National Sustainable Agriculture Coalition

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RIN 0910-AG35

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

On behalf of the represented member organizations[1] of the National Sustainable Agriculture Coalition (NSAC), I submit the following comments on the Draft Environmental Impact Statement (EIS) for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

NSAC's work on the EIS process occurs through a subcommittee of NSAC members. NSAC partners Mindy Goldstein, Jennifer Lamb, Michael McClain, Vivian Wang, and Katherine Lee at the Turner Environmental Law Clinic at Emory University School of Law contributed significantly to these comments.

NSAC looks forward to continuing to work with the FDA to ensure that the FSMA regulations and their implementation are successful and supportive of sustainable agriculture and food systems.

Sincerely,

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Comments

on

FDA Produce Rule DEIS

Submitted by

National Sustainable Agriculture Coalition

Docket No. FDA-2014-N-2244

RIN 0910-AG35

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INTRODUCTION

The National Sustainable Agriculture Coalition (NSAC) welcomes the opportunity to submit these comments on the Draft Environmental Impact Statement (DEIS)[1] for the Food and Drug Administration's (FDA) proposed rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Rule).[2]

NSAC is an alliance of grassroots organizations from across the country that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities. NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and they have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainable agricultural systems. These organizations are invested in the development of a Produce Rule that both reduces the risks of foodborne illness and supports sustainable farm and food systems.

We appreciate FDA's engagement with the public throughout the rulemaking and National Environmental Policy Act (NEPA) process. As FDA is aware, NSAC has been an active participant. Specifically, on November 15, 2013, we submitted comments on the scope of the Produce Rule EIS (Initial Scoping Comments)[3] and comments on the proposed Produce Rule (Initial Rulemaking Comments).[4] On April 18, 2014, we submitted supplemental scoping comments on the Produce Rule EIS (Supplemental Scoping Comments).[5] On December 15, 2014, we submitted comments on FDA's Supplemental Proposed Produce Rule (Supplemental Rulemaking Comments).[6] We also provided oral testimony at the DIES Listening Session (attached as an appendix) on February 10, 2015. All of these comments are incorporated here by reference.

We believe the Produce Rule DEIS represents an important shift in FDA's thinking, recognizing the inextricable link between farming and the environment. We greatly appreciate FDA's efforts to undertake this assessment, though we have concerns with the sufficiency of the DEIS as currently written, which we describe in detail below. Despite the short timeline under which FDA must finalize the Produce Rule, it is our fervent hope that the comments FDA receives to the docket will result in an improved final EIS, and will truly inform the final Produce Rule standards. The NEPA

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[1] Draft Environmental Impact Statement for the Proposed Rule: Standards for Growing, Harvesting, Packing, and
[2] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3,504 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. pts. 16, 112) (Produce Rule); Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Supplemental Notice for Proposed Rulemaking, 79 Fed. Reg. 188 (proposed Sept. 29, 2014) (to be codified at 21 C.F.R 112) (Supplemental Produce Rule). The docket number for the Produce Rule is FDA-2011-N-0921 and the Regulatory Information Number (RIN) is 0910-AG35.

[3] NSAC, *Scoping Notice Comments on FDA Produce Rule*, submitted in Docket No. FDA-2011-N-0921, RIN 0910-AG35, on Nov. 15, 2013 (Initial Scoping Comments).

[4] NSAC, *Comments on the Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, submitted in Docket No. FDA-2011-N-0921, RIN 0910-AG35, on Nov. 15, 2013 (Initial Rulemaking Comments).

[5] NSAC, *Supplemental Scoping Notice Comments on FDA Produce Rule*, submitted in Docket No. FDA-2011-N-0921, RIN 0910-AG35, on Apr. 18, 2014 (Supplemental Scoping Comments).

[6] NSAC, *Comments on the Supplemental Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, submitted in Docket No. FDA-2011-N-0921, RIN 0910-AG35, on Dec. 15, 2014 (Supplemental Rulemaking Comments).

process plays a crucial role in informed agency decision-making. As the adage goes, "an ounce of prevention is worth a pound of cure." Not only does NEPA require a robust, genuine analysis of impacts and alternatives at the outset, but also FSMA's prevention-oriented approach surely supports taking the time necessary to ensure the EIS satisfies NEPA's mandate.

NEPA'S MANDATES

Under NEPA, an agency must prepare an Environmental Impact Statement (EIS) for any major federal action likely to significantly affect the quality of the human environment.[7] In its EIS, the agency must take a "hard look" at the environmental impacts.[8] This includes an analysis of reasonably foreseeable impacts to natural resources – such as water, land, and wildlife – as well as impacts to human health and communities.[9] Further, under NEPA, the agency must consider alternative courses of action it could undertake to avoid or mitigate such impacts.[10]

As stated by the Supreme Court, "[t]he NEPA EIS requirement serves two purposes. First, it ensures that the agency, in reaching its decision, will have available, and will carefully consider, detailed information concerning significant environmental impacts. Second, it guarantees that the relevant information will be made available to the larger audience that may also play a role in both the decision-making process and the implementation of that decision."[11] To satisfy these dual goals, FDA must set forth in the DEIS an in-depth analysis of the Produce Rule's impact on the environment and on farms and communities, particularly small- and mid-sized farms that face a disproportionately large burden to come into compliance with the new rules.

Unfortunately, the DEIS falls short of NEPA's mandate. In Chapters 1 and 2, FDA claims the DEIS analyzes the environmental impacts of several key provisions of the Produce Rule, including: (1) Subpart A, defining which farmers should be obligated to comply with the Rule; (2) Subpart E, establishing a standard for the quality of water used to irrigate produce; (3) Subpart F, determining how biological soil amendments may be applied to produce fields; and (4) Subpart I, adopting measures to reduce food safety risk from animal intrusion into produce fields.[12] In Chapters 4 and 5, however, FDA fails to adequately conduct the analysis it promised. Instead of taking a "hard look," FDA significantly underestimates – and at times, overlooks entirely – the direct, indirect, and

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[7] 42 U.S.C. § 4332(2)(C)(i).

[8] *See* 40 C.F.R. § 1502.16, (adopted by FDA at 21 C.F.R. § 25.42(a)(1)); Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 348 (1989) (NEPA "establishes 'action-forcing' procedures that require agencies to take a 'hard look' at environmental consequences."); Sierra Club v. Marsh, 976 F.2d 763, 767 (1st Cir. 1992) ("those effects that are likely or foreseeable need to be discussed"); Ctr. for Biological Diversity v. U.S. Dep't of Interior, 623 F.3d 633, 646 (9th Cir. 2010) (holding the agency violated its duties under NEPA when it failed to take a hard look at the environmental consequences of a proposed land exchange).

[9] Sierra Club v. Marsh, 976 F.2d 763, 767 (1st Cir. 1992) ("those effects that are likely or foreseeable need to be discussed").

[10] 42 U.S.C. § 4332(2)(E), 40 C.F.R. § 1502.1

[11] U.S. Dep't. of Transp. v. Pub. Citizen, 541 U.S. 752, 768 (2004) (internal citations omitted); *see also* Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 349 (1989) ("Simply by focusing the agency's attention on the environmental consequences of a proposed project, NEPA ensures the important effects will not be overlooked or underestimated only to be discovered after resources have been committed or the die otherwise cast … Publication of an EIS, both in draft and final form, also … provides a springboard for public comment").

[12] 79 Fed. Reg. 188 at 58436 (Subpart A), 58441 (Subpart E), 58457 (Subpart F), and 58463 (Subpart I); DEIS at ES-8 to ES-13.

cumulative impacts to water, air, soil, biological and ecological resources, and human health caused by the Produce Rule.

Specifically, the DEIS fails to satisfy NEPA by:

- Failing to consider certain reasonable alternatives to the Produce Rule provisions and certain actions FDA could take to mitigate the Rule's environmental impacts. We set forth a more detailed explanation of this in Part I of these comments.

- Ignoring certain impacts of the Produce Rule altogether by applying an improper test for determining the significance of an environmental impact, segmenting the analysis of the Rule's impacts on individual resources, failing to consider the cumulative impacts of the Rule, and ignoring impacts to certain groups of people and resources. We set forth a more detailed explanation of this in Part II of these comments.

- Failing to take a "hard look" at certain impacts of the Produce Rule by improperly assuming that compliance with other laws or speculative management decisions by farmers will mitigate environmental harm. We set forth a more detailed explanation of this in Part III of these comments.

By ignoring or underestimating the impacts of the Produce Rule, the DEIS fails to fully ensure informed agency decision-making and promote effective public participation. As a result, FDA may adopt the Produce Rule as proposed – committing valuable resources and causing irreversible environmental impacts – before its effects are properly evaluated. At that time, it will be too late to change course.

Accordingly, NSAC respectfully requests that FDA make significant changes to the final EIS to ensure that the EIS takes the requisite "hard look" at the direct, indirect, and cumulative impacts of the Produce Rule; alternatives to the Produce Rule; and measures that FDA can take to mitigate its impacts. We look forward to continuing to work with FDA on these important revisions.

I. THE DEIS FALLS FAR SHORT OF NEPA'S REQUIREMENTS BY FAILING TO CONSIDER CERTAIN REASONABLE ALTERNATIVES TO PRODUCE RULE PROVISIONS AND ACTIONS FDA CAN UNDERTAKE TO MITIGATE ENVIRONMENTAL IMPACTS.

NEPA requires an agency to consider in its EIS all reasonable alternatives to its proposed action, including the "no-action" alternative and a range of action alternatives.[13] This analysis is important; indeed, the meaningful analysis of alternatives is the heart of the EIS.[14] Because of its importance, a cursory listing of hypothetical and speculative alternatives is insufficient. In fact, courts have repeatedly held that an agency must analyze mitigation alternatives with sufficient detail and analytical support to ensure that environmental consequences have been fairly and fully evaluated.[15]

[13] 40 C.F.R. § 1502.14 (adopted by FDA at 21 C.F.R. § 25.10(a)).
[14] *Id.* ("This section is the heart of the environmental impact statement.").
[15] *Methow Valley Citizens Council*, at 351 (1989) ("One important ingredient of an EIS is the discussion of steps that can be taken to mitigate adverse environmental consequences"); Okanogan Highlands Alliance v. Williams, 236 F.3d 468, 473

In the DEIS, FDA's alternatives and mitigation analyses fall short of NEPA's mandate in three critical ways. First, FDA fails to consider reasonable alternatives put forth by NSAC and other commenters during the public comment periods. Second, FDA's discussion of alternatives to the proposed agricultural water provision of the Produce Rule (Subpart E) fails to meaningfully consider the environmental impacts of an alternative provision that includes drip-irrigated root crops. Third, FDA fails to consider reasonable mitigation measures that it could undertake to reduce the environmental impact of the Produce Rule. This section treats each of these issues in turn.

