope of the Produce Rule EIS. According to the Notice, the purpose of the

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[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 CFR pts. 16, 112) ("Produce Rule"). The docket number for the Rule is FDA-2011-N-0921 and the Regulatory Information Number (RIN) is 0910-AG35.
[2] 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, on Nov. 15, 2013.
[3] 21 U.S.C.A. § 350h (2013).
[4] *Id.*
[5] *Id.*
[6] 78 Fed. Reg. 3,504.
[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, 50,359 (Aug. 19, 2013) ("Scoping Notice").
[8] *Id.*

scoping process is "to determine relevant issues that will influence the scope of the environmental analysis, including potential alternatives, and the extent to which those issues and impacts will be analyzed in the EIS."[9] But contrary to FDA and Council on Environmental Quality (CEQ) regulations, the Notice does not adequately identify the "alternatives" and "impacts" that the EIS will evaluate.

Given these deficiencies, NSAC requested FDA withdraw the Scoping Notice and republish a more complete notice.[10] NSAC contended that FDA had violated NEPA and FDA's implementing regulations by failing to identify alternatives and impacts. Without identifying these key components, the Scoping Notice failed to give the public sufficient information on which to develop comments on the appropriate scope of the EIS. To date, FDA has ignored the request to withdraw the Scoping Notice.

NSAC again requests that FDA withdraw the deficient Scoping Notice and republish a more complete notice. The failure of FDA to set forth alternatives and impacts hinders NSAC's ability to provide meaningful comments on the scope of the EIS. With nothing more on which to rely than its own speculation and hypotheses of FDA's intent, NSAC has prepared these comments. Of course, the opportunity for meaningful public comment on alternatives and impacts to be considered in the forthcoming EIS should rest upon a more solid foundation.

B. LEGAL BACKGROUND

When a federal agency proposes regulations that will "significantly affect[] the quality of the human environment," NEPA requires the agency to consider these impacts in an EIS.[11] As part of the EIS process mandated by NEPA, the agency must take a "hard look" at all impacts of and potential alternatives to the proposed action.[12] While the standard "hard look" cannot be defined with complete precision, courts have found it to "encompass[] a thorough investigation into the environmental impacts of an agency's action and a candid acknowledgment of the risks that those impacts entail."[13]

According to the FDA and CEQ regulations regarding NEPA, as a first step in the process, the agency must determine the appropriate scope and the significant issues to be analyzed in depth in the EIS.[14] The key component of this scoping process is the agency's determination of the range of actions, alternatives, and impacts to be considered in the EIS.[15] With regard to alternatives, agencies must consider the no-action alternative, other reasonable

[9] Scoping Notice, 78 Fed. Reg. at 50,359.
[10] Letter from Mindy Goldstein and Helen Jubran to Leslie Kux, Docket ID No. FDA-2011-N-0921-0216 (Sep. 4, 2013).
[11] National Environmental Policy Act of 1969. 42 U.S.C. § 4321 *et seq.* (1970).
[12] 42 U.S.C. § 4332(2)(C); *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21 (1976)).
[13] *Nat'l Audubon Soc'y v. Dep't of Navy*, 422 F.3d 174, 185 (4th Cir. 2005); *see also Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) ("the adverse environmental effects of the proposed action [must be] adequately identified and evaluated"); *Hughes River Watershed Conservancy v. Johnson*, 165 F.3d 283, 288 (4th Cir. 1999).
[14] 21 C.F.R. § 25.42; 40 C.F.R. § 1501.7.
[15] 40 C.F.R. § 1508.25.

courses of action, and mitigation measures to the proposed action.[16] Regarding impacts, the agency must give a hard look to both the direct and indirect impacts of a proposed rule.[17] Agencies must also consider the cumulative impacts of small actions that may be insignificant alone, but when added together, become significant.[18] Impacts to be evaluated may be ecological, aesthetic, historic, cultural, economic, social, or health-related in nature.[19]

Agencies bear the burden of complying with NEPA, and agencies may not unfairly shift this burden to concerned citizens or environmental groups.[20] When commenting on a proposed action, the public need not conduct a study or intensive research on potential environmental impacts. Instead, it is the agency's job to study and consider the potential impacts suggested by the public.[21] If the agency conducts an insufficient environmental analysis, concerned parties may enforce the obligations of NEPA by judicial remedy.[22]

II. COMMENTS

A. FDA MUST CONSIDER ALTERNATIVES AND MITIGATION MEASURES IN THE EIS.

FDA must take a hard look at the no action alternative, other reasonable alternatives, and mitigation measures to the Produce Rule in its EIS. The requirement to analyze alternatives is the "linchpin"[23] of an EIS, and FDA's analysis must include a rigorous and objective evaluation of all reasonable alternatives.[24] This analysis should compare the net benefit of the proposed action to the environmental impacts presented by alternative courses of action.[25] FDA should also prepare a formal cost-benefit analysis that monetizes the cost and benefits of the proposed action and its alternatives. A cost-benefit analysis would aid FDA in choosing among alternatives with different environmental impacts.[26]

If FDA identifies the current proposed Rule as its preferred alternative, it must consider and discuss mitigation measures that offset the environmental impacts.[27] Mitigation measures include:

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[16] *Id.*
[17] *Id.*
[18] 40 C.F.R. § 1508.7.
[19] 40 C.F.R. § 1508.8.
[20] *E.g.*, *Friends of the Clearwater v. Dombeck*, 222 F.3d 552, 559 (9th Cir. 2000) ("Compliance with NEPA is a primary duty of every federal agency; fulfillment of this vital responsibility should not depend on the vigilance and limited resources of environmental plaintiffs.") (quoting *City of Davis v. Coleman*, 521 F.2d 661, 666 (9th Cir. 1975)).
[21] *See id.* at 558–59.
[22] *See, e.g.*, *W. Watershed Projects v. Bennett*, 492 F.Supp.2d 1271, 1225, 1228–29 (D. Idaho 2005).
[23] *Monroe County Conservation Council, Inc. v. Volpe*, 472 F.2d 693, 697-98 (2nd Cir. 1972) (internal citations omitted).
[24] *See also*, 40 C.F.R. § 1502.14 (describing the alternatives requirement as the "heart" of the EIS).
[25] *Natural Resources Defense Council, Inc. v. Morton*, 458 F. 2d 827 (D.C. Cir. 1999).
[26] 40 C.F.R. § 1502.23
[27] 40 C.F.R. § 1502.14(f)

a. Avoiding the impact altogether by not taking a certain action or parts of an action.
b. Minimizing impacts by limiting the degree or magnitude of the action and its implementation.
c. Rectifying the impact by repairing, rehabilitating, or restoring the affected environment.
d. Reducing or eliminating the impact over time by preservation and maintenance operations during the life of the action.
e. Compensating for the impact by replacing or providing substitute resources or environments.[28]

FDA's deficient Scoping Notice hinders NSAC's ability to meaningfully comment on the alternatives to the proposed Rule and relevant mitigation measures, and NSAC again renews its request that FDA withdraw the deficient notice and re-publish a complete scoping notice. Notwithstanding the deficiency, NSAC attempts to provide meaningful comments on the scope of the EIS and proposes the following alternatives and mitigation measures for consideration in the EIS.

1. FDA Must Consider the No-Action Alternative.

FDA must take a hard look at the no-action alternative. In this instance, the no-action alternative is the decision to refrain from issuing the proposed Produce Rule. Instead of issuing the proposed Produce Rule, however, FDA could issue guidance documents that establish science-based standards for the safe growing, harvesting, packing, and holding of produce, in order to satisfy the mandates of Congress set forth in FSMA.

2. FDA Must Consider Other Reasonable Alternatives and Mitigation Measures.

a. FDA Must Consider Reducing the Number of Farms Subject to the Rule.

FDA must take a hard look at the impacts associated with reducing the number of farms subject to the Produce Rule in its EIS. FDA must weigh the impacts of the proposed Rule against the impacts of this narrowed scope. In conducting this comparison, FDA may consider the costs and benefits of each approach.

As currently drafted, the Rule does not apply to farms whose average annual monetary value of all food sold during a previous three-year period is $25,000 or less.[29] Instead, FDA should consider covering farms based on a calculation of sales of only those foods covered by the Rule, rather than calculating sales based on all foods sold. *See further,* NSAC Rulemaking Comments at 44-45 (explaining in more detail this alternative). Because the number of farms subject to the Rule relates directly to the magnitude of all environmental impacts, covering more farms will create more environmental impacts. Conversely, excluding more small farms from the Rule's coverage will create fewer environmental impacts. FDA must take a hard look at and compare the impacts of such an alternative.

[28] 40 C.F.R. § 1508.20.
[29] Produce Rule, 78 Fed. Reg. at 3,549 (§ 112.4(a)).

b. FDA Must Consider Expanding the Number of Farms Exempt From Most of the Rule's Requirements.

FDA must also take a hard look at the impacts associated with expanding the number of farms with qualified exemptions to the proposed Rule. Again, FDA must weigh the impacts of the proposed Rule against the impacts of this alternative regulatory approach. In conducting this comparison, FDA may consider the costs and benefits of each approach.

The Rule as drafted would exempt certain farms and facilities from the scope of most of the Rule's provisions. Farms qualify for the exemption 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 the 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.[30] Although the Rule would still apply to these farms, because their average annual gross sales exceed $25,000, the Rule would provide an exemption from most provisions.[31] An alternative approach would be to apply the $500,000 threshold only to sales of produce covered by the Produce Rule, rather than sales of all food sold. *See further,* NSAC Rulemaking Comments at 52-53 (explaining in more detail this alternative). The scope of the qualified exemptions relates directly to the number of farming operations that will be subject to the majority of the Rule's provisions and an expanded scope of exemptions would decrease the magnitude of all environmental impacts. FDA must take a hard look at and compare the impacts of exempting more farms from most of the Rule's requirements.

c. FDA Must Consider Adopting an Alternative Water Quality Standard.

FDA must take a hard look at the environmental impacts of using an alternative water standard in its EIS. In doing its alternatives assessment, FDA must acknowledge the defects of its proposed standard—EPA's 1986 Recreational Water Quality Criteria (1986 RWQC)—and take a hard look at the environmental impacts which result from its implementation. In conducting this comparison, FDA may consider the costs and benefits of each approach.

As explained in NSAC's Rulemaking Comments, FDA's proposed water quality standard is defective because it fails to meet two requirements of FSMA.[32] *See further,* NSAC Rulemaking Comments at 60-67. First, FDA failed to establish risk-based and science-based minimum standards for agricultural water when it adopted the 1986 RWQC. FSMA requires FDA to establish "minimum science-based standards for … raw agricultural commodities, based on known safety risks."[33] FDA's adopted standard, however, is not a science-based standard

[30] *Id.* at 3,549 (§ 112.5(a)).
[31] Farms that qualify for the exemption are subject to only three subparts of the Rule and certain labeling requirements. *Id.* at 3,550 (§ 112.6).
[32] FDA's proposed water quality standard is also defective because EPA's 1986 RWQC is outdated. In 2012, the EPA updated its recreational water quality criteria and made several significant changes. *See* "2012 Recreational Water Quality Criteria," 77 Fed. Reg. 71191. For example, EPA's 2012 RWQC provides two sets of recommended criteria, it no longer recommends multiple 'use intensity' values, it consists of both a geometric mean (GM) and a Statistical Threshold Value (STV), and it is comprised of a magnitude, duration, and a frequency of excursion for the GM and STV. *Id.*
[33] 21 U.S.C.A. § 105(a)(b)(1) (2013).

developed to protect human health from consumption of produce. In its proposed Rule, FDA acknowledges, "the EPA recreational water standards were developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers (Ref. 136), *rather than to consumption of produce.*"[34] Additionally, FDA's adopted standard does not adequately establish a risk-based approach. As currently proposed, FDA's standard applies to every farm that must comply with the Rule standards regardless of critical factors such as risk, climate, location, farming system, and water resource.