A. The DEIS Fails to Consider Reasonable Alternatives Set Forth in NSAC's Scoping and Rulemaking Comments.

In the DEIS, FDA fails to consider several reasonable alternatives raised by NSAC and other commenters to reduce the environmental impact of the Produce Rule.[16] When public comments call the agency's attention to a reasonable alternative to a proposed action, the agency must analyze the environmental impacts of that alternative in its EIS.[17]

FDA should have analyzed the environmental impacts of developing a microbial water quality standard for agricultural water as opposed to adopting EPA's recreational water standard in the Produce Rule. NSAC and other commenters have repeatedly requested that FDA take the time to develop an appropriate microbial water standard for agricultural water instead of adopting EPA's ill-fitting recreational water standard.[18] Taking this approach is more consistent with FSMA's mandate to develop an appropriately flexible and risk- and science-based standard for agricultural water.[19] Moreover, developing such a standard significantly reduces the likelihood that the Produce Rule will have negative impacts on the environment because: (1) a flexible, region-specific standard that is

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(9th Cir. 2000) (explaining that "a "mere listing" of mitigating measures, without supporting analytical data . . . is inadequate" under NEPA). Further, mitigation measures must not be hypothetical or speculative. NEPA Law and Litig. § 8:57 (2014) (citing Ohio Valley Envtl. Coal. v. Aracoma Coal Co., 556 F.3d 177 (4th Cir. 2009)).

[16] *See generally* NSAC, *Rulemaking Comments* (Nov. 15, 2013); NSAC *Supplemental Rulemaking Comments* (Dec. 15, 2014); National Association of State Departments of Agriculture (NASDA), *National Association of State Departments of Agriculture Comments on Proposed Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (posted online Dec. 22, 2014); United Fresh, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption - Supplemental Notice of Proposed Rulemaking* (Dec. 15, 2014); Organic Trade Association, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Dec. 15, 2014).

[17] *See* Dubois v. U.S. Dep't of Agric., 102 F. 3d 1273, 1291 (1st Cir. 1996) ("In respect to alternatives, an agency must on its own initiative study all alternatives that appear reasonable and appropriate for study at the time, and must also look into other significant alternatives that are called to its attention by other agencies, or by the public during the comment period afforded for that purpose," *quoting* Seacoast Anti-Pollution League v. Nuclear Reg. Comm., 598 F. 2d 1221, 1230 (1st Cir. 1979)).

[18] NSAC, *Rulemaking Comments* at 66 (Nov. 15, 2013); NSAC, *Supplemental Rulemaking Comments* at 28-29 (Dec. 15, 2014); NSAC, *Produce Rule Comments* at 66 (Nov. 15, 2013); *NSAC Supplemental Produce Rule Comments* at 28-29 (Dec. 15, 2014); National Association of State Departments of Agriculture (NASDA), *National Association of State Departments of Agriculture Comments on Proposed Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* at 10-11 (posted online Dec. 22, 2014) (calling for research to develop a water standard for growing produce); United Fresh, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption - Supplemental Notice of Proposed Rulemaking* at 5 (Dec. 15, 2014) (recommending that water testing provisions reside in guidance); Organic Trade Association, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* at 3-4 (Dec. 15, 2014) (expressing that the water standard should be issued in guidance if the scientific evidence behind the standard is inconclusive).

[19] *See* NSAC, *Rulemaking Comments* at 64-66.

developed for agricultural water is less likely to be over-inclusive, thus affecting fewer farmers and allowing those farmers that are affected to avoid more extreme or expensive management decisions to achieve compliance; and (2) farmers will be able to consider their local environment in determining the best manner to keep agricultural water safe.[20] As a result, farmers will be less likely to pursue environmentally harmful measures, such as irrigating with groundwater or chemically treating their water source.[21] Further, this standard is also likely to have fewer impacts for human health and safety, as fewer agricultural workers will be exposed to harmful chemicals.[22] Because compliance with this standard would likely be less expensive, it also allows more farmers to continue to provide consumers with economically priced, healthy food choices.[23] In its DEIS, FDA should have analyzed the environmental impacts associated with adopting a standard designed by FDA specifically for agricultural water.

FDA should have analyzed the environmental impacts of developing a manure standard that appropriately accounts for application of biological soil amendments that fall between fresh manure and composted material, such as the application of aged manures.[24] NSAC strongly supports FDA's decision to move forward with a research agenda to establish a risk- and science-based standard for manure that considers the source and type of manure, the method of application, climatic conditions, type of commodity, and soil characteristics.[25] However, in the DEIS, FDA fails to consider developing a more flexible manure standard that appropriately accounts for the risks created by passive composting methods, such as aged manure or agricultural teas.[26] Creating a clear regulatory framework to allow for application of passive composting products alleviates some of the pressure on farmers to store or dispose of manure.[27] Thus, this option serves to mitigate some of the environmental impacts to water, soil, biological and ecological resources, waste disposal, and air likely to result from on-site manure storage.[28] In its DEIS, FDA should have analyzed the environmental impacts associated with developing a flexible manure standard that appropriately addresses passive composting practices.

FDA should have analyzed the impacts of codifying language to promote co-management and actively guard against habitat destruction. NSAC suggested in its comments certain proactive provisions to encourage co-management and to protect against habitat destruction.[29] In its DEIS, FDA should have analyzed the environmental impacts associated with these alternative provisions.[30]

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[20] *Id.*
[21] DEIS at 4-23 and 4-24.
[22] *Id.* at 4-35.
[23] *See* Part II.D.2 to 4.
[24] NSAC, *Supplemental Rulemaking Comments* at 35.
[25] 79 Fed. Reg. 58460.
[26] *See* DEIS at 4-40, 4-61.
[27] *Id.* at 4-44.
[28] *Id.* at 4-40 to 4-53.
[29] NSAC, *Supplemental Rulemaking Comments* at 40-41.
[30] As discussed in more detail in Part II.D.1., FDA assumes that its proposed language in § 112.84 is sufficient to prevent the destruction of habitat (and, presumably, the language proposed by NSAC is therefore not needed). *See* DEIS at 4-73, 4-74. However, § 112.84, as currently proposed, may not go far enough. The proposed provision simply *does not authorize or require* covered farms to take actions that would harm endangered species or destroy animal habitat. *See* DEIS at ES-

Failure to address in the DEIS those primary alternatives suggested through public comment directly undermines one of the critical goals of NEPA: allowing the public to play a role in the consideration and implementation of a major federal action.[31] NSAC's genuine and continued participation throughout the comment process further supports the consideration of its proposed alternatives.[32] As demonstrated above, each of the alternatives proposed by NSAC serves to mitigate the environmental impacts of FDA's Produce Rule. FDA's failure to assess these alternatives renders the DEIS inadequate.

B. The DEIS Fails to Take a Hard Look at the Impacts of an Alternative Agricultural Water Standard that Includes Drip-Irrigated Root Crops.

NSAC has repeatedly expressed its support for a water standard that excludes drip-irrigated root crops.[33] However, FDA fails to make clear in its proposed Produce Rule or Supplemental Rule that it will actually exclude drip-irrigated root crops from compliance with the water standard. Such confusion is perpetuated in the DEIS.

In the DEIS, FDA conducts its proposed alternatives analysis for the water standard exclusive of root crops.[34] FDA then notes that the environmental impacts of including root crops in the water standard would have "similar but slightly greater" effects.[35] Such a brief statement is inadequate; it fails to meaningfully analyze the considerable local and regional effects of sweeping drip-irrigated root crop production under the standard.[36] An appropriate analysis would instead look closely at the direct, indirect, and cumulative impacts caused by farmers changing irrigation water sources or increasing chemical treatment of agricultural water to comply with the water standard.[37] To the extent that the final Rule includes drip-irrigated root crops in the water standard (a result NSAC strongly discourages), the DEIS provides an inadequate assessment of the Rule's environmental impact.

C. The DEIS Fails to Consider Mitigation Measures It Could Undertake to Reduce the Environmental Impact of the Produce Rule.

NSAC commends FDA for its inclusion of a mechanism to account for microbial die-off before harvest as a means to mitigate the environmental impact of the water standard and provide flexibility to farmers faced with an otherwise inappropriate water quality standard.[38] However, FDA's analysis

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11. But, *not requiring* certain actions is not the same thing as *expressly prohibiting* them. And, the environmental impacts associate with both versions of the provision should have been analyzed in the DEIS.

[31] *See* Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 349 (1989) ("Publication of an EIS, both in draft and final form. . . provides a springboard for public comment").

[32] *See* Dubois v. U.S. Dep't of Agric., 102 F. 3d 1273, note 21 (1st Cir. 1996) (in deciding whether an agency has adequately studied all reasonable alternatives, a reviewing court may consider the extent and sincerity of the public's participation).

[33] NSAC, *Supplemental Rulemaking Comments* at 33.

[34] DEIS at 4-40.

[35] *Id.*

[36] *See* Part II.A.

[37] *See* DEIS at 4-243, 4-24.

[38] *See id.* at 4-37 to 4-38.

of mitigation alternatives still falls short for the water standard (and other provisions of the Rule) by relying solely on mitigation activities that can be undertaken by farmers, rather than actions of FDA itself.[39] Because FDA does not control the actions of farmers (nor has it tried to influence or encourage such actions through incentives or other requirements),[40] these actions are speculative at best. NEPA prohibits agencies from relying upon such speculative mitigation measures.[41] Further, focusing entirely on farmer management decisions impermissibly shifts the agency's burden to mitigate the impacts of its actions onto affected farmers. Instead, FDA must provide a reasoned discussion, supported by analytical data, of mitigation measures within its control.[42]

II. THE DEIS FAILS TO SATISFY NEPA BY IGNORING CERTAIN IMPACTS ALTOGETHER.

In the DEIS, FDA ignores certain impacts altogether by: (1) adopting a narrower test for significance than the test clearly required by its own regulations; (2) segmenting the Rule into smaller separate actions and treating the environmental impacts of those actions on each resource separately; (3) failing to place the Rule in its proper context of past, present, and reasonably foreseeable future actions; and (4) excluding impacts to particular groups and resources entirely from its analysis. This section addresses each of these inadequacies in turn.

A. The DEIS Adopts an Incorrect and Limited Test for "Significant Impacts."

NEPA requires agencies to prepare a "detailed statement . . . on the environmental impacts" of all "major federal actions *significantly* affecting the quality of the human environment."[43] The required content of an EIS is therefore determined by what impacts are termed as "significant." FDA regulations establish an exhaustive two-pronged test for identifying those significant impacts, which requires the agency to consider both the context of the action and the intensity of its effects.[44] Under the context prong, the agency must consider local and regional effects, and short- and long-term effects.[45] In assessing intensity, the test provides – among other factors – that the agency must consider effects that exist even if the agency believes that on balance those effects will be beneficial, effects that are highly uncertain or unknown, and individually insignificant effects that may have a cumulative impact.[46]

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[39] *See, e.g., id.* at 4-25, 4-26, 4-33, 4-36. For a specific enumeration of some of these management decisions, *see* Part III.B.

[40] *See* Part I.A.

[41] *See* NEPA Law and Litig. § 8:57 (2014) (citing Ohio Valley Envtl. Coal. v. Aracoma Coal Co., 556 F.3d 177 (4th Cir. 2009)) ("mitigation measures cannot be hypothetical or speculative").

[42] Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 351 (1989) ("One important ingredient of an EIS is the discussion of steps that can be taken to mitigate adverse environmental consequences"); Okanogan Highlands Alliance v. Williams, 236 F.3d 468, 473 (9th Cir. 2000) (explaining that "a "mere listing" of mitigating measures, without supporting analytical data . . . is inadequate" under NEPA). The failure of FDA to take a hard look at actions it might undertake to mitigate environmental impacts is even more egregious given the suggestions from NSAC and other commenters of viable mitigation options, like those discussed above in Part I.A above.

[43] 42 U.S.C. § 4332(2)(C)(i) (emphasis added).

[44] 40 C.F.R. § 1508.27 (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).

[45] *Id.*

[46] *Id.* at § 1508.27(b).

Deviating sharply from its own regulations, FDA constructs an alternate test for significance that more narrowly defines the impacts that must be considered.[47] Specifically, FDA defines "significant impacts" as *only those* that are "readily apparent; the overall impacts may be the result of a deliberate or essential shift in management practices, which may cause an overall substantial beneficial or adverse consequence."[48] The DEIS goes on to find "no significant impacts" where "there would be minimal, moderate, or no measurable changes to the environment or resource component investigated," or where impacts could be "mitigated to avoid permanent impacts to the resource."[49] By creating this new, stricter standard for "significance," FDA overlooks many environmental impacts that should have been considered in the DEIS.

1. The DEIS Ignores Certain Impacts from Subpart E: Agricultural Water Standards.

FDA's NEPA regulations require consideration of "both short- and long- term effects."[50] In its analysis for Subpart E, FDA acknowledges that the agricultural water standards could cause farmers to use chemical treatments to bring water into compliance with the Rule.[51] However, FDA states that the increased use of chemical treatments – which can form toxic byproducts – will have no significant impact because "the effects may be reversible and are not permanent."[52] This analysis impermissibly ignores the potentially significant short-term impacts associated with the increased use of chemical water treatments.

FDA's NEPA regulations further require that the agency consider effects that are both beneficial and adverse.[53] FDA conflates these requirements when it wrongly concludes that there will be no impacts to agricultural worker health caused from increased exposure to chemicals used to treat agricultural water. According to FDA, this is so because the Produce Rule will result in a net benefit to public health through enhanced food safety.[54] We find it hard to believe, and quite concerning, that FDA would claim that a net benefit in public health could somehow cancel out the very real health hazards that farm workers face. FDA must separately acknowledge impacts to worker health and propose measures the agency may undertake to mitigate these impacts.[55]

2. The DEIS Ignores Certain Impacts from Subpart F: Biological Soil Amendments.

As noted above, FDA regulations require consideration of "both short- and long- term effects."[56] In its analysis for Subpart F, FDA states that although the biological soil amendment (BSA) standards

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[47] DEIS at 4-3, 11-8, and 11-9.
[48] *Id.* at 4-3.
[49] *Id.* at 4-3 to 4-4. FDA uses this standard for water resources and biological and ecological resources. For air quality and greenhouse gases, FDA says that an impact will not be significant if it can be "adequately mitigated using existing practices."
[50] 40 C.F.R. § 1508.27(a) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).
[51] DEIS at 4-18, 4-21, 4-37, 4-39.
[52] *Id.* at 4-39.
[53] 40 C.F.R. § 1508.27(b)(1) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).
[54] DEIS at 4-35.
[55] Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 351 (1989).
[56] 40 C.F.R. § 1508.27(a) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).

may cause farmers to switch to chemical fertilizers, the resulting impacts to soil health are not significant because they are reversible.[57] This analysis improperly ignores the potentially significant short-term soil health impacts, and the long-term impacts that degraded soil has on other biological and aquatic resources, that could result from the increased use of chemical fertilizers.

Additionally, NEPA requires consideration of potentially significant effects not only nationally, but also at the local and regional levels.[58] However, in its analysis for Subpart F, FDA improperly dismisses potentially significant impacts of the biological soil amendment standard on the basis that these impacts would not occur on a national scale. For example, FDA states that many impacts from Subpart F will be insignificant because of the relatively small percentage of farmers who use BSAs nationally.[59] This analysis does not account for the fact that BSA users may be regionally or locally concentrated, and the standard could cause a significant local or regional impact. FDA also states that although a required application interval for BSAs of animal origin would lead to increased storage and transportation of manure, the resulting increase in emissions of particulate matter, greenhouse gases (GHGs), and ozone precursors are not significant because they would be localized.[60] This analysis again directly contravenes FDA's obligation to consider local and regional impacts, and thus impermissibly ignores the potentially significant impacts that could result from the increased storage and transportation of manure.

And, as with the agricultural water standard discussed above, FDA misapplies the consideration of both beneficial and adverse effects in its assessment of public health impacts from the BSA standard.[61] FDA acknowledges that workers will face increased chemical exposure in application of chemical inputs.[62] Yet the DEIS weighs the impacts on these workers against the public health benefits of the Rule.[63] As a result, FDA fails to consider that the effects to workers may be significant, even if there is an overall health benefit from pathogen reduction. Again, FDA must separately acknowledge the risks posed to agricultural workers and propose activities the agency can undertake to mitigate these impacts. Failure to do so treats farm worker health as somehow separate from public health, and sacrifices the health of farm workers to further the good of the consuming public. This would be an unconscionable result.

3. The DEIS Ignores Certain Impacts from Subpart I: Standards Directed to Domesticated and Wild Animals.

FDA's NEPA regulations require consideration of "both short- and long- term effects."[64] However, in its analysis for Subpart I, FDA dismisses short-term or reversible impacts as insignificant in two places. First, FDA states that although requiring a waiting period for harvesting after the intrusion of domesticated animals on crop areas would result in more concentrated livestock (and therefore soil compaction and more concentrated waste runoff), the impacts are not significant because they

[57] DEIS at 4-57.
[58] 40 C.F.R. § 1508.27(a) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).
[59] DEIS at 4-45 (water), 4-55 (air quality), 4-56 (human health and safety), 4-57 (water).
[60] *Id.* at 4-54.
[61] *Id.* at 4-56.
[62] *Id.*
[63] *Id.*
[64] 40 C.F.R. 1508.27(a) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).

are short-term.[65] Second, FDA states that although requiring farmers to wait an appropriate length of time to harvest produce after evidence of wild animal intrusion may result in an increased use of herbicides, rodenticides, and other chemicals to exclude wildlife, the impacts are not significant because the chemical components last a short-term after application.[66] FDA's analysis in these two instances impermissibly ignores the potentially significant short-term impacts to water, soils, and biological and ecological resources that could result from the standards under Subpart I.

FDA also fails to consider regional and local effects of the proposed provisions regarding grazing in produce fields.[67] FDA correctly acknowledges that the exclusion of animals from grazing in produce fields may require farmers to restrict animals to other pastures or to confine animals in feedlots,[68] echoing a concern raised in NSAC's scoping comments.[69] However, because the standard would apply to "only a small amount of produce," FDA does not consider the effect of increased manure accumulation and disposal to be significant.[70] Similarly, FDA recognizes that increased animal confinement may result in increased particulate matter emissions from manure storage and farms transitioning to chemical pesticides, but dismisses the impact because of the relatively small number of farms likely to be affected.[71] In reaching these conclusions, FDA abdicates its responsibility to consider the regional and local impacts of its Rule.

B. The DEIS Impermissibly Segments the Rule.

When evaluating the potential environmental impacts of a proposed action, NEPA prohibits an agency from labeling a particular action as insignificant "by breaking it down into small component parts."[72] As numerous courts have found, this "prevent[s] agencies from dividing one project into multiple individual actions each of which individually has an insignificant environmental impact, but which collectively have a substantial impact."[73] To that end, in a single EIS, reviewing agencies must consider all "connected actions" – including those actions that are "interdependent parts of a larger action and depend on the larger action for their justification."[74]

FDA considers the impacts to water, soil, biological and ecological resources, and air separately in the DEIS for standards directed to agricultural water (Subpart E), standards directed to biological soil amendments of animal origin (Subpart F), and standards directed to domesticated and wild animals (Subpart I) of the Produce Rule. Although FDA makes an effort to unify its segmented analyses at the end of Chapter 4 of the DEIS,[75] this section merely restates the conclusions from

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[65] DEIS at 4-67.
[66] *Id.* at 4-75.
[67] *Id.* at 4-70 to 4-71.
[68] *Id.* at 4-70.
[69] NSAC, *Initial Scoping Comments*, at 26-28.
[70] DEIS at 4-70
[71] *Id.* at 4-71.
[72] 40 C.F.R. § 1508.27(b)(7) (adopted by FDA at 21 C.F.R. § 25.10 5(a)(19)).
[73] *See e.g.,* Del. Riverkeeper Network v. FERC, 753 F.3d 1304, 1314 (D.C. Cir. 2014) (internal quotation marks omitted) (holding that FERC violated NEPA by impermissibly segmenting its environmental review).
[74] 40 C.F.R. § 1508.25(a)(1)(3) (adopted by FDA at 21 C.F.R. § 25.10(a)).
[75] DEIS at 4-88 to 4-95.

Sections 4.2 through 4.6 of the DEIS sequentially, without providing an assessment of the entire, collective impact all the various provisions of the Produce Rule have on each individual resource.

This structure of the DEIS – segmenting the Rule into singular provisions and analyzing impacts on individual resources separately for each provision – leads FDA to underestimate the Rule's complete environmental impacts on water, soil, biological and ecological resources, and air quality.

Water. FDA claims that there will be no adverse impacts to water related to Subpart F's standards for BSAs or Subpart I's standards for wildlife intrusion.[76] Further, though FDA recognizes that the agricultural water standards in Subpart E could cause significant impacts related to groundwater drawdown, FDA claims that impacts to groundwater quality and water availability will not be significant, despite recognizing that Subpart E could cause increased pesticide use.[77] However, FDA fails to adequately consider the impacts to water of the entire Rule, considered in the aggregate. FDA must take a hard look at the overall impacts to water quality that could result from the combination of increased pesticide use, animal confinement or other exclusionary measures, and decreased water availability.

Soil. FDA does not consider at once all the effects of each subpart of the Produce Rule that could lead to a decrease in soil health.[78] In its separate analyses for Subparts E and F, FDA acknowledges that both subparts could cause short-term impacts to soils, primarily from increased chemical fertilizer and pesticide use.[79] Similarly, FDA finds that Subpart I could cause short-term impacts to soils because of increased soil compaction and nutrient run-off.[80] However, at the end of Chapter 4 of the DEIS, where FDA purports to consider the impacts of all these subparts together, FDA only considers the impacts to soils from Subpart F.[81] FDA must consider the aggregate impacts to soils that could result from all of the Rule's subparts, particularly the combined impact of increased soil compaction, nutrient run-off, chemical fertilizers, and pesticides.