Second, FDA failed to provide sufficient "flexibility" to farmers, as required by FSMA.[35] As noted above, FDA's water quality standard is inflexible because it applies regardless of risk, climate, location, farming system, or water system.

FDA must take a hard look at the following alternative water quality standards and their impacts:

1. Using a new science-based water quality standard developed from research correlating the risks of gastrointestinal illness from agricultural water to consumption of produce, which might vary according to the region. For any such new standard FDA must take a hard look at the impacts from including such a standard in guidance, not in the regulation itself. This allows for the standard to be updated if new research becomes available about appropriate water quality standards. *See further*, NSAC Rulemaking Comments at 60-67 (explaining that FDA must consider creating a new water quality standard).

2. Using an alternative risk-assessment process. Specifically, FDA should require farmers to collect monthly baseline information about their water systems in the first growing season and base future actions and testing frequencies on those results, instead of requiring weekly water testing. *See further*, NSAC Rulemaking Comments at 60-67 (explaining that FDA must consider a more flexible water quality standard).

3. Using the World Health Organization's ("WHO") *E. coli* water quality standard. As FDA notes, the WHO standard is less-restrictive than FDA's proposed standard.[36] Conversely, the 1986 RWQC *E. coli* standard is overly-restrictive,[37] encourages farmers to use chemically treated water, municipal water, and groundwater, and

[34] Produce Rule, 78 Fed. Reg. at 3.569 (§ 112.44(c)) (emphasis added).
[35] 21 U.S.C.A. § 105(a)(a)(3)(A) (2013) (requiring FDA to "provide sufficient flexibility to be applicable to various types of entities engaged in production and harvesting of fruits and vegetables that are raw agricultural commodities).
[36] "The proposed standard is more stringent than the WHO standard." *Id.* at 3,569 (§ 112.44(c)); *See also* World Health Organization and United Nations Environmental Programs, *WHO Guidelines for the Safe Use of Wastewater, Excreta and Greywater*, Geneva, Switzerland: WHO Press, 2006 (concluding that the minimum microbial quality for water used on root crops that are eaten raw is 1,000 CFU generic E. coli per 100 ml and 10,000 CFU generic E. coli per 100 ml in leaf crops).
[37] The 1986 RWQC, as used in the Produce Rule, prohibits farmers from using agricultural water that contains more than 235 colony forming units (CFU) generic E coli. per 100 mL for any single sample or a rolling geometric mean of more than 126 CFU per 100 mL of water. Produce Rule, 78 Fed. Reg. 3,504 (§ 112.44(c)).

causes numerous environmental effects. FDA must take a hard look at the WHO standard in its EIS and evaluate its environmental effects. FDA must then compare those effects to the effects of the 1986 RWQC.

d. FDA Must Consider Aligning Soil Amendment Standards with those of the National Organic Program.

FDA must take a hard look at the impacts associated with aligning the Rule's soil amendment standards to those used in the U.S. Department of Agriculture's (USDA) National Organic Program. FDA must weigh the impacts of the standards proposed in the Rule against the impacts of this alternative approach. In conducting this comparison, FDA may consider the costs and benefits of each.

FDA's proposed standards require significant waiting periods between the application of an untreated biological soil amendment of animal origin and harvest of covered produce, under certain conditions.[38] Alternatively, FDA could align its biological soil amendments of animal origin standards with those standards for the use of manure and compost in the National Organic Program. For example, FDA could reduce section 112.56(a)(1)(i)'s nine-month required interval between application of untreated manure and harvest to the four-month (120-day) interval required by the National Organic Program. Similarly, FDA could reduce section 112.56(a)(4)(i)'s 45-day required interval between application of compost and harvest to a zero-day interval, if the compost is treated by a process in accordance with the requirements of section 112.54(c) to meet the microbial standard in section 112.55(b). FDA must take a hard look at and compare the impacts associated with each of these alternatives, as set forth in more detail in the recommendations in NSAC's Rulemaking Comments. *See further,* NSAC Rulemaking Comments at 81-84.

e. FDA Must Consider Ways to Mitigate the Environmental Impacts Caused by Certain Provisions and Preferences in the Proposed Rule.

In addition to considering the alternatives listed above, FDA must consider ways to mitigate environmental impacts that result from the provisions and preferences of the Rule as proposed. As discussed in detail below, the Rule's provisions and preferences create substantial and varied environmental impacts to water, land, air, animals, and human health. Specifically, in its EIS, FDA should consider ways to mitigate the environmental impacts caused by:[39]

- The preference for chemical water treatment (see Section II.B.1. of these comments);
- The preference for use of municipal and public water supplies (see Section II.B.2. of these comments);
- The preference for use of groundwater supplies (see Section II.B.3. of these comments);
- The preference for use of synthetic fertilizers (see Section II.B.4. of these comments);
- The preference for treatment of biological soil amendments of animal origin (see Section II.B.5 of these comments);

[38] *See* section II.B.4.-7. of this document for description.
[39] This is not an exhaustive list.

- The restrictions on use of raw manure and composting (see Section II.B.6. of these comments);
- The preference for conventional growing methods[40] (see Section II.B.7. of these comments);
- The preference for use of new packing materials (see Section II.B.8. of these comments);
- The preference for domestic animal confinement (see Section II.B.9. of these comments);
- The preference for the exclusion of wild animals from cropland (see Section II.B.10. of these comments);
- The requirement to monitor for and exclude pests from buildings (see Section II.B.11. of these comments);
- The aggregate human health impacts of the Rule (see Section II.B.12. of these comments).

B. FDA MUST CONSIDER DIRECT AND INDIRECT ENVIRONMENTAL IMPACTS IN THE EIS.

In its EIS, FDA must take a hard look at the direct, indirect, and cumulative impacts to the environment caused by its proposed Rule.[41] This analysis is necessary so that FDA can evaluate the benefits of the proposed action in light of its environmental impacts.[42] In its EIS, FDA must also consider unquantified environmental amenities and values.[43]

Direct effects are effects caused by the agency action and occur at the same time and place.[44] Indirect effects are defined as effects that are caused by the agency action and are later in time or farther removed in distance, but are still "reasonably foreseeable."[45] Cumulative effects are incremental environmental impacts of the action added to other past, present, and reasonably foreseeable future actions, regardless of what agency undertakes such other action.[46] Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.[47]

FDA's deficient Scoping Notice hinders NSAC's ability to meaningfully comment on the environmental impacts of the proposed Rule, and NSAC again renews its request that FDA withdraw the deficient notice and re-publish a complete scoping notice. Notwithstanding the

[40] Conventional farming includes industrial methods that rely on monocultures and purchased synthetic chemicals and other non-sustainable or non-organic practices.
[41] 42 U.S.C.A. § 4332(C)(i). *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) (agencies must take a "hard look" at environmental consequences in its EIS) (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21 (1976)); *see also* 40 C.F.R. § 1508.8 (agencies must consider and discuss the direct, indirect, and cumulative effects to the environment in its review of the environmental consequences of its action).
[42] *Natural Resources Defense Council, Inc. v. Morton*, 458 F. 2d 827 (D.C. Cir. 1999).
[43] 42 U.S.C.A. § 4332(B).
[44] 40 C.F.R. § 1508.8.
[45] *Id.*
[46] 40 U.S.C.A. § 1508.7.
[47] *Id.*

deficiency, NSAC attempts to provide meaningful comments on the scope of the EIS. The following comments are based on NSAC's best efforts to anticipate and evaluate the environmental impacts of the proposed Rule.

The following sections describe preferences that the Produce Rule creates for certain agricultural production practices. In each section, preferences are accompanied by the environmental impacts they create to water, land, air and energy, animals, or human health. FDA must take a hard look at each of these environmental impacts in its EIS.

1. FDA Must Consider the Water, Animal, and Human Health Impacts Created by the Preference for Chemical Water Treatment.

a. Preference for Chemical Water Treatment

The Produce Rule likely encourages farmers to use chemically treated water in two ways. First, the FDA's use of the 1986 RWQC discourages farmers from using untreated surface water. Second, the Produce Rule exempts farmers that chemically treat their surface water from extensive requirements.

The Rule discourages farmers from using untreated surface water. Section 112.44(c) of the Produce Rule requires farmers to meet EPA's 1986 RWQC during growing activities. [48] Farmers must ensure any water that is directly applied to produce contains no more than 235 colony forming units (CFU) of *E. coli* per 100 ml.[49] In many parts of the country, surface water cannot meet this criterion without chemical water treatment.

The Produce Rule also discourages farmers from using untreated surface water by creating inspection, monitoring, modification, and testing requirements for farmers that use it. Farmers that use untreated surface water during growing activities in a manner that directly contacts covered produce must:

- Ensure that the water meets water quality standards borrowed from the Environmental Protection Agency's 1986 RWQC;[50]
- Discontinue use, re-inspect, make necessary changes, and retest any time testing shows that they violate these microbial standards;[51]
- Test their water at the beginning of each growing season;[52]
- Test their water at least every 7 days during the growing season if the surface water is from any source where a significant amount of runoff is likely to drain into the source, such as a river or a natural lake;[53]
- Keep additional records.[54]

[48] Produce Rule, 78 Fed. Reg. 3,568 (§ 112.44(c)).
[49] *Id.*
[50] *Id.*
[51] *Id.* at 3,567-68 (§ 112.44(b)-(c)).
[52] *Id*. at 3,570 (§ 112.45(a)).
[53] *Id*. at 3,571 (§ 112.45(b)(1)).
[54] *See id.* at 3,572 (§ 112.50(b)(2), (4), and (5)).

Taken together, these requirements clearly discourage farmers from using untreated surface water. In some cases, these requirements may prohibit farmers from using it altogether.

The Rule then encourages farmers to use chemically treated surface water by *exempting* farmers that use it from all of the requirements listed above. Farmers that use chemically treated agricultural water are exempt from testing their agricultural water at the beginning of the growing season or any time thereafter, they automatically meet microbial water quality criteria, and they are exempt from numerous reporting requirements. The Rule specifically clarifies that chemical treatment is a form of acceptable water treatment.[55] Thus, the Rule likely discourages farmers from using untreated surface water and creates a clear preference for farmers to use chemically treated agricultural water.

b. Preference for Chemical Water Treatment Creates Impacts to:

i. Water

FDA must take a hard look at the environmental impacts to water of creating a preference for chemical water treatment.[56] FDA should take a hard look at which chemicals farmers are most likely to use and how those chemicals will likely impact water quality. For example, FDA should take a hard look at the likely environmental impacts to water resources and aquatic animals that result from agricultural runoff and leachate containing chemically treated irrigation water. If chemically treated agricultural water leaches into groundwater, community drinking water might be affected.

ii. Animals

FDA must take a hard look at the environmental impacts to animals caused by a preference for chemical water treatment. Agricultural runoff that contains chemically treated water may harm aquatic life and livestock or terrestrial wildlife that drinks from affected waterways. Harm to aquatic life likely includes fish and wildlife kills and food source contamination.

iii. Human Health

FDA must take a hard look at the human health impacts caused by a preference for chemical water treatment. These impacts may include negative health conditions due to the

[55] *See id.* at 3,566 (§ 112.43(b)).

[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.

increased use of chemicals in the water treatment process. Humans are likely to encounter these chemicals directly through drinking water, produce consumption, working on farms, or agricultural runoff.

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

a. Preference for Municipal and Public Water Supplies

The Produce Rule likely encourages farmers to use municipal water and public water supplies over any other water source. The proposed Rule creates this preference in two ways. First, the proposed *E. coli* standard places a burden on farmers that use other sources of surface water. As discussed above, farmers that use other sources of surface water are required to test the water or chemically treat it in order to comply with this standard.

Second, the Rule exempts farmers that use municipal or public water from these testing and treatment requirements.[57] It is likely that some farmers will pay for municipal or public water in order to avoid of the higher costs of testing and treating other sources of water in compliance with the proposed *E. coli* standard. Thus these exemptions likely create a preference for farmers to use municipal or public water.

b. Preference for Municipal and Public Water Supplies Creates Impacts to:

i. Water

FDA must take a hard look at the environmental impacts to water of creating a strong preference for municipal water and public water. For example, the FDA should consider the environmental impacts of creating an increased demand on already-stressed municipal waters,[58] construction of new water treatment facilities, and construction of new water supply reservoirs to accommodate the increased water supply need.[59]

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[57] *See id.* at 3,570 (§ 112.45 ("The standard in § 112.44(a) is derived from the EPA drinking water standard … we are not aware of anything suggesting a need for additional testing at its delivery point to the farm"); *id.* at 3,571 ("Under the sampling, testing, and reporting requirements of 40 CFR 141, we tentatively conclude that additional actions by the grower to assure its safety are unwarranted").

[58] Water scarcity is a well-known problem in many metropolitan areas, including Los Angeles, California. *See* Hilda Blanco et al., *Water Supply Scarcity in Southern California: Assessing Water District Level Strategies* 1–10 (2013), *available at* http://sustainablecities.usc.edu/research/publications.html. For situations in which farmers were previously using groundwater, the increased demand on municipal water supplies will be particularly noticeable.

[59] Increased demands for water, including water used for irrigation, put stress on water management systems. *See* Herman Bouwer, *Integrated Water Management: Emerging Issues and Challenges* 45 Agric. Water Mgmt. 217, 218 (2000). If agricultural demands were made on municipal water supplies, the effects could be very significant, given current growth in demand for municipal water. A 2006 EPA survey showed that 52.6% of capital investments made by public and private water supply companies were directed toward system expansion, such as new facilities and transmission systems. U.S. EPA, *2006 Community Water Survey* 28–31 (2009), *available at* http://water.epa.gov/infrastructure/drinkingwater/pws/upload/cwssreportvolumeI2006.pdf.

ii. Animals

FDA must take a hard look at the environmental impacts to animals caused by a preference for municipal and public water supplies. Municipal and public water sources are already subject to several competing uses and pollution sources. Encouraging farmers to use municipal and public water will likely decrease minimum flows and therefore harm aquatic life.[60]

3. FDA Must Consider the Water and Animal Impacts Created by the Preference for Use of Groundwater Supply.

a. Preference for Use of Groundwater Supply

The Produce Rule likely encourages farmers to use groundwater over surface water. The Rule creates this preference by adopting an overly-restrictive *E. coli* water quality standard, which encourages farmers to avoid costly testing and treatment requirements by switching to groundwater.

First, the Rule encourages farmers to use groundwater by placing costly testing requirements on surface water. Farmers that use untreated surface water must test the water at the beginning of each growing season and every three months thereafter.[61] Farmers that use untreated surface water must additionally test it at least every seven days during the growing season, if it is exposed to significant quantities of runoff.[62] Farmers that use groundwater, however, are only required to test their water once every month during the growing season.[63]

Second, the Rule encourages farmers to use groundwater by placing costly treatment requirements on surface water. As discussed above, FDA's *E. coli* standard will also likely eliminate entire sources of untreated surface water from agricultural use. Farmers will be forced to either conduct chemical water treatment, or switch to groundwater sources. [64] A significant number of farmers across the nation will likely switch from surface water to groundwater sources in order to avoid water treatment requirements. The Rule therefore burdens farmers who use untreated surface water and thus creates a preference for the use of groundwater sources. *See further,* NSAC Rulemaking Comments at 60-67.

[60] *Flow 101*, U.S. EPA, http://water.epa.gov/scitech/datait/models/dflow/flow101.cfm.
[61] Produce Rule, 78 Fed. Reg. at 3,570 (§ 112.45(a)).
[62] *Id.* at 3,571 (§ 112.45(b)(1)).
[63] *Id.* at 3,504 (§ 112.45(b)(2)) ("any source where underground aquifer water is transferred to a surface water containment").
[64] Farmers are likely to use groundwater because groundwater sources are far less likely to be contaminated with *E. coli* than surface water sources. *See id.* at 3,561 ("water obtained from a public water source is least likely to be a vehicle for pathogen contamination of produce, followed by water obtained from deep underground aquifers, shallow wells, and surface water, in that order").

b. Preference for Use of Groundwater Supply Creates Impacts to:

i. Water

FDA must take a hard look at the environmental impacts to water of creating a preference for the use of groundwater supplies. This preference will increase reliance on already-strained groundwater resources and will force some farmers to relocate farming activities.

FDA must take a hard look at the environmental impacts to water of potentially dramatically increasing dependency on groundwater supplies. According to the USDA, in 2007 three-fourths of irrigated agriculture in the United States took place in seventeen western states. Across these states, 52 percent of the water sources used were surface water sources.[65] Forcing farmers to consider using groundwater is likely to exacerbate already competing demands for water resources,[66] and in turn substantially impact the environment. These impacts might include extreme drops in groundwater levels and possible depletion of groundwater resources in some areas. Other potential environmental impacts to water include reductions in streamflow, harm to terrestrial ecosystems, and destruction of wildlife habitat.[67]

FDA must also take a hard look at the environmental impacts to water (and land, air and energy, animals, and human health) of forcing some farmers to shift farming activities to new regions as a result of this preference. In some cases, groundwater may not be available as an alternative to untreated surface water. Farmers in these areas will likely be forced either to re-locate entire farms, at tremendous cost, in search of a new water sources, or to stop farming altogether.

ii. Animals

FDA must take a hard look at the environmental impacts to animals caused by a preference for groundwater supplies. Potential environmental impacts associated with competition for groundwater resources include harm to aquatic life.[68]

4. FDA Must Consider the Water, Land, Air, Animal, and Human Health Impacts Created By the Preference for Synthetic Fertilizers.

a. Preference for Synthetic Fertilizers

The Rule, taken as a whole, will likely create a preference for farmers to use synthetic fertilizers as opposed to biological soil amendments. The Rule creates this preference by

[65] Glenn D. Schaible & Marcel P. Aillery, USDA, *Water Conservation in Irrigated Agriculture: Trends and Challenges in the Face of Emerging Demands*, at ii (2012), *available at* http://www.ers.usda.gov/media/884158/eib99.pdf.
[66] The USDA goes on to examine future supply and demand issues associated with irrigated agriculture, finding that threats to groundwater supply and quality are growing with the expansion of biofuels, global climate change, the growing popularity of hydrofracking, and an increase in crop irrigation across the eastern states. *See id.* at 8–13.
[67] William M. Alley, et al., USGS, *Sustainability of Ground-Water Resources* 34 (1999).
[68] *Id.*

distinguishing between biological and non-biological soil amendments and imposing additional requirements on the use of biological soil amendments.[69] These requirements govern handling, conveying, storing, treatment, microbial standards, application method and minimum intervals, and reporting.[70] Because of the restrictions proposed on biological soil amendments of animal origin, FDA creates a significant incentive for farmers to use synthetic fertilizers, which have been widely shown to result in significant environmental impacts. Indeed, FDA acknowledges in the Scoping Notice that the proposed biological soil amendment requirements "are expected to result in changes in current use of treated and untreated biological soil amendments of animal origin *or potentially greater use of synthetic fertilizers*."[71]

For example, the Rule requires minimum application intervals for soil amendments, based upon the type of amendment used.[72] Biological soil amendments of animal origin, if untreated, require a minimum application period of nine months, in addition to other application restrictions.[73] Biological soil amendments of animal origin that are treated by a composting process in accordance with the requirements of section 112.54(c) require a 45-day interval between application and harvest.[74] Synthetic fertilizers, however, have no minimum interval for application.

Additionally, the Rule prescribes a method of application of soil amendments, based upon the type of amendment used.[75] Biological soil amendments of animal origin, when untreated, must be applied in a manner that does not contact produce during application and minimizes the potential for contact with produce after application, in order to reduce contamination.[76] In contrast, synthetic fertilizers are not subject to restrictions on the method of application. By virtue of the limitations imposed on biological amendments, the Rule burdens farmers who use biological soil amendments and thereby creates a very strong preference for synthetic fertilizers. *See further,* NSAC Rulemaking Comments at 68-72 (explaining the incentives for farmers to rely on chemical fertilizers instead of biological amendments).

b. Preference for Synthetic Fertilizers Creates Impacts to:

i. Water

FDA must take a hard look at the environmental impacts to water of encouraging farmers to use synthetic fertilizers. Increased use of synthetic fertilizers is widely shown to lead to agricultural runoff and pollution. Correspondingly, the impacts of this preference include nutrient pollution, eutrophication, and contamination of drinking water.

Nitrogen-based soil amendments are often applied as nitrate, ammonium, and/or urea; the latter two are rapidly converted to nitrate by soil life. Because nitrate is highly soluble and

[69] Produce Rule, 78 Fed. Reg. 3,504 (§ 112.3(c)).
[70] *See id.* at 3,577-85 (§§ 112.52, 112.54, 112.55, 112.56, and 112.60).
[71] Scoping Notice, 78 Fed. Reg. at 50,359 (emphasis added).
[72] Produce Rule, 78 Fed. Reg. at 3,581-84 (§ 112.56).
[73] *Id.* at 3,581 (§ 112.56(a)(1)).
[74] *Id.* at 3,583 (§ 112.56(a)(4)(i)).
[75] *Id.* at 3,581-84 (§ 112.56).
[76] *Id.* at 3,581 (§ 112.56(a)(1)).

mobile, its use can lead to nuisance growth of algae, mostly in downstream estuaries, and cause contamination of drinking water.[77] The use of nitrogen-based synthetic soil amendments is also linked to degradation of nitrogen and carbon resources naturally occurring in soil, which further increases reliance on synthetic soil amendments to maintain crop yields.[78] Such reliance is dangerous, in part, because excess fertilizer application contributes to eutrophication and dead zones in waters, which is harmful to water resources and aquatic life.[79]

Phosphorus is applied to soil as phosphate, and phosphate runoff can also lead to nuisance algae and plant growth, often in freshwater streams, lakes, and estuaries, including critically impaired waters such as the Chesapeake Bay and the Gulf of Mexico.[80]

Because of the preference for synthetic fertilizers, less untreated or composted animal manure and poultry litter will be used for crop production. The reduced use of these wastes will result in increased accumulation of wastes on livestock farms and at the sites of animal feeding operations (AFOs), including concentrated animal feeding operations (CAFOs) and poultry houses. Such waste accumulation contaminates both surface and groundwater resources with nutrients and pathogens.

ii. Land

FDA must take a hard look at the environmental impacts to land of creating a preference for synthetic fertilizers. For example, the use of nitrogen-based soil amendments is linked to

[77] Nitrate pollution in drinking water supplies can cause serious illness or death. *Basic Information About Nitrate Pollution in Water*, U.S. EPA, http://water.epa.gov/drink/contaminants/basicinformation/nitrate.cfm (last updated May 21, 2012).