Biological and Ecological Resources. FDA does not consider the aggregate effects of each subpart of the Produce Rule that could cause a degradation of ecosystems or wildlife diversity.[82] In its analysis of the agricultural water standards under Subpart E, FDA finds that, although the standards could increase chemical water treatment and degrade surface and groundwater quality, the standards will not significantly impact biological and ecological resources.[83] For Subpart F, FDA finds that the standards for BSAs could cause minimal but not significant impacts from increased chemical fertilizer use, peat mining, and runoff from manure storage.[84] Finally, for Subpart I, FDA states that there could be minimal impacts from increased herbicides, rodenticides, and pesticide use, land

[76] *Id.* at 4-74 (wildlife intrusion) and 4-89 (BSAs).
[77] *Id.* at 4-81, 4-89.
[78] *Id.* at 4-90.
[79] *Id.* at 4-57
[80] *Id.* at 4-70.
[81] *Id.* at 4-90.
[82] *Id.* at 4-89 to 4-90.
[83] *Id.* at 4-37 to 4-38.
[84] *Id.* at 4-46 to 4-48.

clearing, hunting and trapping, and the disruption of wildlife corridors.[85] However, in its purported analysis of the cumulative impacts of these subparts, FDA merely restates its conclusions from each individual subpart, and does not consider that there could be a significant impact to biological and ecological resources when all the Produce Rule standards are taken together.[86] In particular, FDA must consider the aggregate impacts to biological and ecological resources that could result from increased chemical use, land clearing, hunting and trapping, peat mining, and nutrient runoff caused by the Produce Rule.

Air Quality. FDA does not consider the aggregate impacts from each subpart of the Produce Rule that could lead to local, regional, or national increases in GHGs, particulate matter, and ozone precursor emissions.[87] FDA admits that there could be small, localized increases in emissions from each of Subparts E, F, and I.[88] However, in its analysis for all these subparts together, FDA merely states that "[t]here are minimal adverse impacts … associated with air quality and greenhouse gases."[89] Through this conclusory statement, FDA fails to consider that the small, localized increases in air emissions from each subpart could, in the aggregate, lead to significant impacts. FDA must assess these impacts in the DEIS.

C. The DEIS Fails to Include a Meaningful Cumulative Impacts Analysis.

When evaluating the potential environmental impacts of a proposed action, NEPA requires agencies to consider "[c]umulative actions, which when viewed with other proposed actions have cumulatively significant impacts."[90] This is because some actions may cause significant environmental impacts only when viewed in conjunction with all other related actions.[91]

Thus, to satisfy NEPA's mandates, agencies are required to take a hard look at "the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time."[92]

Chapter 5 of the DEIS contains FDA's cumulative impacts analysis for the Produce Rule.[93] While citing to the correct regulations,[94] the DEIS nevertheless inadequately considers a number of significant cumulative environmental effects. Specifically, FDA unreasonably limits the foreseeable future impacts it considers in the DEIS, fails to consider impacts of the Rule taken together with impacts from other regulations promulgated under FSMA, impermissibly relies on the speculative

[85] *Id.* at 4-75 to 4-76.
[86] *Id.* at 4-89 to 4-90.
[87] *Id.* at 4-91.
[88] *Id.* at 4-33 (Subpart E), 4-53 (Subpart F), 4-71 (Subpart I).
[89] *Id.* at 4-91.
[90] 40 C.F.R. 1508.25(a)(2) (adopted by FDA at 21 C.F.R. § 25.5(a)(18)).
[91] 40 C.F.R. § 1508.27(b)(7) (adopted by FDA at 21 C.F.R. § 25.5(a)(19)).
[92] 40 C.F.R. § 1508.7 (adopted by FDA at 21 C.F.R. § 25.5(a)(3)).
[93] DEIS at 5-1 to 5-30.
[94] *Id.* at 5-1.

management decisions of farmers to mitigate cumulative impacts, and fails to consider local and regional cumulative effects of the Produce Rule over time.

1. The DEIS artificially limits the reasonably foreseeable future impacts of the Rule.

In the DEIS, FDA artificially limits the "reasonably foreseeable future" impacts it considers to those impacts arising within the six-year period following promulgation of the Produce Rule.[95] While there is no regulatory standard for the length of time an agency must consider in its assessment of cumulative impacts, its decision must be reasonable – i.e. the agency must consider the "relevant factors" and demonstrate a "rational connection between the facts found and the choice made."[96]

In the DEIS, FDA made no showing that the reasonably foreseeable future impacts of the Produce Rule should be limited to this six-year window. Indeed, the only rationalization provided for this limited time-frame is that it reflects the date by which all farms must come into compliance with the Produce Rule's requirements.[97] But that date marks the *beginning* of when the complete impacts from the Produce Rule can be assessed, not the end. The Produce Rule's impacts will extend far into the future, and FDA must consider those impacts in its cumulative impact analysis.

2. The DEIS fails to consider the impacts of the Rule in conjunction with the impacts of the other FSMA rules.

In the DEIS, FDA dismisses from consideration any cumulative impacts from the suite of FSMA rules by simply noting that each of the other five FSMA rules has been categorically excluded from the NEPA process.[98] This reasoning, of course, circumvents the very purpose of a cumulative impact analysis, which is to ensure that even those actions that seem insignificant in isolation do not have significant environmental impacts when viewed in the context of other related actions.[99] In fact, NSAC has repeatedly expressed concern that, in light of the combined costs of compliance with the Produce Rule and Preventive Controls Rule, small farms may close and significant environmental impacts – including impacts to public health, farmers, and communities – may result.[100] FDA's failure to meaningfully consider the combined effect of the suite of FSMA regulations renders the cumulative impacts analysis in the DEIS inadequate.

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[95] *Id.*

[96] Selkirk Conservation Alliance v. Forsgren, 336 F. 3d 944, 962 (9th Cir. 2003) (recognizing that the scope of the EIS is a "delicate choice" and should be entrusted to the agency, but the agency must have "considered the relevant factors and articulated a rational connection between the facts found and the choice made").

[97] *See* DEIS at 5-1 and Table 2.1-8.

[98] These regulations include the Intentional Adulteration Rule, the Sanitary Transportation of Human and Animal Food Rule, the Preventative Controls for Human Food Rule, the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals Rule, and the Third Part Accreditation Rule. DEIS at 5-3 to 5-4.

[99] Hanly v. Kleindienst, 471 F.2d 823, 831 (2d Cir. 1972) ("it must be recognized that even a slight increase in adverse conditions that form an existing environmental milieu may sometimes threaten harm that is significant. One more factory polluting air and water in an area zoned for industrial use may represent the straw that breaks the back of the environmental camel.").

[100] *See* NSAC, *Supplemental Rulemaking Comments* at 26; NSAC, *Comments on the Supplemental Proposed Rule for Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventive Controls for Human Food* at 26 (Dec. 15, 2014) .

3. The DEIS impermissibly relies on management decisions of farmers to mitigate the cumulative impacts of the Rule.

FDA also dismisses the cumulative impacts of the Produce Rule when examined with past, present, and reasonably foreseeable future agency actions by reasoning that farmers will make certain management decisions to mitigate the impacts. The problem with relying on the speculative and voluntary actions of farmers to mitigate impacts is more fully discussed in Part I.C of these comments.[101] Within its cumulative impacts analysis, FDA impermissibly relies on speculative farmers' decisions to mitigate the impacts of the Produce Rule with regard to water, soil, and biological and ecological resources.

Water. With respect to the agricultural water standards under Subpart E, FDA states that the ability of farmers to apply the microbial die-off rate will mitigate the impacts that could occur from a switch to chemical treatment.[102] In addition, FDA states that farmer participation in voluntary marketing programs, including Good Agricultural Practices (GAPs) certification, will further mitigate the impacts of the Rule.[103] With respect to Subpart F, FDA states that although a switch to chemical fertilizers in response to an imposed application interval for BSAs of animal origin may contaminate surface and groundwater, there is no significant cumulative environmental impact because those effects may be mitigated by farmers adopting best management practices.[104] FDA provides no data to support its wide-ranging assumptions. NEPA requires FDA to consider the impacts that may arise if farmers choose to chemically treat water, choose not to participate in voluntary marketing programs, or choose not to adopt certain nutrient management practices.

Soil. FDA states that, although a switch to chemical fertilizers in response to an imposed application interval for BSAs of animal origin will have detrimental effects on soil health, there is no significant cumulative environmental impact because these effects can be mitigated through green manuring, no-till practice, and the use of cover crops.[105] While we certainly support such mitigation measures, we do not share the agency's optimism regarding their adoption. As discussed in more detail below in Part III.B.3, the current rates of adoption of these practices are actually quite low, which casts serious doubts on the agency's assumption. FDA provides no data to support its assumption that farmers will adopt such practices,[106] and NEPA requires FDA to consider the impacts if farmers choose not to them.

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[101] *See* Part I.C.

[102] DEIS at 5-18.

[103] *Id.* FDA further acknowledges that it does not know the number of farmers participating in such programs relative to the total number of farms that would be covered by the Produce Rule, making its reliance on voluntary programs even more suspect.

[104] *Id.* at 5-19.

[105] *Id.* at 5-21.

[106] Notably, as discussed in Part III.A.6, many of these activities are promoted by the Natural Resource Conservation Service (NRCS). However, FDA provides no explanation that NRCS will likely have the resources available to facilitate adoption of these activities by farmers or that farmers will, in fact, choose to adopt them.

Biological and Ecological Resources. FDA states that grower participation in voluntary marketing programs will limit the adverse effects to biological and ecological resources caused by an increase in chemical treatment of agricultural water.[107] FDA also assumes that because §112.84 of the Produce Rule does not require farmers to destroy animal habitat or clear farm borders, farmers will never to choose to take these measures.[108] NEPA requires FDA to consider the impacts that will arise if farmers make other reasonable management decisions.

4. The DEIS fails to consider future local and regional effects of the Rule.

As discussed in more detail in Part II.A of these comments, NEPA requires consideration of potentially significant effects not only nationally, but also at the local and regional levels. Throughout the DEIS, FDA improperly limits its definition of significant impacts to those that occur at a national scale.[109] In its cumulative impacts analysis, FDA commits this legal error in at least three places:

(1) FDA states that the Rule will cause no significant cumulative effects on biological or ecological resources because these measures cannot be measured on a national scale.[110] However, significant impacts can occur at a local or regional scale, and these impacts must be assessed.
(2) FDA states that because the Rule does not impact air quality at a national level, the cumulative effects of the Rule on air quality are not significant.[111] This analysis impermissibly ignores potentially significant local or regional impacts on air quality.
(3) FDA states that there is no significant cumulative impact to water quality as a result of the Rule's standards under Subpart F because only 2.3 percent of farms nationally could switch from untreated BSAs to chemical fertilizers.[112] We are not convinced that this statistic is accurate at the national level, and furthermore, this analysis does not account for the fact that BSA users may be regionally or locally concentrated, resulting in a significant local or regional impact due to the regulation.