[78] R.L. Mulvaney et al., *Synthetic Nitrogen Fertilizers Deplete Soil Nitrogen: A Global Dilemma for Sustainable Cereal Production,* 38 J. Envtl. Quality 2295, 2307–08 (2009). Specifically, synthetic soil amendments fail to support soil health and nutrient content, which indicates that using synthetic soil amendments is a less sustainable farming practice. Paul Hepperly et al., *Compost, Manure and Synthetic Fertilizer Influences Crop Yields, Soil Properties, Nitrate Leaching and Crop Nutrient Content*, 17 Compost Sci. & Utilization 117, 125 (2009).

[79] *See Nutrient Pollution*, U.S. EPA, http://www2.epa.gov/nutrientpollution/ (last updated Mar. 25, 2013) (providing, throughout the website, explanations of the sources and effects of nutrient pollution).

[80] *Fertilizer Applies for Agricultural Purposes: What Are the Trends in Chemicals Used on the Land and Their Effects on Human Health and the Environment*, U.S. EPA, http://cfpub.epa.gov/eroe/index.cfm?fuseaction=detail.viewInd&lv=list.listByAlpha&r=216629&subtop=312 (last visited Mar. 28, 2013). Mining phosphorous for phosphate fertilizers also releases radionuclides like uranium and radium-226. *About Phosphogypsum*, U.S. EPA, http://www.epa.gov/radiation/neshaps/subpartr/about.html (last updated July 31, 2012). Some studies indicate that a "peak phosphorous" phenomenon could occur, as mining of phosphate rock increases and resources become scarcer. *E.g.*, Patrick Déry & Bart Anderson, *Peak Phosphorous*, Energy Bull., Aug. 13, 2007, *available at* http://www.resilience.org/stories/2007-08-13/peak-phosphorus. As the U.S. Geological Survey succinctly explains, "There are no substitutes for phosphorous in agriculture." U.S. Geological Survey, *Mineral Commodity Summaries 2013*, at 119 (2013). In the future, if U.S. sources of phosphate soil amendments are depleted, farmers could be compelled to import phosphate fertilizers.

degradation of nitrogen and carbon resources naturally occurring in soil, which further increases reliance on synthetic soil amendments to maintain crop yields.[81]

Again, the reduced use of untreated or composted animal manure and poultry litter for crop production will result in increased accumulation of these wastes on livestock farms and at the sites of AFOs, including CAFOs and poultry houses. This accumulation will likely lead to greater nutrient and pathogen overloads in concentrated areas, and less input of manure at rates that would otherwise enhance soil fertility and quality over much larger areas of cropland.

iii. Air and Energy

FDA must take a hard look at the air and energy impacts caused by a preference for synthetic fertilizers over biological soil amendments. These impacts may include additional emissions and energy expenditure to produce synthetic fertilizers. During and after application, the use of synthetic fertilizers also creates air impacts. In addition, the formation and release of nitrous oxide (N_2O, a greenhouse gas 300 times as potent as CO_2) during wet soil conditions is aggravated by the presence of high concentrations of soluble nitrogen, as occur after synthetic fertilizer application. Slow-release nitrogen sources, such as compost, are less likely to release large amounts of N_2O. Impacts may also include increased transportation emissions, due to many farmers obtaining synthetic fertilizer from another source and transporting it to their farms.

iv. Animals

FDA must take a hard look at the environmental impacts to animals caused by a preference for synthetic fertilizers. The eutrophication and dead zones in waters—caused by synthetic fertilizer application—harm aquatic life. See the Water section above for more detail.

v. Human Health

FDA must take a hard look at the human health impacts caused by a preference for synthetic fertilizers over biological soil amendments. These impacts may include an increase in chronic and acute health conditions due to the increased use of chemical fertilizers.[82] Humans may come in contact with these fertilizers directly from produce consumption, working on farms, or through agricultural runoff. These impacts may also include increased human exposure to pathogens in irrigation water. Nitrates can lead to growth of algae in water. Some kinds of pathogenic bacteria survive longer when attached to algae.[83] UV penetration in water, important

[81] R.L. Mulvaney et al., *Synthetic Nitrogen Fertilizers Deplete Soil Nitrogen: A Global Dilemma for Sustainable Cereal Production,* 38 J. Envtl. Quality 2295, 2307–08 (2009). Specifically, synthetic soil amendments fail to support soil health and nutrient content, which indicates that using synthetic soil amendments is a less sustainable farming practice. Paul Hepperly et al., *Compost, Manure and Synthetic Fertilizer Influences Crop Yields, Soil Properties, Nitrate Leaching and Crop Nutrient Content*, 17 Compost Sci. & Utilization 117, 125 (2009).

[82] Nitrate pollution in drinking water supplies can cause serious illness or death. *Basic Information About Nitrate Pollution in Water*, U.S. EPA, http://water.epa.gov/drink/contaminants/basicinformation/nitrate.cfm (last updated May 21, 2012).

[83] Y.A. Pachepsky et al., *Irrigation Waters As a Source of Pathogenic Microorganisms in Produce: A Review*, Advances in Agronomy 113 (2011).

in reducing pathogens, is diminished with the presence of algae.[84] Therefore, increasing nitrate runoff from fields may increase algae and pathogens in irrigation surface water.[85]

5. FDA Must Consider the Land and Air Impacts Created by the Preference for Treatment of Biological Soil Amendments.

a. Preference for Treatment of Biological Soil Amendments of Animal Origin

The Rule, taken as a whole, creates a preference for treating biological soil amendments of animal origin (as opposed to leaving such amendments untreated) due the additional requirements imposed upon untreated biological soil amendments of animal origin. These additional requirements include restrictions on handling, conveying, storing, application intervals, and method of application.

The Rule requires farmers to determine the status of any biological soil amendments of animal origin, which are divided into categories of treated or untreated, based on several parameters.[86] Once sorted, the Rule provides specific instructions for handling, conveying, and storing treated amendments so they do not get contaminated with untreated amendments.[87] In order to avoid taking these precautions against contamination, farmers may treat all or most animal-based amendments. Treatment of biological soil amendments of animal origin must be conducted according to acceptable processes.[88] Treatments are generally physical (heating) or chemical, which FDA acknowledges require large amounts of energy.[89]

The Rule also requires minimum application intervals and prescribes a method of application for untreated biological soil amendments of animal origin, compared to satisfactorily treated biological soil amendments of animal origin.[90] Untreated amendments require a minimum application period of nine months if the produce is likely to contact the soil after application.[91] Amendments that have been physically or chemically treated to satisfaction, however, have no waiting period or minimum application period.[92] Regarding method of application, untreated biological soil amendments of animal origin must be applied in a manner that does not contact produce during application and minimizes the potential for contact with produce after application, in order to reduce contamination.[93] Satisfactorily treated biological soil amendments of animal origin, on the other hand, do not have any application restrictions and may come in

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[84] *Id.*
[85] *See* J.D. Brookes, J. Antenucci et al., *Fate and Transport of Pathogens in Lakes and Reservoirs*, 30 Environment International 741-759 (2004); J.A. Baumgartner, *Farmer's Guide to Food Safety and Conservation: Facts, Tips, and Frequently Asked Questions*, Wild Farm Alliance and Community Alliance for Family Farmers (2013), *available at* http://www.wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm.
[86] Produce Rule, 78 Fed. Reg. at 3,576-77 (§ 112.51).
[87] *Id.* at 3,577 (§ 112.52).
[88] *Id.* at 3,578 (§§ 112.54, 112.55).
[89] *Id.* at 3,578-79 (§ 112.54(a)-(c)).
[90] *Id.* at 3,581-84 (§ 112.56).
[91] *Id.* at 3,581 (§ 112.56(a)(1)).
[92] *Id.* at 3,581-82 (§§ 112.54(a), 112.56(a)(2)).
[93] *Id.* at 3,581 (§ 112.56(a)(1)).

contact with produce during growing and harvesting.[94] Again, farmers are likely to treat all or most biological soil amendments to avoid these limitations.

b. Preference for Treatment of Biological Soil Amendments of Animal Origin Creates Impacts to:

i. Land

FDA must take a hard look at the environmental impacts to land of a preference for treatment of biological soil amendments of animal origin. Biological soil amendments make a key contribution to healthy soil life, by providing a great diversity of microorganisms. Biologically active soils deliver plant nutrients more efficiently (thereby reducing or eliminating the need for synthetic fertilizers), reduce the risk of nutrient leaching or runoff, and make the soil less hospitable to foodborne pathogens.[95] Eliminating these microorganisms from soil amendments may negatively impact soil health.[96] FDA should consider the environmental impacts to land of imposing physical and chemical treatment processes on soil amendments, rather than allowing the use of untreated biological amendments.

ii. Air and Energy

FDA should take a hard look at environmental impacts to air and energy that result from a preference for treatment of biological soil amendments of animal origin. FDA should take a hard look at the energy expenditure required of the treatment process. FDA should also consider the air impacts that will result from the transportation required to obtain treated soil amendments. FDA acknowledges that conducting physical or chemical treatments onsite may be impracticable for many farms,[97] which may require farms to import treated amendments and export untreated amendments. FDA should therefore take a hard look at the air impacts of transportation emissions, due to increased imports and exports.

6. FDA Must Consider the Water, Land, Air, and Human Health Impacts Created by the Restrictions on Use of Raw Manure and Composting.

a. Restrictions on Use of Raw Manure and Composting

Certain provisions of the Rule discourage the use of raw manure as a soil amendment. The Rule's limitations on untreated biological soil amendments of animal origin essentially

[94] *Id.* at 3,581-82 (§§ 112.54(a), 112.56(a)(2)).
[95] For instance, the high populations and diversity of non-pathogenic microorganisms in soil managed organically with biological soil amendments may shorten survival of foodborne pathogens in soil. A.V. Semenov et al., *Estimating the Stability of Escherichia Coli O157:H7 Survival in Manure-Amended Soils with Different Management Histories*, 10 Envtl. Microbiol. 1450-59 (2008);
X.P. Jiang et al., *Fate of Escherichia Coli O157:H7 in Manure Amended Soil*, 68 Appl. Envtl. Microbiol. 2605-09 (2002); X.P. Jiang et at., *Fate of Listeria Monocytogenes in Bovine Manure-Amended Soil,* 67 J. Food Prot. 1676-81 (2004).
[96] J.D. van Elsas, P. Hill, et al., *Survival of Genetically Marked Escherichia coli O157 : H7 on Soil As Affected by Soil Microbial Community Shifts*, 1 Isme Journal 204-14 (2007).
[97] Produce Rule, 78 Fed. Reg. at 3,579 (§ 112.53)

prohibit farms from using raw manure for any period less than nine months before harvest, if the produce is likely to contact the soil after application.[98] FDA imposes this requirement because it finds "the use of raw manure at a time close to harvest, during organic or conventional production, presents a significant likelihood of contamination of covered produce if produce is reasonably likely to contact the soil."[99] In parts of the country, the nine-month waiting period will be longer than the growing season. To comply with the waiting period, farmers applying raw manure during a growing season will be forced to fallow the field for that entire growing season and harvest in the following year. The extended waiting period, even for farms with longer growing seasons, presents a serious impediment to the use of raw manure. The impediments of the waiting period are likely to discourage farmers from using raw manure as a soil amendment. *See further,* NSAC Rulemaking Comments at 69-71 (explaining the impacts of the Rule's restrictions on use of manure).

In addition, the Rule taken as a whole likely discourages farms from composting materials such as manure, table scraps,[100] and other materials of animal origin for use as soil amendments because it requires additional treatment measures. Because FDA does not consider composting alone to be a pathogen-elimination step,[101] the Rule requires additional treatment processes to be undertaken.[102] Under the Rule, material must be composted to at least 131 degrees Fahrenheit for a minimum of 3 days for a static aerated pile and a minimum of fifteen days for a turned pile, and then cured with proper insulation. After treatment, the compost must be applied to crops at least 45 days before harvest.[103] The treatment process and waiting period impose additional burdens on farmers using compost that will discourage the composting of manure or other material of animal origin. *See further,* NSAC Rulemaking Comments at 79-81 (explaining the impacts of the Rule's treatment and insulation requirements on the use of composting).

In addition, FDA's proposed standards for compost are misinformed and are likely to push farmers using compost toward sterilized soil amendments. As FDA acknowledges, composting is widely recognized as an effective process to kill pathogens and produce a hygienic product from waste. Indeed, a substantial body of scientific literature supports the pathogen-suppressing effects of the naturally occurring microbial communities in compost. *See generally,* NSAC Rulemaking Comments at 72-81 (explaining more fully the importance of biologically-active compost).

[98] Produce Rule, 78 Fed. Reg. at 3,581-82 (§ 112.56(a)(1)(i)).
[99] *Id.* at 3,574.
[100] The Rule classifies post-consumer waste, or table waste, such a plate scrapings, as "animal waste" for the purposes of the definition of biological soil amendments of animal origin. *Id.* at 3,574. Therefore, in order to be applied to produce, table scraps require the same level of treatment as biological soil amendments of animal origin, such as manure.
[101] *Id.* at 3,579-80 (§ 112.54(a)-(c)).
[102] *Id.* at 3,580 (§ 112.54(c)).
[103] *Id.* at 3,583 (§ 112.56(a)(4)(i)).

b. Restrictions on Use of Raw Manure and Composting Create Impacts to:

i. Water

FDA must take a hard look at the water impacts caused by the Rule's restrictions on use of raw manure and composting. Restrictions on the use of manure will likely cause an excess of animal waste that farmers may accumulate in manure stockpiles. Excess animal waste contaminates runoff and can degrade water resources, such as groundwater and surface water. Animal waste contains significant levels of phosphorus and nitrogen, which enter the water and contribute to low levels of dissolved oxygen and cause fish kills.[104] Decomposing organic matter in the water can contribute to toxic algae blooms.[105]

ii. Land

FDA must take a hard look at the land impacts caused by the Rule's restrictions on use of raw manure and composting. FDA must consider the impacts of decreased nutrient loads in soil and potential pathogen overload that may result from these restrictions.[106]

As described above, biological soil amendments such as manure contribute to healthy soil life by providing a great diversity of microorganisms. Biologically active soils deliver plant nutrients more efficiently and reduce the risk of nutrient leaching or runoff. Compost's suppressive capacity also helps to reduce plant pathogens in the following plants: beetroot, bean, apple, eggplant, cauliflower, and tomato.[107] Reducing the use of raw manure and compost in soil amendments may negatively impact soil health. FDA must take a hard look at the environmental impacts to land of restricting the use of raw manure and compost in soil amendments. For example, FDA must consider the likely increase in plant pathogens resulting from reduced use of compost.[108]

In addition, the restrictions on use of raw manure are likely to cause more accumulation of untreated or composted animal manure and poultry litter at or near livestock farms and at the sites of AFOs, including CAFOs and poultry houses. This accumulation will likely lead to greater nutrient and pathogen overloads in concentrated areas, and less input of manure at rates that would otherwise enhance soil fertility and quality over much larger areas of cropland.

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[104] *How Do CAFOs Impact the Environment?*, EPA Region 7, http://www.epa.gov/region07/water/cafo/cafo_impact_environment.htm (last accessed Oct. 24, 2013).
[105] *Id.*
[106] *See* A.V. Semenov et al., *Estimating the Stability of Escherichia Coli O157:H7 Survival in Manure-Amended Soils with Different Management Histories*, 10 Envtl. Microbiol. 1450-59 (2008); X.P. Jiang et al., *Fate of Escherichia Coli O157:H7 in Manure Amended Soil*, 68 Appl. Envtl. Microbiol. 2605-09 (2002); X.P. Jiang et at., *Fate of Listeria Monocytogenes in Bovine Manure-Amended Soil,* 67 J. Food Prot. 1676-81 (2004).
[107] V. Stan et al., *Waste Recycling and Compost Benefits*, 37 Notulae Botanicae Horti Agrobotanici Cluj-Napoca (2009)
[108] H.A.J. Hoitink and M.E. Grebus, *Status of Biological Control of Plant Disease With Composts*, 2 Compost Sci. and Utilization 6-12 (1994); M. Pugliese, B.P. Liu, et al., *Microbial Enrichment of Compost With Biological Control Agents to Enhance Suppressiveness to Four Soil-Borne Diseases in Greenhouse*, 118 J. Plant Diseases and Prot. 45-50 (2011).

iii. Air and Energy

FDA must take a hard look at the air and energy impacts caused by the Rule's restrictions on use of raw manure and composting. This restriction likely creates excess manure and food scraps because smaller quantities of those biological materials will be composted for crop application. The impacts from this preference may include air emissions caused by anaerobic decay of large concentrations of these wastes. The impacts also likely include increased transportation emissions, because farmers will need to dispose of manure, bedding materials, and table scraps offsite that otherwise would have been composted onsite and applied to crops. Increased transportation emissions may also result if farmers import fertilizer or soil amendments, instead of using a ready-source of composted material. Transporting compost could have greater transportation impacts than transporting synthetic fertilizer. Additional impacts may include increased air pollution, due to stockpiles of unused manure that otherwise would have been composted and applied to crops.

iv. Human Health

FDA must take a hard look at the human health impacts caused the restrictions on composting. Excess animal waste, due to limitations on composting, may create impacts such as an increase in chronic and acute health conditions, due to the air and water pollution that results from excess manure stockpiles. This accumulation of waste will also likely increase human exposure to foodborne pathogens. Also, reduced inputs of raw manure and compost due to the Rule's restrictions will lower microbial diversity in the soil and will likely increase pathogen survival.[109] Farmworkers may encounter these pathogens directly on the farm.

7. FDA Must Consider the Water, Land, Air, Animal, and Human Health Impacts Created by the Preference for Conventional Growing Methods.

a. Preference for Conventional Growing Methods

The soil amendment preferences, in aggregate, create a preference for farmers to grow produce using conventional methods, as opposed to using more sustainable methods,[110] including but not limited to growing according to USDA National Organic Program standards. The legislation authorizing the proposed Rule, however, prohibits FDA from creating any provisions that directly conflict with the National Organic Program[111] and accordingly, FDA "tentatively"

[109] Microbial diversity helps to reduce pathogen survival. Non-pathogenic beneficial microbes usually prevail if diverse populations are present, by outcompeting the pathogens for food, water, and space by killing and consuming the pathogens, and by generally making conditions unfavorable to the pathogens. *See* J.A. Baumgartner, *Farmer's Guide to Food Safety and Conservation: Facts, Tips, and Frequently Asked Questions*, Wild Farm Alliance and Community Alliance for Family Farmers (2013), *available at* http://www.wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm.

[110] While this section discusses organic methods, the preferences and implications discussed apply much more broadly to other sustainable growing methods as well.

[111] "[I]n the case of production that is certified organic, [the proposed rulemaking shall] not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990, while providing the same level of public health

concludes that compliance with the Rule will not preclude compliance with organic certification.[112] In practice, however, the Rule may create a preference for conventional growing due to its restrictions on raw manure and compost application, and the Rule's corresponding preference for synthetic fertilizers. These preferences will severely compromise the ability of certified organic producers to comply with the National Organic Program regulations.

As discussed above, the Rule prohibits the application of raw manure to crops where the produce is likely to contact the soil after application, for any period less than nine months (270 days) before harvest.[113] The National Organic Program, however, sets the minimum threshold for application of raw manure at only 120 days before harvest, if application will contact the edible portion of crops, or 90 days before harvest if the edible portions will not contact the soil.[114] Regarding composting, the proposed Rule requires a 45-day waiting period after application of compost.[115] In contrast, the National Organic Program regulations do not set a minimum waiting period for the application of manure treated by a composting process.[116]

The Rule restricts practices that sustainable and organic farmers rely upon for soil, nutrient, fertility, and pest management. Namely, the extended waiting periods imposed by the Rule may completely deter the application of manure and compost to cropland, and will at least deter application at appropriate rates and consistent with good nutrient management. For instance, farmers who use manure and observe the nine-month interval between application of raw manure and harvest will realize a lower efficiency of nutrient capture and utilization by the crop than would be realized with the 120-day interval currently required by the National Organic Program. Yet, the application of biologically based fertilizers such as manure and compost are foundational practices in sustainable and organic farming. In addition, the proposed intervals will significantly limit the ability of organic farmers to rotate crops as part of preventive pest and disease control, which will conflict with the National Organic Program's requirements of crop rotation or biological diversity.[117] These restrictions imposed by the Rule are likely to make it more difficult for farmers to grow produce using organic methods. *See generally,* NSAC Rulemaking Comments at 68-89 (explaining in more detail the Rule's conflicts with soil amendment practices of organic methods), and at 97-98 (explaining in more detail the Rule's conflicts with the conservation practices of organic production).

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protection as the requirements under guidance documents, including guidance documents regarding action levels, and regulations under the FDA Food Safety Modernization Act." 21 U.S.C.A. § 350h(a)(3)(E).

[112] Produce Rule, 78 Fed. Reg. at 3,519, 3,574.

[113] *Id.* at 3,581-82 (§ 112.56(a)(1)(i)).

[114] 7 C.F.R. § 205.203(c)(1).

[115] Produce Rule, 78 Fed. Reg. at 3,583 (§112.54).

[116] 7 C.F.R. § 205.203(c)(2).