D. The DEIS Fails to Consider Particular Resources and Affected Groups.

Beyond the environmental impacts that FDA has overlooked by applying an incorrect test for significance, segmenting the Rule, and ignoring cumulative impacts, the DEIS also altogether ignores the following significant environmental impacts of the Produce Rule.

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[107] DEIS at 5-19.
[108] *Id.* at 5-20. For a fuller discussion of the problems with this assumption, see Part II.D.1.
[109] *See* Part II.A.
[110] DEIS at 5-20.
[111] *Id.* at 5-22.
[112] *Id.* at 5-19. The 2.3 percent referenced in the DEIS is cited to the Regulatory Impact Analysis of the Proposed Produce Rule, which in turn cites to the Washington State NASS website, and not any particular study or report.

1. The DEIS fails to consider impacts to endangered species.

Proposed § 112.84 states: "Nothing in this regulation authorizes the "taking" of threatened or endangered species as that term is defined by the Endangered Species Act … This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages."[113] FDA misinterprets the effect of this provision and, throughout the DEIS, FDA assumes that the language "does not authorize or require" has the same effect as "prohibits." Thus, FDA concludes that the provision will entirely prevent farmers from impacting endangered species. This is simply incorrect. The Rule does not prohibit such action, and FDA must consider the impacts to endangered species that may arise from farmers taking measures to exclude animals.[114]

2. The DEIS often ignores impacts on the continued operation of small farms.

The Produce Rule will have a disproportionate impact on small and very small farms. Indeed, in the DEIS, FDA acknowledges that "small and very small farms may not be able to afford the added cost burden of complying" with the Rule's provisions.[115] FDA avoids assessing the impact of the closure of these small and very small farms by both (1) claiming that data are unavailable to make such an assessment, and (2) assuming that small farms will not choose to close. NEPA, however, requires more.

FDA states that the data are unavailable or too uncertain to make any conclusions about the impacts that the closure of small and very small farms will have on the environment, food access, socioeconomic outcomes, and human health.[116] But when data are unavailable, NEPA does not allow an agency to simply ignore impacts. Rather, NEPA requires FDA to use theoretical approaches or research methods generally accepted in the scientific community to estimate these impacts.[117]

FDA assumes that, despite the high costs of compliance, small and very small farms will make management decisions to stay in operation and continue growing covered produce.[118] But, as discussed more fully below in Section III, FDA must consider all reasonable management decisions farmers may take in response to the Produce Rule, including the decision to cease or drastically change operations.[119]

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[113] *Id.* at 4-7.
[114] For a more detailed discussion, *see* Part III.A.3.
[115] DEIS at ES-28 to ES-29, 4-92. The burden of compliance with the Rule is likely greater than FDA acknowledges because FDA failed to consider additional costs arising from (1) the significant record keeping requirements imposed by Subpart O of the Produce Rule, and (2) the additional requirements that could be imposed from buyers/third-party auditors in response to the Produce Rule.
[116] *Id.* at ES-28 to ES-29, 4-93.
[117] 40 C.F.R. § 1502.22(b) (adopted by FDA at 21 C.F.R. § 25.10(a)).
[118] *See* Part III.B.1; DEIS at 4-28.
[119] *See* Part III.B.1.

3. The DEIS ignores impacts to prospective farmers.

In addition to affecting the decision of farmers to remain in operation, the high cost of compliance with the Produce Rule may also deter prospective farmers from deciding to grow covered produce.[120] This is especially disconcerting given the aging farm population and the decline of younger entrants into the market.[121] But nowhere in the DEIS does FDA assess impacts to these prospective farmers. NEPA requires such an assessment, even if "the possible effects on the human environment are highly uncertain or involve unique or unknown risks."[122]

4. The DEIS ignores impacts to vulnerable populations resulting from reduced access to fresh produce, including minorities.

If the costs of compliance with the Produce Rule lead some small farms to close (as discussed in Part II.D.2 above), or slows the entry of new farmers into the market (as discussed in Part II.D.3 above), small, rural, or underserved communities may have decreased access to fresh produce. Moreover, for farms that remain in operation, the increased costs of compliance may be passed on to consumers.[123] Small, rural, and underserved communities may not be able to afford increased food prices.

NEPA mandates that FDA assess *all* the impacts of decreased access to fresh produce on these communities, even if the impacts are difficult to predict. FDA's decision to only evaluate (1) the limited impact on these populations as a result of Subpart F's requirements,[124] and (2) the Produce Rule's socioeconomic impacts on farm operators and farm workers, is unacceptable, especially where the health of older or otherwise sensitive populations is disproportionately at risk.

Moreover, while FDA acknowledges that Indian tribes may be disproportionately affected by the Rule,[125] FDA ignores impacts to other minority groups. For example, in considering the increased use of pesticides, FDA concludes that "there are no impacts anticipated on human health as a result of secondary or worker exposure to pesticides. Therefore, there are also no anticipated significant impacts to minority groups."[126] By generalizing impacts from minority agricultural workers and

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[120] DEIS at 4-91. Table 4-7 summarizes the costs of complying with the Produce Rule for existing farmers. While FDA does not provide data specifically addressing the cost of compliance for new entrants, it is reasonable to extend estimations from Table 4-7 to that group. *See also* NSAC *Supplemental Rulemaking Comment* at 19, 25.

[121] Jim Mitchell, et. al., *The Aging Farm Population and Rural Aging Research,* 13 J. of Agromedicine 95, (2008) ("from 1954 to 1997 the number of younger persons choosing farming as an occupation decreased from 15 to 8%, while the proportion of farmers aged 55 and over increased from 37 to 61%."); *Ag 101: Demographics*, ENVIRONMENTAL PROTECTION AGENCY, *available at* http://www.epa.gov/agriculture/ag101/demographics.html ("The average age of a principal operator of a farm has increased from 54 years old in 1997 to 57 years old in 2007. (USDA, 2007 Census of Agriculture). The percentage of principle farm operators 65 years or older has increased almost 10 percent since 1969").

[122] 40 C.F.R. §1508.27 (adopted by FDA at 21 C.F.R. §25.5(a)(19)).

[123] DEIS at 5-24.

[124] DEIS at 4-58.

[125] *Id.* at 4-24.

[126] *Id.* at 4-35.

applying them wholesale to minority groups, FDA ignores potentially significant impacts to these sensitive populations.

III. THE DEIS FAILS TO SATISFY NEPA BY SIGNIFICANTLY UNDERESTIMATING ENVIRONMENTAL IMPACTS.

In the DEIS, FDA significantly underestimates certain environmental impacts, by making a series of misplaced assumptions about the mitigating effects of (1) compliance with other environmental laws and voluntary programs, and (2) the management decisions of farmers. Individually, each of these assumptions erodes significant components of FDA's environmental analysis. Cumulatively, these assumptions lead FDA to conclude that a regulation of tremendous scope – designed to alter the way produce is grown, packed, and held in this country – will have only minor environmental impacts.[127] To satisfy its obligations under NEPA, FDA must revisit and correct each of these mistaken assumptions.

A. The DEIS Improperly Assumes that Compliance with a Law, Permit, or Voluntary Program will Result in Minimal or No Environmental Impact.

When an agency presumes that compliance with another agency's requirements means that the environmental effects of a proposed action are insignificant, the agency impermissibly abdicates its NEPA obligations.[128] In particular, courts have rejected agencies' reliance on the Endangered Species Act (ESA) to avoid consideration of environmental impacts to endangered species.[129]

Throughout the DEIS, FDA improperly assumes that the compliance with the Clean Water Act (CWA), the Fungicide, Insecticide, and Rodenticide Act (FIFRA), the ESA, and state regulatory programs will result in minimal or no environmental impact from the Produce Rule's key provisions. FDA repeats this mistake in a more egregious manner by likewise assuming that compliance with voluntary food safety certification programs and voluntary marketing agreements will also result in minimal or no environmental impact. Below we provide examples of these misplaced assumptions.

1. The DEIS improperly relies on the CWA and complimentary state nutrient management plans to underestimate impacts.

FDA's misplaced reliance on the CWA and state nutrient management plans causes it to underestimate impacts to:

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[127] FDA ultimately concludes that the only potentially significant environmental impact of the Produce Rule is that it may result in further depletion of groundwater resources. *Id.* at 4-38.

[128] Calvert Cliffs' Coordinating Comm., Inc. v. Atomic Energy Comm'n, 449 F.2d 1109, 1122-23 (D.C. Cir. 1971) (stating that if an agency could rely entirely on the environmental judgments of other agencies, NEPA would "wither away in disuse", and that such a tactic is in fundamental conflict with NEPA's purpose). *See also* Southern Oregon Citizens Against Toxic Sprays, Inc. v. Clark, 720 F.2d 1475, 1480 (9th Cir.1983) ("[o]ne agency cannot rely on another's examination of environmental effects under NEPA").

[129] *See, e.g.,* Makua v. Rumsfeld, 163 F. Supp. 2d 1202, 1218 (D. Ha. 2001) (holding that agency's reliance on assurances that its action would not "jeopardize the continued existence of a species" under the ESA is not equivalent to a finding that there would be "no significant impact" on a given species); *see also* 40 C.F.R. § 1508.27(b)(9) (indicating that any action that adversely affects endangered or threatened species or their critical habitats, as defined by the ESA, should likely be considered in an EIS).

- Water resources (for example, DEIS at 4-45, 4-57, 4-89)
- Biological and ecological resources (for example, DEIS at 4-11, 4-47, 4-68, 4-69)
- Soil (for example, DEIS at 4-49)
- Waste generation, disposal, and resource use (for example, DEIS at 4-50, 4-52, 4-84)

First, throughout the DEIS, FDA grossly overestimates the number of farms that are required to obtain National Pollutant Discharge Elimination System (NPDES) discharge permits under the CWA.[130] For farms, NPDES permits are the exception, and most agricultural operations are specifically exempted from needing these permits to operate.[131] Only when a farm is operating a concentrated animal feeding operation (CAFO) is that farm required to apply for a NPDES permit.[132] And even then, many farmers are able to simply avoid the permitting process.[133]

For the dredge and fill permit program, CWA regulations also make explicit exceptions for ongoing farming operations and irrigation activities.[134] In the DEIS, FDA ignores these exceptions, and again overestimates the number of farms that will be regulated by the CWA through this permitting program.

Second, the DEIS incorrectly assumes that, if a farm has a NPDES permit or dredge and fill permit (and, perhaps, even if it does not), adherence to permit requirements will prevent any significant environmental impact.[135] Here, FDA fundamentally misunderstands the nature of CWA permitting programs. By design, NPDES permits *allow* for the discharge of pollutants into water.[136] A dredge and fill permit likewise recognizes that the activities undertaken will result in impacts to water resources.[137] Therefore, FDA cannot rely on permits that fundamentally allow for pollution as a means to mitigate environmental harm.