[117] *See* 7 C.F.R. § 205.205. The National Organic Program natural resources standard requires organic farmers to maintain or improve the natural resources of their operation, including soil, water, wetlands, woodlands, and wildlife. The definition of organic production includes biodiversity conservation, and the rotation standard requires that perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation, to assist with pest control. Failure to implement crop rotation as part of a preventive pest management program will force organic producers out of compliance with current USDA organic regulations and may prompt organic certifiers to pursue adverse action.

Farmers need to use fertilizer to grow crops and the burdens on use of manure and compost may require more farmers to rely on synthetic fertilizer out of necessity. However, synthetic fertilizers are not permitted in organic growing methods. As such, the extended waiting periods will interfere with the organic practices of farmers that currently grow according to the standards of the National Organic Program. As a result, some farmers may be pushed to adopt conventional growing methods and to abandon the National Organic Program altogether. *See further,* NSAC Rulemaking Comments at 81-84.

b. Preference for Conventional Growing Methods Create Impacts to:

i. Water

FDA must take a hard look at the environmental impacts to water caused by a preference for conventional growing methods and a tension with the National Organic Program. A shift away from organic growing practices in favor of conventional growing practices will likely produce greater use of pesticides, synthetic fertilizer, and chemical treatment of agricultural water.[118] Pesticides and synthetic fertilizers both accumulate in agricultural runoff. The environmental impacts from agricultural runoff containing pesticides and excessive nitrate and phosphate include direct harm to aquatic life and the generation of algae blooms, resulting in reduced levels of dissolved oxygen as well as release of toxins harmful to other life forms. Impacts to water from chemical water treatment may include decreased water quality, disrupted ecosystems, and damage to aquatic life.

ii. Land

FDA must take a hard look at the environmental impacts to land caused by a preference for conventional growing methods and a tension with the National Organic Program. A shift away from organic growing practices in favor of conventional growing practices will likely produce greater use of pesticides and synthetic fertilizer. Impacts likely include decreased soil fertility, decreased biodiversity above and below ground, increased soil compaction, and increased erosion. The reduction in organic inputs to the soil will further degrade soil quality and leave the soil more erodible. For instance, organic practices, such as use of biological soil amendments, provide a great diversity of microorganisms in soil and contribute to healthy soil life.[119] Soils under long-term organic management have improved physical, chemical, and biological properties.[120] In addition, organic practices may reduce foodborne pathogens.[121] Eliminating these microorganisms from soil amendments may negatively impact soil health.

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[118] *See also* Section II.B.1.b. of these comments for the environmental impacts that are likely to accrue from an increase in the chemical treatment of agricultural water.

[119] *See* Section II.B.5.b.i. and II.B.6.b.ii of these comments for the environmental impacts to land that are likely to accrue from restrictions on the use of untreated biological soil amendments, such as raw manure.

[120] C. Kremen, A. Miles, *Ecosystem Services in Biologically Diversified Versus Conventional Farming Systems: Benefits, Externalities, and Trade-Offs*, 17 Ecology and Soc'y (2012).

[121] A.V. Semenov et al., *Estimating the Stability of Escherichia Coli O157:H7 Survival in Manure-Amended Soils with Different Management Histories*, 10 Envtl. Microbiol. 1450-59 (2008); X.P. Jiang et al., *Fate of Escherichia Coli O157:H7 in Manure Amended Soil*, Appl. Envtl. Microbiol. 68:2605-2609 (2002); X.P. Jiang et at., *Fate of Listeria Monocytogenes in Bovine Manure-Amended Soil,* 67 J. Food Prot. 1676-81 (2004).

FDA should consider the environmental impacts to land of discouraging organic practices that incorporate biological soil amendments.

iii. Air and Energy

FDA must take a hard look at the air and energy impacts of a preference for conventional methods. A shift away from organic growing practices in favor of conventional growing practices will likely produce greater use of pesticides and synthetic fertilizer. Impacts may include additional air emissions and energy expenditure to produce synthetic fertilizers and petroleum-based pesticides, as well as increased nitrous oxide emissions from soils amended with synthetic nitrogen fertilizer. In addition, lower soil quality can lead to increased wind erosion and associated airborne particulates.

iv. Animals

FDA must take a hard look at the impacts to animals of a preference for conventional methods. A shift away from organic growing practices in favor of conventional growing practices will likely produce greater use of pesticides and synthetic fertilizer. Pesticides and synthetic fertilizers both accumulate in agricultural runoff, where they may generate algae blooms, disrupt ecosystems, and damage aquatic life. Some pesticides are also harmful to terrestrial wildlife and bird populations. Lower soil quality resulting from reduced organic inputs can also compromise livestock health.

v. Human Health

FDA must take a hard look at the human health impacts of a preference for conventional methods. A shift away from organic growing practices in favor of conventional growing practices will likely produce greater use of pesticides and synthetic fertilizer. Impacts may include health problems resulting from pesticide exposure of farmworkers and those who consume produce. Negative health effects may include neurologic, endocrine, and psychological problems, cancer, and other diseases. Nitrate in drinking water from agricultural runoff is another threat to human health. Finally, reduced use of organic soil amendments will result in reduced soil microbial diversity and biological activity, and thereby may prolong the half-life of foodborne pathogens in soil.

8. FDA Must Consider the Land and Air Impacts Created by the Preference for Use of New Packing Materials.

a. Preference for Use of New Packing Materials

The Rule creates a preference for farmers to use new packing materials, rather than recycling and using reusable packaging. The Rule requires operations to either use new packing materials or ensure that reusable packaging is clean and sanitized, in order to harvest and transport produce.[122] Farming operations may use new packing materials in order to avoid the requirements imposed on reusable packing materials.

[122] Produce Rule, 78 Fed. Reg. at 3,589 (§ 112.116).

b. Preference for Use of New Packing Materials Creates Impacts to:

i. Land

FDA must take a hard look at the land impacts caused by a preference for new packing materials over reused or recycled packing materials. Such a preference will likely lead to an increased consumption of new materials, shorter useful life of packing materials, and additional waste. Therefore, the impacts may include a greater use of landfills, due to increased disposal of packaging materials.

ii. Air and Energy

FDA must take a hard look at the air and energy impacts caused by a preference for new packing materials over reused or recycled packing materials. Such a preference will likely lead to an increased consumption of new materials, shorter useful life of packing materials, and additional waste. The increased manufacturing of new packing materials will likely produce air impacts, in the form of increased emissions. Impacts may also include increased air emissions due to the need to transport and dispose of more packing materials.

9. FDA Must Consider the Water, Land, Air, Animal, and Human Health Impacts Created by the Preference for Domestic Animal Confinement.

a. Preference for Domestic Animal Confinement

The Rule, taken as a whole, creates a preference for animal confinement because the Rule places restrictions on domestic animal grazing in produce fields and domestic animal contact with agricultural water sources. If animals are allowed to graze in fields where produce is grown and there is a reasonable probability that grazing will contaminate the produce, farmers must use a waiting period between grazing and harvest.[123] Therefore, if domestic animals are allowed to graze in produce fields, crop harvesting will be delayed for a period of time. FDA provides that the agency "would not expect it to be necessary for such time periods to exceed 9 months, which is the application interval [proposed] for use of raw manure as a soil amendment."[124] FDA thereby implies that feces left from grazing animals is of similar risk as manure applications, which require a nine-month interval. *See further*, NSAC Rulemaking Comments at 98-99. The Rule also requires famers to keep all agricultural water sources free from domestic animals.[125]

FDA claims that these requirements will not impact the environment because the Produce Rule does not expressly prohibit grazing by domesticated animals.[126] However, the requirement for an "adequate" waiting period—which FDA implies is nine months—will likely create pressure for farmers to prevent (or at least reduce) domesticated animals from grazing and will impact the environment by compelling farmers to find alternative ways to feed domesticated animals, including purchasing livestock feed.[127] Further, if farmers do not allow animals to

[123] *Id.* at 3,587 (§ 112.82).
[124] *Id.*
[125] *Id.* at 3,565 (§ 112.42(b)).
[126] *Id.* at 3,586.
[127] *See* Don Ball et al., Grazing Lands Conservation Initiative, *Extending Grazing and Reducing Stored*

graze, they may feed livestock in CAFOs. Confinement is likely to be a solution that some farmers adopt to separate domestic animals and agricultural water sources, and to prevent animals grazing in crop fields. The restrictions on domestic animals, therefore, create a preference for animal confinement, which farmers may deem to be an attractive alternative to otherwise burdensome limitations.

Despite FDA's claims that the requirements do not prohibit grazing, FDA is required to consider in its EIS all impacts that are not "remote and speculative." So, even if some farmers may not increase confinement of domestic animals, if it is reasonable to conclude that some may, then consideration of the environmental impacts of taking such measures is required.

b. Preference for Domestic Animal Confinement Creates Impacts to:

i. Water

FDA must take a hard look at the water impacts caused by a preference for domestic animal confinement over pastured practices. Confined animals living on CAFOs produce tremendous amounts of concentrated waste. Excess animal waste contaminates runoff and can degrade water resources, such as groundwater and surface water. Animal waste contains significant levels of phosphorus and nitrogen, which enter the water and contribute to low levels of dissolved oxygen, cause fish kills,[128] and contribute to toxic algae blooms.[129] Severe weather events can aggravate these problems by causing spillage of animal waste from CAFO manure lagoons. For example, in 1999, flooding by Hurricane Floyd resulted in catastrophic regional water contamination and livestock deaths throughout the tidewater region of North Carolina.[130] In addition to the waste issue, CAFOs require a significant amount of water for operation. Therefore, the preference may create additional water impacts, such as increased pollution and a strained water supply.

ii. Land

FDA must take a hard look at the land impacts caused by a preference for domestic animal confinement over pastured practices. These impacts may include deforestation and habitat destruction for animal grazing, raising feed crops, and soil erosion from conversion of pasture or prairie to row crops for feed grain production. Impacts may also include increased soil contamination if chemicals and pathogens are deposited on land in the vicinity of CAFOs. The enormous amount of animal waste generated by CAFOs is also likely to cause impacts.[131]

Feed Needs 1 (2008), *available at* http://agebb.missouri.edu/mfgc/2009extgraz.pdf (explaining that, as farmers are able to use grazing less, they rely more on livestock feeds).

[128] *How Do CAFOs Impact the Environment?,* EPA Region 7, http://www.epa.gov/region07/water/cafo/cafo_impact_environment.htm (last accessed Oct. 24, 2013).

[129] *Id.*

[130] *See* S. Wing et al., *The Potential Impact of Flooding on Confined Animal Feeding Operations in Eastern North Carolina*, 110 Envtl. Health Perspect. 387-91 (2002) (explaining the potential impact of flooding on confined animal feeding operations in eastern North Carolina).

[131] *See* section II.B.6.b.iv. of this document.