Finally, for those farms that are not obligated to apply for a NPDES permit, FDA states that compliance with state nutrient management plans will also mitigate the Rule's environmental impact.[138] This assumption is simply inaccurate. Agricultural runoff is the leading cause of pollution in our waterways[139] – despite the CWA or the implementation of state nutrient management plans.

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130 DEIS at 4-45, 4-52. *See also id.* at 4-50 ("Many farms and/or CAFOs that generate animal waste are required to comply with NPDES or other permits.").
131 *See* 33 U.S.C. § 1362 (6) and (14).
132 *See id.* Moreover, when a farm applies for NPDES permit for the operation of a CAFO, that permit has no bearing upon manure management in produce production activities. Instead, it only restricts discharges from the CAFO itself.
133 Only CAFOs that discharge must apply for a permit. *See* U.S. EPA, Concentrated Animal Feeding Operations Final Rulemaking—Factsheet, (2008), *available at:* http://www.epa.gov/npdes/pubs/cafo_final_rule2008_fs.pdf.
134 40 C.F.R. § 232.3(c)(1).
135 *See, e.g.*, DEIS at 4-45, 4-47, and 4-52.
136 *See* 33 U.S.C. § 1342(a)(1).
137 *Id.* at § 1344.
138 DEIS at 4-45.
139 National Water Quality Inventory: Report to Congress (2004) at 12. *See also* Jan G. Laitos & Heidi Ruckreigle, *The Clean Water Act and the Challenges of Agricultural Pollution,* 37 Vt. L. Rev. 1033, 1037 (2013) ("agricultural pollution accounts for approximately half of the country's water pollution").

Thus, FDA's reliance on the CWA to mitigate the impacts to water from increased agricultural chemical runoff,[140] unintentional releases of stored manure,[141] moving livestock to new land for grazing,[142] and adding fencing to exclude domesticated animals from produce fields[143] is entirely misplaced. The CWA simply does not apply to most farming activities; and in any event, the CWA and state nutrient management plans do not prohibit environmental harm. FDA must meaningfully consider the significant environmental impacts that may arise from the Produce Rule, even while farmers adhere to the limited mandates of the CWA.

2. The DEIS improperly relies on FIFRA to underestimate impacts.[144]

FDA's misplaced reliance on FIFRA causes it to underestimate impacts to:

- Water resources (for example, DEIS at 4-21, 4-28, 4-30, 4-45, 4-68, 4-69, 4-74, 4-76)
- Biological and ecological resources (for example, DEIS at 4-30, 4-76, 4-77, 4-89, 4-90)
- Human health (for example, DEIS at 4-35, 4-77)

FIFRA regulates the labeling, sale, and distribution of pesticide and herbicide products.[145] These pesticides and herbicides, by design, are intended to kill or disrupt living organisms. Consequently, their intentional release into the environment poses significant risks to water, biological and ecological resources, and human health. FIFRA does not completely eliminate these risks.[146] Indeed, because FIFRA does not establish a permitting system for pesticide use and instead regulates solely through registration and labeling, risks associated with the release of pesticides in a particular geographic location at a particular time are not even evaluated.[147] As such, FDA cannot discharge its duty under NEPA to take a hard look at the impacts of pesticide use by merely stating that pesticides are regulated under FIFRA. Agricultural chemical runoff is a serious cause of environmental harm to water resources and the biological and ecological resources that depend upon water, notwithstanding FIFRA's requirements.

In addition, the DEIS impermissibly assumes that no environmental impact will be caused by the chemical treatment of water. FDA posits that because EPA may someday approve a label for the chemical treatment of agricultural water under FIFRA, this prospective process will protect the water from harm.[148] Such reliance on a future treatment product (that hasn't even been proposed to let alone approved by EPA) is impermissible – NEPA requires FDA to take a hard look at the reasonably foreseeable impacts of increased chemical treatment of agricultural water, and FDA cannot assume that speculative future actions of EPA will entirely mitigate these impacts.[149]

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[140] DEIS at 4-43

[141] *See id.* at 4-45, 4-52.

[142] *Id.* at 4-67.

[143] *Id.* at 4-69.

[144] *Id.* at 4-37.

[145] *See* ENVTL. PROT. AGENCY. Fungicide, Insecticide, and Rodenticide Act, http://www.epa.gov/agriculture/lfra.html.

[146] FIFRA's standard of "unreasonable harm" does not preclude environmental impacts due to increased use of pesticides. 7 U.S.C. § 136a (c)(5).

[147] Instead of a permitting program, EPA's regulation of pesticides is accomplished through labeling restrictions. *See* 40 C.F.R. § 156.10.

[148] DEIS at 4-21.

[149] NEPA Law and Litig. § 8:57 (2014) (citing Ohio Valley Envtl. Coal. v. Aracoma Coal Co., 556 F.3d 177 (4th Cir. 2009)) ("mitigation measures cannot be hypothetical or speculative").

3. The DEIS improperly relies on the ESA to underestimate impacts.[150]

FDA claims that the "proposed requirements [of the Produce Rule] do not propose any activity that may result in impacts to threatened or endangered species."[151] FDA reaches this conclusion because proposed § 112.84, discussed in more detail in Part II.D.1, does not *require* the taking of endangered species. Of course, *not requiring* something is not the same as *prohibiting* it. And thus, impacts to endangered species could certainly occur even while a farmer adheres to the Produce Rule's mandates.

FDA avoids consideration of these impacts, however, because it assumes the U.S. Fish and Wildlife Service (USFWS) will protect endangered species under the ESA.[152] By this logic, no EIS (other than an EIS prepared by the USFWS) would ever address impacts to endangered species. That, of course, is not what NEPA requires. Rather, both FDA and Council on Environmental Quality regulations require the agency to take a hard look at impacts to endangered species.[153] FDA may not rely on the ESA to entirely avoid NEPA's mandate.

4. The DEIS improperly relies on state and county permits for hunting, trapping, or poisoning of wildlife to underestimate impacts.

FDA correctly recognizes that farmers may resort to increased hunting, trapping, or poisoning of wildlife to prevent animal intrusion into produce fields.[154] Instead of taking a hard look at the impacts to the environment from these management decisions, FDA reasons that because such activities will be regulated at the state or local level there will be no environmental harm.[155] However, increased hunting, trapping, or poisoning of wildlife in response to the Rule, even if legally permissible and regulated by states or counties, will still negatively impact biological and ecological resources. NEPA prohibits FDA from ignoring these impacts.

Moreover, FDA consistently places impacts from fencing, trapping, hunting, and poisoning in the same category. However, each of these practices can have substantially different impacts on wildlife. As such, FDA should have considered these measures separately to assess their relative impacts.

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150 DEIS at 4-6 to 4-8.

151 *Id.* at 4-6, 4-74.

152 DEIS at 4-7 to 4-8. ("To the extent a grower of produce takes an action that may impact a threatened or endangered species, such action would be subject to the independent oversight and authority of the USFWS … we would consider the regulatory oversight of the USFWS for such an action to sufficiently mitigate the potential for any significant environmental impact under NEPA.")

153 *See* 40 C.F.R. § 1508.27(b)(9) (in evaluating the severity of an impact, an agency should consider "the degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973") (adopted by FDA at 21 C.F.R. § 25.10(a)).

154 DEIS at 4-75.

155 *Id.*

5. The DEIS improperly relies on voluntary marketing programs or Good Agricultural Practices to underestimate impacts.

FDA's misplaced reliance on voluntary marketing programs and GAPs causes it to underestimate impacts to:[156]

- Water resources (for example, DEIS at 4-21)
- Waste generation, disposal, and resource use (for example, DEIS at 4-50)

FDA hypothesizes that impacts to water from the Produce Rule will be minimized because some voluntary marketing agreements maintain more restrictive standards than the Rule, and thus many farmers would not have to change their current practices to come into compliance with the Rule's requirements.[157] This hypothesis, however, does not account for the fact that these programs are voluntary and often commodity-specific. Consequently, (1) some farmers have chosen not to opt into the programs, (2) some farmers grow produce not covered by these programs, and (3) some farmers may choose to opt out of these programs in the future. For all of these farmers, the severity of impacts caused by the Produce Rule's water standards will not be minimized, and FDA must take a hard look at these impacts.

In addition, the DEIS wrongly implies that no environmental impact will be caused by farmers switching to treated BSAs, so long as they adhere to industry standards or GAPs.[158] However, compliance with industry standards or GAPs is voluntary. Moreover, industry standards and GAPs do not necessarily have a bearing on environmental health, as neither aim to improve environmental outcomes. As such, reliance on industry standards or GAPs to entirely mitigate environmental impacts is misplaced, and FDA must take a hard look at impacts that may be caused by farmers switching to treated BSAs, or synthetic ones.

6. The DEIS improperly relies on Natural Resources Conservation Service (NRCS) conservation programs to underestimate impacts.

FDA's misplaced reliance on NRCS conservation programs causes it to underestimate impacts to:

- Water resources (for example, DEIS at 4-45)

While NRCS programs are established and available at the county level throughout the country, participation in these programs is voluntary and undertaken in accordance with a farmer's own initiative.[159] Thus, for farmers who opt not to use NRCS programs, these programs cannot mitigate the environmental impacts of their management decisions. Moreover, and perhaps more importantly, NRCS programs primarily focus on activities beyond food safety on produce farms.[160]

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[156] *Id.* at 4-51.
[157] *Id.*
[158] *Id.*
[159] *See* U.S. DEP'T OF AGRIC., Natural Resources Conservation Service, *available at* http://www.nrcs.usda.gov/.
[160] DEIS at 4-11, 5-5 ("NRCS's natural resources conservation programs help people reduce soil erosion, enhance water supplies, improve water quality, increase wildlife habitat, and reduce damages caused by floods and other natural disasters.").

Individual NRCS offices simply may not have the resources or expertise to mitigate the specific environmental impacts caused by the Produce Rule. As a result, FDA's reliance on NRCS programs to entirely mitigate the environmental impacts of its Rule is again misplaced.

In addition, FDA wrongly relies upon farmers adopting technologies traditionally promoted through technical assistance of the NRCS to mitigate impacts from its Rule. For example, throughout the DEIS, FDA claims farmers will practice strip tillage, use green manuring, and implement riparian buffers.[161] Not only does this impermissibly shift FDA's burden to mitigate environmental impacts to farmers, but it also impermissibly relies on the expenditure of another agency's resources to mitigate the environmental impacts of the Produce Rule.[162]

B. The DEIS Fails to Consider the Environmental Impacts Arising from All Reasonably Foreseeable Management Decisions.

NEPA requires agencies to take a "hard look" at *all* reasonably foreseeable impacts when preparing an EIS.[163] And while agencies can take into account mitigation measures that may reduce these impacts, these measures may not be hypothetical, speculative, or unsupported by data.[164] Despite this mandate, in the DEIS, FDA focuses entirely on management decisions that farmers may voluntarily adopt to mitigate the environmental impacts of the Rule, while ignoring other possible management decisions that farmers may make that would increase environmental impacts.[165] FDA provides little support for its choice to conduct such a narrow review.