Moreover, farmers typically apply animal waste to fields, as manure. FDA should consider the land impacts due to stockpiles of animal manure that can no longer be composted or land-applied. The Rule itself contemplates animal excreta and requires farmers to locate manure piles away from locations where covered produce is grown or packaged.[132] However, when farmers allow manure on CAFOs to accumulate, the manure can contribute to the growth of dangerous organisms like Pfiesteria piscicida.[133] One way to more effectively manage manure in CAFOs is to compost and sell the manure, but as discussed above, the Produce Rule discourages composting.

iii. Air and Energy

FDA must take a hard look at the air and energy impacts caused by a preference for domestic animal confinement over pastured practices. These impacts may include increased air emissions due to the need to produce and import livestock feed and the need to transport away and dispose of animal waste. Impacts may also include air emissions resulting from the production of the petroleum-based pesticides used to grow additional livestock feed. The effects of transporting these crops to farms across the country are also likely to produce emissions. Finally, impacts are likely to include air pollution due to toxic releases from CAFOs, such as methane emissions, hydrogen sulfide, ammonia, and pathogen-laden dust.

iv. Animals

FDA must take a hard look at the impacts to animals caused by a preference for domestic animal confinement over pastured practices. These impacts may include restricting animals to a grain-fed diet, poor sanitation and disease, and the inability to express natural animal behaviors. Impacts may also include harm to aquatic life. Agricultural runoff containing phosphorus and nitrogen from animal waste may deplete oxygen levels in water and lead to fish kills.

v. Human Health

FDA must take a hard look at the human health impacts caused by a preference for domestic animal confinement over pastured practices, including:

- Human disease that is more virulent and difficult to treat, due to an increase in antibiotic-resistant bacteria and the transmission of pathogens from domestic animals to humans;[134]
- The transmission of antibiotic-resistant genes to soil bacteria where food is grown;[135]
- Increased respiratory problems and lung disease among farmworkers and neighbors due to dust and odors generated by CAFOs;[136]

[132] Produce Rule, 78 Fed. Reg. at 3,594 (§ 112.134).
[133] *See* Michael A. Mallin, Lawrence B. Cahoon, *Industrialized Animal Production—A Major Source of Nutrient and Microbial Pollution to Aquatic Ecosystems*, 24 Population & Env't 369, 378–79 (2003).
[134] Mary Gilchrist et al., *The Potential Role of Concentrated Animal Feeding Operations in Infectious Disease Epidemics and Antibiotic Resistance*, 115 Envtl. Health Perspectives 313 (2007).
[135] S. Jechalke, C. Kopmann, et al., *Increased Abundance and Transferability of Resistance Genes After Field Application of Manure From Sulfadiazine-Treated Pigs*, 79 Appl. Envtl. Microbiol. 1704-11 (2013).
[136] *How Do CAFOs Impact the Environment?,* EPA Region 7, http://www.epa.gov/region07/water/cafo/cafo_impact_environment.htm (last accessed Oct. 24, 2013).

- Increased incidence of heart disease, diabetes, and other degenerative diseases animals from increased consumption of CAFO-raised meat. Meat from animals raised in CAFOs likely have a less healthful balance of fatty acids than meat from grass-fed animals;
- Increased exposure of humans to pathogens for three reasons. First, pathogen survival increases with a field history of artificial fertilizer compared with manure and compost.[137] Second, a USDA comprehensive review indicates that *E. coli* is higher in cattle that are fed grain diets in CAFOs.[138] Third, more people encountering wastes and pathogens in their drinking water due to contamination of water resources.

10. FDA Must Consider the Land, Animal, and Human Health Impacts Created by the Preference for Wild Animal Exclusion.

a. Preference for Wild Animal Exclusion

The Rule, taken as a whole, creates a preference for farmers to exclude wild animals from outdoor growing areas because farmers may be unable to harvest affected produce where wild animal intrusion occurs and because it fails to protect conservation practices. The Rule requires farmers to monitor areas for animal intrusion and if intrusion occurs, evaluate whether produce can be harvested.[139] FDA's provisions for animal monitoring are triggered when the circumstances of the farm suggest it to be necessary (i.e., when animal excreta or other evidence of animal intrusion is present). FDA states that this provision "should not be construed to require the 'taking' of an endangered species, as the term is defined in the [ESA]" or to require farms to take measures to exclude animals from outdoor growing areas or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.[140]

To avoid the animal monitoring requirements of the Rule, farmers are likely to take actions that prevent animal intrusion, such as destroying habitat and clearing farm borders. These measures are likely to conflict with conservation efforts and the USDA Natural Resources Conservation Service's (NRCS) Conservation Practice Standards.[141] Farmers experiencing

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[137] E. Franz, A. V. Semenov et al., *Manure-Amended Soil Characteristics Affecting the Survival of E-Coli O157 : H7 In 36 Dutch Soils*, 10 Envtl. Microbiol. 313-27 (2008).
[138] *Id.*
[139] Produce Rule, 78 Fed. Reg. at 3,587 (§ 112.83).
[140] *Id.* at 3,587 (§ 112.83).
[141] *See* Natural Resources Conservation Service, Constructed Wetlands (#656); Wetland Restoration (#657); Wetland Creations (#658); Wetland Enhancement (#659); Fencing (#382) Prescribed Grazing (#528); Stream Habitat Improvement and Management (#395); Mulching (#484); Animal Trails and Walkways (#575); Restoration and Management of Rare and Declining Habitats (#643); Wetland Wildlife Habitat Management (#644); Upland Wildlife Habitat Management (#645); Shallow Water Development and Management (#646); Tailwater Recovery System (#447); Tillage Management Practices (#329, 344, 345, 346); Roof Runoff Structure (#558); Well Water Testing (#355); Monitoring Well (#353); and Integrated Pest Management (#595) *available at* http://www.nrcs.usda.gov/wps/portal/nrcs/detailfull/national/technical/?cid=nrcs143_026849; *See also* J.A. Baumgartner, *Farmer's Guide to Food Safety and Conservation: Facts, Tips, and Frequently Asked Questions*, Wild Farm Alliance and Community Alliance for Family Farmers, http://www.wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm (2013) (depicting many conservation practices NRCS provides).

significant intrusion of wild animals may take control measures that exclude or destroy *all* wild animals and their habitat, instead of only excluding those pest animals. Therefore, the monitoring requirements and threats to harvest create a preference for animal exclusion, which farmers may regard as preferable to monitoring. *See generally,* NSAC Rulemaking Comments at 90-98 (for more detailed discussion of wild animal exclusion).

Food safety policy and market changes may intensify habitat destruction and the loss of participation in conservation efforts.[142] Some farmers may be pressured to adopt these measures in response to purchasers and third-party auditors requiring habitat destruction. Purchasers that do not require habitat destruction may refrain from purchasing produce grown within hundreds of feet of wildlife habitat or conservation plantings. This practice, which currently occurs in the Salinas Valley, may further encourage farmers to destroy habitat. Personal interviews conducted with growers after the spinach contamination indicate that, in many cases, growers face serious ethical dilemmas and feel pressured by large processing and retail firms to adopt measures they find environmentally destructive and unethical.[143]

Despite FDA's claims that the Rule does not require farmers to take animal exclusion measures, FDA is required to consider in its EIS all impacts that are not "remote and speculative." So, even if some farmers may not take these measures, if it is reasonable to conclude that some may, then consideration of the environmental impacts of taking such measures is required.

b. Preference for Wild Animal Exclusion Creates Impacts to:

i. Land

FDA must take a hard look at the land impacts caused by a preference for wild animal exclusion. In the past, farmers have reacted to similar food safety requirements by taking measures that threaten habitat and wild animal populations. For example, a 2007 survey conducted by the Resource Conservation District of Monterey County in California's Central Coast region found that 89% of surveyed growers had adopted at least one measure to actively discourage or eliminate wild animal intrusion because of food safety concerns.[144] Examples of these measures include: removal of non-crop vegetation, elimination of conservation practices, bare ground buffers, fencing, trapping, poison bait traps, hunting, removal of water bodies, changing crop types, and changing crop locations. Farmers reported that some of their efforts resulted in the clearing of vegetation along stream corridors and other water bodies. These reports were corroborated by an aerial photography study of the Central Coast region conducted by the Nature Conservancy, which identified areas where habitats adjacent to water bodies were

[142] *See* D. Stuart and S. Gillon, *Scaling Up to Address New Challenges to Conservation on U.S. Farmland*, 31 Land Use Policy 223-36 (2013).
[143] D. Stuart, *Constrained Choice and Ethical Dilemmas in Land Management: Environmental Quality and Food Safety in California Agriculture*, 22 J. Agric. & Envtl. Ethics 53-71 (2009).
[144] Resource Conservation District of Monterey County, *A Grower's Survey: Reconciling Food Safety and Environmental Protection* (2007); M. Beretti, and D. Stuart, *Food Safety and Environmental Quality Impose Conflicting Demands on Central Coast Growers*, 62 California Agriculture 68-73 (2008); The Nature Conservancy, *Comments for FDA Docket (FDA-2010-N-0085)*, at 10 (July 23, 2010).

replaced by bare or sparsely vegetated ground. It is likely that farmers will engage in these measures in response to the Produce Rule.

Removing non-crop vegetation may create significant impacts to the environment, due to destruction of flora and fauna.[145] For instance, if non-crop vegetation is replaced with bare ground or crop vegetation not equivalent to the original non-crop vegetation, physical changes to the soil could occur, including increased erosion.[146] The removal of non-crop vegetation may also increase nutrient runoff, decrease soil fertility, and attract pests.[147] In addition, bare ground has been found to facilitate the movement of pathogenic organisms into nearby waterways[148] and certain vegetative buffers have been shown to reduce certain pathogens by at least 95 percent.[149]

ii. Animals

FDA must take a hard look at the impacts to animals caused by a preference for wild animal exclusion. Farmers taking wild animal exclusion measures will likely harm wild animals (including endangered animals) through the use of traps, poisoning, and hunting.[150] In addition, the fencing of fields may eliminate wild animal habitat to the extent that wild animals directly utilize fields for food, shelter, and breeding and are unable to do so after the imposition of fencing. Fencing may also indirectly eliminate wild animal habitat by restricting movement.[151] The removal of non-crop vegetation and the creation of bare ground buffers may have a similar effect on wild animal habitat by directly eliminating opportunities for food, shelter, and breeding and indirectly limiting the movement of species that need non-crop vegetation to travel.[152] These

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[145] *See* Robert J. Naiman et al., *The Role of Riparian Corridors in Maintaining Regional Biodiversity*, 3 Ecological Applications 209 (1993).
[146] *See* Kevin D. Reid et al., *Runoff and Erosion in a Piñion-Juniper Woodland: Influence of Vegetation Patches*, 63 Soil Sci. Soc'y of Am. J. 1869, 1876 (1999) (finding distinct runoff and erosion properties for different vegetative and bare ground patches).
[147] *See generally* Wei Zhang et al., *Ecosystem Services and Dis-services to Agriculture*, 64 Ecological Econ. 253, 255 (2007) (describing the use of non-crop vegetation in increasing soil fertility and in pest control). Many farmers use non-crop vegetation to improve soil fertility and to attract pests away from crops, or grow complementary crops to enhance crop yields. *See* David Tillman, *Global Environmental Impacts of Agricultural Expansion: The Need for Sustainable and Efficient Practices*, 96 Proc. Nat'l Acad. Sci. 5995, 5999 (1999) (explaining the positive effect of species diversity on agricultural productivity).
[148] *Food Safety Considerations for Conservation Planner: A Field Guide for Practitioners,* Resource Conservation District of Monterey County (2009), www.rcdmonterey.org.
[149] Gerald M. Sapers et al., *The Produce Contamination Problem: Causes and Solutions,* Academic Press 87 (2009); Kenneth W. Tate et al., *Significant Escherichia Coli Attenuation by Vegetative Buffers on Annual Grasslands*, 35 J. Envtl. Quality (2006): doi10.2134/jeg2005.0141.
[150] The Nature Conservancy, *Comments for FDA Docket (FDA-2010-N-0085)*, at 11 (July 23, 2010) (indicating that some farmers engaged in hunting and shooting, used poison to kill rodents, and trapped wildlife out of concern for food safety).
[151] *See* David K. Person & David H. Hirth, *Home Range And Habitat Use of Coyotes in a Farm Region of Vermont*, 55 J. Wildlife Mgmt. 433, 437 (1991) (finding seasonal use of open agricultural land by coyotes).
[152] *See* David N. Cherney, *Securing the Free Movement of Wildlife: Lessons from the American West's Longest Land Mammal Migration*, 41 Envtl. L. 599, 603 (2011) (discussing problems encountered by some migratory land animals due to fencing).