NEPA mandates that FDA take a broader look – the agency must consider *all reasonably foreseeable management decisions* that a farmer could make (taking into account the many factors that may affect a farmer's decision, including crop type, soil conditions, environmental conditions, and cost) to comply with the Rule, and then assess the environmental impacts that could arise from each of these decisions.[166]

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[161] *Id.* at 4-49, 4-51, 4-62.

[162] *See* Part III.A.

[163] *See* 40 C.F.R. § 1502.16, (adopted by FDA at 21 C.F.R. § 25.42(a)(1)); Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 348 (1989) (NEPA "establishes 'action-forcing' procedures that require agencies to take a 'hard look' at environmental consequences."); Sierra Club v. Marsh, 976 F.2d 763, 767 (1st Cir. 1992) ("those effects that are likely or foreseeable need to be discussed"); Ctr. for Biological Diversity v. U.S. Dep't of Interior, 623 F.3d 633, 646 (9th Cir. 2010) (holding the agency violated its duties under NEPA when it failed to take a hard look at the environmental consequences of a proposed land exchange).

[164] NEPA Law and Litig. § 10:43 (2014).

[165] In Chapters 1 and 2 of the DEIS, FDA claims that it will assess all reasonably foreseeable management decisions. But, FDA's list of management decisions is incomplete, failing to include certain decisions raised in NSAC's previous comments. In addition, the impact analysis FDA conducts in Chapter 4 does not even include all the management decisions listed in Chapters 1 and 2 of the DEIS. In effect, the FDA limits its analysis to only those management decisions that will significantly mitigate environmental impacts – notwithstanding economic considerations, ease of implementation, and practicality.

[166] DEIS at 2-12.

1. Subpart A. General Provisions.

In its analysis for Subpart A, in which FDA purports to assess the impacts related to all of the provisions of the Produce Rule together, FDA entirely fails to analyze the direct or indirect impacts of a management decision to cease farming.

Despite the fact that many provisions of this Rule will impose new and substantial administrative, financial, and operational burdens on farmers, FDA repeatedly asserts that the possibility that farmers may choose to cease farming (instead of taking on these new burdens) is both unlikely and too speculative to analyze.[167] We respectfully disagree. It is reasonably foreseeable that the burden may be too large for some farms to bear, and FDA must, at a minimum, address in its DEIS the theoretical environmental impacts that would result – including direct impacts to land and indirect socioeconomic and human health impacts (if, for example, certain at-risk populations have reduced access to fresh produce and certain farmers cannot find new employment).[168]

2. Subpart E. Agricultural Water Standard.

FDA omits reasonably foreseeable management decisions from its analysis. In its analysis of Subpart E, FDA fails to consider two reasonably foreseeable management decisions that farmers could take to comply with the agricultural water standard: the decision to close down small farms and the decision to switch to municipal water.

- FDA fails to consider the management decision, particularly of small and very small farms, to cease farming.[169] FDA does not meaningfully analyze the direct or indirect environmental impacts of those closures, stating that there are no data to suggest when such a decision would be made.[170] As discussed previously in Part II.D, it is reasonably foreseeable that farmers could elect to close down their farms instead of coming into compliance with the Rule, and thus FDA is required to analyze the direct, indirect, and cumulative environmental impacts that would result. To the extent data are unavailable, FDA must nevertheless evaluate impacts based upon theoretical approaches.[171]

- While FDA admits that the agricultural water standard could cause farmers to switch to groundwater,[172] it does not analyze the impacts from a farmer's decision to switch to

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[167] *See, e.g., id.* at 4-28 to 4-29.
[168] *See* 40 C.F.R. § 1502.22(b) (adopted by FDA at 21 C.F.R. § 25.10(a)).
[169] In addition, FDA fails to adequately consider impacts related to a decision to switch from growing covered produce to raising livestock or growing non-covered produce because several comments the agency received claimed that those were not "preferred management decision[s]." DEIS at 4-28. NEPA, however, requires an agency to consider all reasonably foreseeable impacts, not just those that were identified in initial comment periods. *See* 40 C.F.R. § 1502.16, (adopted by FDA at 21 C.F.R. § 25.42(a)(1)).
[170] DEIS at 4-28 to 29.
[171] 40 C.F.R. § 1502.22(b) ("If the information relevant to reasonably foreseeable significant adverse impacts cannot be obtained because the overall costs of obtaining it are exorbitant or the means to obtain it are not know, the agency shall include within the environmental impact statement … (4) the agency's evaluation of such impacts based upon theoretical approaches or research methods generally accepted in the scientific community.") (adopted by FDA at 21 C.F.R. § 25.10(a)).
[172] DEIS at 4-30, 4-32.

municipal water. Considering that sprout growers already use municipal water to conduct agricultural activity[173] and given the scarcity of surface and groundwater supplies, it is reasonably foreseeable that some farmers could choose to switch to municipal water.[174] To comply with NEPA, FDA must consider the environmental impacts of this decision.

FDA improperly assumes farmers will take voluntary measures to mitigate the impacts of Subpart E. As established in Part I.C, FDA cannot rest its conclusions about the impacts of the Produce Rule on voluntary and speculative management decisions by farmers. Within its impacts analysis for Subpart E, FDA does so in three places:

- FDA acknowledges that Subpart E could cause farmers to increase their use of chemicals, particularly pesticides, to treat water. Pesticide pollution, of course, has serious adverse effects on water, biological and ecological resources, and human health.[175] FDA claims that these significant impacts would be "mitigated by the ability of covered farmers to choose other management decisions," including "switching water sources, switching the irrigation method to a non-contact method, or adding mechanisms to account for microbial die-off in the field and post-harvest."[176] But, FDA does not provide support for (1) its assumption that farmers will always choose one of these alternative management decisions, or (2) that these alternative decisions would mitigate the impacts from increased chemical treatment.

- While FDA is correct in its conclusion that non-contact irrigation methods result in fewer environmental impacts than other irrigation methods,[177] FDA incorrectly relies on non-contact irrigation – along with other voluntary measures by growers – to avoid a full discussion of the environmental impacts associated with Subpart E if farmers do not switch irrigation methods. Importantly, the switching of irrigation method is an option for only a limited variety of crops.[178]

- Alternative I under Subpart E (the preferred alternative) allows farmers to use microbial die-off and/or removal – instead of chemical treatment or switching water sources – to meet the proposed agricultural water standards.[179] While this added flexibility may decrease the number of farms that either use chemical treatment or decide to switch water source,[180] FDA goes too far in its conclusion that microbial die-off will "overall mitigate the potential need for or significant impacts associated with other management decisions."[181] In times of drought, farmers may not have the luxury of being able to wait the appropriate amount of time for the die-off rate. FDA fails to explain why it is not reasonably foreseeable that some farmers will still choose to chemically treat water or switch water sources. The impacts of these management decisions must be assessed.

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[173] *Id.* at ES-24.
[174] NSAC, *Supplemental Scoping Comments* at 4.
[175] DEIS at 4-21, 4-23.
[176] *Id.* at 4-23 (water), 4-36 (human health); *see also* 4-27 (discussing die-off) and 4-37 to 4-38.
[177] *Id.* at 4-26.
[178] *Id.*
[179] *Id.* at 4-18.
[180] *Id.* at 4-18, 4-23.
[181] *Id.* at 4-27, 4-37 (because farmers will have the option to use microbial die-off, there will be no significant impacts from long-term chemical treatment of water).

In assuming that farmers will always adopt certain management decisions (and by making all the other improper assumptions discussed throughout these comments), FDA fails to take a hard look at the impacts of the water provision.

3. Subpart F. Biological Soil Amendments – Untreated and Treated.

FDA's omits reasonably foreseeable management decisions from its analysis. In its analysis for Subpart F, treated BSAs, FDA fails to consider any management decision except compliance with the proposed waiting period. This is because FDA assumes that growers who are already using treated BSAs will continue to do so, as §112.56(a)(4)(i) of the Produce Rule does not impose a waiting period.[182] However, the application waiting period is only one part of the proposed treated BSA standard; the Rule also requires certain procedures regarding the use, handling, and storage of BSAs, as well as record-keeping requirements.[183] The additional administrative and procedural burdens required by the Rule could result in farmers electing to switch to chemical fertilizer, stop growing covered produce, or shut down the farm. NEPA requires FDA to analyze the environmental impacts of these reasonably foreseeable management decisions.

FDA improperly assumes that farmers will take voluntary measures to mitigate the impacts of Subpart F. As established in Part I.C, FDA cannot rest its conclusions about the impacts of the Produce Rule on voluntary and speculative management decisions by farmers. Within its impacts analysis for Subpart F, FDA does this in two places:

First, as FDA acknowledges, implementing a longer application interval under Alternatives I, III, IV, and V would require longer manure storage times and could result in increased manure runoff.[184] However, FDA finds that this would cause no significant adverse impacts to water quality or biological and ecological resources.[185] To reach this conclusion, FDA improperly relies on best management practices by farmers, claiming that farmers' implementation of these voluntary measures will significantly mitigate the potential for impacts to surface water, groundwater, and soils.[186]

Second, the use of chemical fertilizers has serious adverse effects on soils, water systems, and biological and ecological resources.[187] Subpart F of the Rule may impose restrictions on the use of BSAs of animal origin, which could cause farmers to switch to chemical fertilizers. In concluding that the resulting impacts would be insignificant, FDA partly relies on its assertion that there is a "growing trend away from chemical fertilizers to practices such as green manuring."[188] As noted throughout these comments, it is unreasonable for FDA to rely so heavily on a trend that is both voluntary and wholly outside of the agency's control.

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[182] *Id.* at 4-61 to 4-62.
[183] *Id.* at 4-61, 4-90.
[184] DEIS at 4-45.
[185] *Id.* at 4-45, 4-47 to 4-48.
[186] *Id.* at 4-49, 4-57.
[187] *Id.* at 4-47, 4-49.
[188] *Id.* at 4-57.

Although we strongly support green manure and cover crop practices, we do not agree with the agency's assumption regarding the pervasiveness of the practice. While a few farmers on the cutting edge of the soil health initiative are growing the kind of high biomass, multispecies cover crops and using the kind of minimum-till minimum-chemical methods needed to protect soil health, most vegetable producers, including many organic producers who try their best to take good care of the soil, are working their soil hard and need BSAs to maintain soil quality. Moreover, green manuring and cover crops serve different roles in a crop system: cover crops protect and feed soil biota by adding nitrogen and carbon to the soil, BSAs replenish the soil microbtioa and mineral nutrients.

The reality is that, in some parts of the country (i.e. the Corn Belt), practices like green manuring are around 2 percent of total acreage. While that figure is likely to be higher among produce growers, it is very unlikely to be above 30 - 40 percent, and may be considerably less. Vegetable production is a very intensive system, and both the soil and the farmer are often too occupied for effective cover cropping. Even when a cover crop is planted, it may not reach the size / biomass needed to ameliorate soil quality, either because it was planted too late (due to the late harvest of cash crop or a busy farmer) and/or because it had to be terminated too early (its time to plant the next cash crop, or due to weather complications).