actions may have a disproportionate effect on wild animals that utilize riparian land.[153] In addition, substantial food safety management changes may impact regional water quality and the wildlife that depends upon it.[154] Because farmers have reported that conserving a wildlife corridor "dramatically reduced the pressure from wildlife—especially deer," on the crop, the destruction of wildlife corridors may increase contamination of produce by wildlife.

iii. Human Health

FDA must take a hard look at the human health impacts caused by a preference for wild animal exclusion. The impacts of clear-cutting or destruction of habitat may have negative public health effects. For instance, conservation buffers that serve as habitat can help with water purification,[155] flood control,[156] more available water, and the plentiful supply of food due to good pollination.[157] Vegetation[158] and grasses,[159] wetlands,[160] and windbreaks[161] can also reduce

[153] *See* Andrew F. Bennett et al., *Corridor Use and the Elements of Corridor Quality: Chipmunks and Fencerows in a Farmland Mosaic*, 68 Biological Conservation 155, 155 (1993) (finding the use of wooded fencerows adjacent to agricultural land by chipmunks for both residential habitat and movement corridors but identifying no such use for grassy land adjacent to agricultural land).
[154] D. Stuart, *Coastal Ecosystems and Agricultural Land Use: New Challenges on California's Central Coast*, 38 Coastal Management 42-64 (2010).
[155] Koelsch et al., *Vegetative Treatment Systems for Management of Open Lot Runoff: Review of Literature*, 22 Applied Engineering In Agriculture 141-153 (2006).
[156] Richard Lowrance et al., *Water Quality Functions of Riparian Forest Buffers in Chesapeake Bay Watersheds*, 21 Envtl. Mgmt 687-712 (1997).
[157] A. Brittain Klein, A et al., *Wild Pollination Services to California Almond Rely on Semi-Natural Habitat*, 49 J. Applied Ecology 723-732 (2012).
[158] Vegetation can help reduce the movement of pathogens across the farm by filtering pathogens, increasing infiltration of water into the soil, and serving as a structure for biological competition to take place. J.A. Baumgartner, *Farmer's Guide to Food Safety and Conservation: Facts, Tips, and Frequently Asked Questions*, Wild Farm Alliance and Community Alliance for Family Farmers (2013), *available at* http://www.wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm.
[159] Grasses and other types of vegetative buffers filter pathogens in runoff before they reach a pond or stream. The vegetation also slows surface water flow and allows for increased infiltration rates. Tate et al., *Significant Escherichia Coli Attenuation by Begetative Buffers on Annual Grassland*, 35 J. Envtl. Quality 795-805 (2006).
[160] Wetlands decrease pathogen levels due to increased oxygen levels in the water, antagonistic root exudates, and by fostering antagonism in biofilms. These processes that act to reduce pathogens in water work best when the water has a long residence time—it moves slowly through the vegetation—a proper hydraulic loading rate—the volume of water flowing through is suited to the size of the planted vegetation, and appropriate settling rates of suspended sediments. Hench et al., *Fate of Physical, Chemical and Microbial Contaminants in Domestic Wastewater Following Treatment by Small Constructed Wetlands*, 37 Water Research. 921-27 (2003); Diaz et al., *Efficacy of Constructed Wetlands for Removal of Bacterial Contamination From Agricultural Return Flows*, 97 Agric. Water Mgmt. 1813-21 (2012); Knox et al., *Efficacy of Natural Wetlands to Retain Nutrient, Sediment And Microbial Pollutants* 37 J. Envtl. Quality 1837-46 (2008).
[161] Windbreaks can intercept dust that may be carrying pathogens. When dust trapped on the leaves of a windbreak is exposed to sunlight and other desiccation effects, they help to destroy pathogens. H.K. Burley et al., *The Potential of Vegetative Buffers to Reduce Dust and Respiratory Virus Transmission From Commercial Poultry Farms*, 20 J. Appl. Poultry Research 210-22 (2011).

human exposure to pathogens.[162] The destruction of conservation buffers eliminates these beneficial public health functions.

11. FDA Must Consider the Animal Impacts of the Rule's Pest Control Requirements.

FDA must take a hard look at the animal impacts that result from the Rule, on its face, related to pest control. The Rule requires farmers to monitor for and exclude pests from fully-enclosed buildings, and prevent them from becoming established in partially-enclosed buildings.[163] This requirement may lead farmers to use pesticides or rodenticides to prevent animal intrusion. First and second generation rodenticides are typically used exclusively as control agents around structures, often having side effects of poisoning predatory wildlife. Of the 492 California non-target animals analyzed between 1995 and 2011, approximately 75% had residues of one or more rodenticide, and the overwhelming majority were from at least one second generation anticoagulant rodenticide.[164] Many species of raptors and four-footed predators have died, including the endangered San Joaquin kit fox,[165] the California fisher (a candidate for listing under the federal Endangered Species Act),[166] and the protected mountain lion. FDA must take a hard look at the impact of these pest-control requirements on wildlife, and potentially endangered or threatened species.

12. FDA Must Consider the Human Health Impacts of the Rule as a Whole.

FDA must take a hard look at the human health impacts of the Rule, taken as a whole. For instance, FDA should consider generally the Rule's impacts to food security or availability of fresh produce and the relationship to human health. By FDA's own admission, implementation of the Produce Rule as currently proposed will likely discourage the entry of new farmers into production, and will likely slow the growth of local food systems. Independent analysis and farmer testimony indicate that some current producers of vegetables, fruits, and value-added products would go out of business. This will likely reduce the availability of fresh produce to consumers, especially low income and senior citizens, and those who live in historically underserved areas (e.g., food deserts). Reduced consumption of fresh produce may aggravate the epidemics of childhood obesity, degenerative disease of elders, and type-2 diabetes at all ages. These effects may disproportionately impact the food-insecure. Thus, any regulation that makes it harder for farmers and food entrepreneurs to provide fresh produce and quality value-added foods will adversely impact the public health.

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[162] Rodent control efforts that potentially reduce biodiversity may also increase pathogen exposure. *See* C. Kilonzo et al., *Fecal Shedding of Zoonotic Food-Borne Pathogens by Wild Rodents in a Major Agricultural Region of the Central California Coast*, 79 Appl. Envtl. Microbiol. 6337-44 (2013).
[163] Produce Rule, 78 Fed. Reg. at 3,592 (§ 112.128).
[164] D. Daniels, *Second Generation Anticoagulant Rodenticides Memorandum*, Calif. Dept. of Pesticide Regulation (Sep. 19, 2012).
[165] S. McMillin *Anticoagulant Rodenticides: Secondary Poisoning of Wildlife in California*, California Department of Fish and Game, Powerpoint presentation (2012).
[166] M.W. Gabriel et al,, *Anticoagulant Rodenticides on our Public and Community Lands: Spatial Distribution of Exposure and Poisoning of a Rare Forest Carnivore*, 7 PLoS ONE: e40163. doi:10.1371/journal.pone.0040163 (2012).

In addition, FDA should consider the human health impacts from air pollution emissions generated by the additional energy expenditure that the Rule promotes (e.g., energy expenditure for soil amendment treatment). Similarly, FDA should consider the human health impacts from air pollution generated by the additional transportation that the Rule promotes (e.g., transportation of synthetic fertilizers).

C. FDA MUST CONSIDER CUMULATIVE IMPACTS IN THE EIS.

FDA must take a hard look at the cumulative impacts of the Rule to the environment in its EIS. The cumulative impacts of the Rule include the direct and indirect impacts of the Rule to the environment together with impacts caused by other agencies' actions, FDA's other pending actions, and the actions of private individuals. FDA should place special consideration on the Rule's cumulative impact to impaired resources and endangered animals across different regions of the United States. The scope of this analysis is broad because the Rule impacts farms across the United States and internationally.

1. FDA Must Consider the Cumulative Impacts to Water, Land, Air, Animals, and Human Health.

FDA must take a hard look at reasonably foreseeable cumulative impacts of the Rule to water, land, air, animals, and human health in its EIS, together with impacts caused by the following:

- Pollution from point and nonpoint sources such as municipal wastewater discharges, industrial and agricultural storm water discharges, CAFOs, and industrial and agricultural runoff;
- Impacts to 303(d) impaired waters where discharges already exceed the waters' assimilative capacity to absorb pollution;
- Brownfield contamination, habitat destruction and deforestation, land degradation, soil contamination, and litter and waste disposal;
- Groundwater depletion;
- Climate change; and
- Impacts to endangered species across different regions of the United States.

2. FDA Must Consider the Preventive Controls Rule.

FDA must take a hard look at the cumulative impacts to water, land, air, animals, and human health from the Rule, together with impacts caused by implementation of its Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Rule (Preventive Controls Rule).[167] Given that FDA has broadly defined the activities that result in an operation being considered a "facility," many farms will be subject to the Preventive Controls Rule. *See further,* NSAC Preventive Controls Rulemaking Comments.[168]

[167] 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).
[168] NSAC's Preventive Controls Rulemaking Comments, submitted in Docket No. FDA-2011-N-0920, on Nov. 15, 2013.

Compliance with the Preventive Controls Rule will be costly and some farms may decide to stop operating and sell their farms. The loss of farmland may result in development of that land for residential or commercial purposes. This development will likely result in impacts to wildlife habitat for threatened and endangered species, and impacts to greenhouse gas emissions from additional reliance on foods sourced more than 275 miles from the point of consumption.

FDA must consider the incremental impacts of the Produce Rule, in combination with the impacts of the Preventive Controls Rule. First, even if farms do not stop operating due to the exceptional expense imposed by the Preventive Controls Rule, the additional cost of compliance associated with the Produce Rule may require some farms to shut down. FDA must consider the impacts of these additional farms shutting down. Second, FDA must consider the additional environmental degradation imposed by the Produce Rule on top of any environmental impacts already imposed by the Preventive Controls Rule.

3. FDA Must Consider International Impacts.

FDA must take a hard look at the environmental impacts of foreign farms complying with the Produce Rule. The cumulative effects of foreign farms complying with the Produce Rule could be significant and potentially impact the United States as well as the global commons.

III. CONCLUSION

The Produce Rule will change farming practices across the United States and will necessarily have environmental impacts. Therefore, FDA must take a hard look at alternatives and mitigation measures to the proposed Rule in its EIS. Additionally, FDA must take a hard look at the direct, indirect, and cumulative impacts of the proposed Rule, as required by NEPA.