In assuming or overemphasizing that farmers will always adopt certain management decisions (and by making all the other improper assumptions discussed throughout these comments), FDA fails to take a hard look at the impacts of the BSA provision.

4. Subpart I. Standards Directed to Domesticated and Wild Animals/Grazing – § 112.82(a).

FDA omits reasonably foreseeable management decisions from its analysis of § 112.82(a). FDA identifies several management decisions that a farmer may take to comply with the standards of §112.82(a): fencing or other measures to exclude domesticated animals, and observing an adequate waiting period after grazing and prior to harvest.[189] FDA also acknowledges that farmers may confine animals to small pasture and/or feedlots, which would result in greater accumulation of manure at times when these animals would be permitted to graze.[190] Yet FDA ignores other potential management decisions, such as the likelihood that farms with integrated crop-livestock systems would stop raising livestock and/or stop growing covered produce. This reduces the diversity of the farming operation, with attendant environmental impacts and impacts to public health and communities. However, most notably, FDA largely ignores the possibility that farmers may clear conservation buffers from field borders or riparian areas and drainages that would attract roaming livestock.[191]

To reach this conclusion, FDA relies partly on §112.84 of the Produce Rule, which states that farmers are not *required* to "take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas."[192] Because

[189] *Id.* at 4-66.
[190] *Id.* at 4-70.
[191] *Id.* at 4-68.
[192] *Id.*

farmers are not required to fence or clear-cut, FDA states that farmers will instead choose to purchase other food sources for their domestic animals or use other land for grazing.[193] But, §112.84 does not *prohibit* fencing or clear-cutting, and FDA fails to adequately explain why it is not reasonably foreseeable that some growers will choose to build new fences or use clear-cutting to exclude animals.[194] It is well documented that clearing habitat/non-crop vegetation including weeds can negatively affect bees, monarch butterflies, and birds.[195] The impact of these omitted management decisions must be assessed.

FDA improperly assumes farmers will take voluntary measures to mitigate the impacts of Subpart I - § 112.82(a). As established in Part I.C, FDA cannot rest its conclusions about the impacts of the Produce Rule on voluntary and speculative management decisions by farmers. Within its impacts analysis for §112.82(a), FDA does this in at least one place:

- To reduce the incentive for farmers to clear field borders, the DEIS implicitly assumes that farmers will purchase alternative food sources for livestock or use other land for grazing.[196] However, FDA does not provide any data to substantiate the availability of these alternatives or to support the likelihood that farmers would adopt such alternatives as opposed to clearing field or drainage borders. As such, FDA's mere listing of these speculative activities fails to discharge the agency's obligation under NEPA.

In assuming that farmers will always adopt certain management decisions (and by making all the other improper assumptions discussed throughout these comments), FDA fails to take a hard look at the impacts of the domesticated animal provision.

5. Subpart I. Standards Directed to Domesticated and Wild Animals/Animal Intrusion – § 112.83(b).

FDA omits reasonably foreseeable management decisions from its analysis of § 112.83(b). Alternative I of this Subpart (the preferred alternative) requires farmers to monitor fields for animal intrusion, evaluate whether produce can be harvested safely, and if the produce is contaminated, to forego harvesting that portion of the crop.[197] In its impacts analysis for this alternative, FDA assumes that farmers will not take measures to prevent wildlife intrusion, such as clearing farm borders or increasing use of toxic chemicals.[198] Because the only management decisions that FDA

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[193] *Id.*

[194] *Id.* at 4-72. FDA also claims that because most dual-purpose farms already have fencing in place, the construction of new fencing is unlikely. *Id.* at 4-69. However, FDA fails to provide support for this argument, and therefore this statement fails to satisfy the agency's obligations under NEPA.

[195] *See* Arlettaz, R. et al. 2012. Journal of Ornithology doi:10.1007/s10336-011-0737-7; Gillespie, M. and Â S.D. Wratten. 2012. Journal of Insect Conservation doi:10.1007/s10841-011-9390-y; Requier, F. et al. 2014. Honey bee diet in intensive farmland habitats reveals an unexpectedly high flower richness and a major role of weeds. Ecological Applications doi: 10.1890/14-1011.1; Pleasants, JM and Oberhauser KS (2013), Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population. Insect Conservation and Diversity, 6:Â 135–144. doi:Â 10.1111/j.1752-4598.2012.00196.x; and Beecher, N. A., R. J. Johnson, et al. (2002). Agroecology of birds in organic and nonorganic farmland. Conservation Biology 16(6): 1620-1631.

[196] *Id.* at 4-68.

[197] *Id.* at 4-77.

[198] *Id.* at 4-77 to 78.

considers is that farmers will monitor their fields or potentially establish fences to exclude animals from produce fields, FDA concludes that there will be "no significant adverse effects … to any resource component" from §112.83(b).[199]

To reach this conclusion, FDA relies on §112.84, which states that farmers are not required to destroy animal habitat or clear farm borders.[200] However, as discussed in Part II.D, the Produce Rule does not forbid farmers from clear-cutting or destroying animal habitat, and thus FDA's conclusion that farmers will never take these measures is unreasonable. In fact, California farmers have taken this very action to comply with GAPs measures to prevent wildlife intrusion into farmers' fields.[201] In some cases, this has resulted in farmers abandoning conservation practices they had previously adopted.[202] Measures taken by farmers include the removal of tailwater recovery ponds and irrigation reservoirs, grassed waterways, filter and buffer strips, trees and shrubs.[203]

FDA is required to consider all reasonably foreseeable impacts, and therefore must assess the impacts to water, biological and ecological resources, and soils that would result if farmers chose to clear-cut or otherwise destroy animal habitat or use toxic chemicals to prevent animal intrusion. In light of past experience, ignoring the potential environmental impacts of this provision by unreasonably assuming that farmers will somehow respond differently to a mandatory rule than to a voluntary food safety program flies in the face of FDA's obligations under NEPA.

Although new §112.83(b) provides some clarity that farmers do not have to destroy animal habitat under the rules, it does not – as discussed above – forbid farmers from clear-cutting or destroying habitat, nor does it encourage farmers not to, and to instead co-manage for conservation and food safety. Thus, FDA's conclusion that farmers would never take these measures is unreasonable.

FDA improperly assumes farmers will take voluntary measures to mitigate the impacts of Subpart I - § 112.83(b). As established in Part I.C, FDA cannot rest its conclusions about the impacts of the Produce Rule on voluntary and speculative management decisions by farmers. Within its impacts analysis for §112.83 (b), FDA does this in at least one place:

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[199] *Id.* at 4-74.

[200] *Id.*

[201] *See* David M. Chron & Mary L. Bianchi, *Research Priorities for Coordinating Management of Food Safety and Water Quality*, 37 J. ENVTL. QUALITY 1411, 1412 (2008). The concern that adopting measures for food safety may undermine efforts to promote water quality led 100 food safety and water quality experts to meet to develop a research agenda to accommodate both concerns. *Id.* at 1411; *see also* Resource Conservation District of Monterey County, *Challenges to Co-Management of Food Safety and Environmental Protection: A Grower's Survey* Jul. 2009, available at: http://caff.org/wp-content/uploads/2011/09/Challenges_Grower_Survey_July2009. pdf; Wild Farm Alliance, Environmental Destruction in the Salinas Valley: 'Food Safety' Requirements to Remove Habitat Make Leafy Greens Less Safe, (2008), *available at* http://wildfarmalliance.org/resources/WFA%20FS%20EnvDestruct2.pdf; Sasha Gennet, et al., *Farm practices for food safety: an emerging threat to floodplain and riparian ecosystems,* 11 FRONTIERS IN ECOLOGY AND THE ENV'T. 236 (2013); Diana Stuart, *Coastal Ecosystems and Agricultural Land Use: New Challenges on California's Central Coast* 38 COASTAL MGMT. 1, 42-64 (2010); Diana Stuart & Sean Gillon. *Scaling Up to Address New Challenges to Conservation on U.S. Farmland*, 31 LAND USE POL'Y 223 (2013).

[202] David M. Chron & Mary L. Bianchi, *Research Priorities for Coordinating Management of Food Safety and Water Quality*, 37 J. ENVTL. QUALITY 1411, 1412 (2008).

[203] *See id.*

- FDA claims that any potential adverse impacts to wildlife resulting from the standards in §112.83(b) will be mitigated because there are co-management measures and best management practices available that allow farmers to direct wildlife away from fields while still providing adequate habitat.[204] Because these measures and practices are voluntary and fall completely outside of FDA's control, it is unreasonable and impermissibly speculative for FDA to rely upon them to mitigate impacts.[205] Moreover, as set forth in the outset of these comments, FDA did not consider the impact of codifying language that would create incentives for farmers to preserve wildlife habitat.[206] If FDA were to explicitly support such practices in the regulations, then it would be more reasonable for FDA to assume that farmers would use co-management to mitigate impacts. To the extent that FDA relies on this misplaced assumption, its discussion of environmental impact is inadequate.

In assuming that farmers will always adopt certain management decisions (and by making all the other improper assumptions discussed throughout these comments), FDA fails to take a hard look at the impacts of the wild animal provision.

CONCLUSION

NEPA requires FDA to conduct an in-depth review of the environmental impacts of the Produce Rule. Unfortunately, the DEIS fails to satisfy the requisite analysis. As set forth in more detail above, the DEIS:

- Fails to consider reasonable alternatives to the Produce Rule's provisions that were raised in public comment;
- Fails to consider activities that FDA could undertake to mitigate the environmental impacts of the Produce Rule;
- Ignores certain impacts of the Produce Rule altogether; and
- Significantly underestimates certain impacts of the Produce Rule.

These failures undermine informed agency decision-making and meaningful public participation. Consequently, NSAC respectfully requests that FDA take the time necessary to improve the DEIS so that it takes the requisite "hard look" at the direct, indirect, and cumulative impacts of the Produce Rule; alternatives to the Produce Rule; and measures FDA can take to mitigate its impacts. NSAC looks forward to continued work with FDA during the duration of this NEPA process.

[204] DEIS at 4-75.
[205] *See* Part III.B. and Part II.D.1.
[206] *See* Part I.A.

National Sustainable Agriculture Coalition

February 10, 2015

FDA Public Listening Session on the Draft Environmental Impact Statement for the Proposed Rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Re: NSAC Comments on the Draft Environmental Impact Statement

Thank you for this opportunity to comment on the Draft Environmental Impact State (DEIS). My name is Sophia Kruszewski and I am a Policy Specialist for the National Sustainable Agriculture Coalition (NSAC). NSAC is an alliance of over 100 grassroots organizations across the country that advocate for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities.

NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainable agricultural systems, including access to fresh, healthy food. Many NSAC member organizations work directly with small and mid-sized sustainable and organic farmers and on-farm food processors who conduct activities within the scope of FDA's proposed rules. Many also work directly with farmers and USDA's Natural Resources Conservation Service field staff at the state and county level to enroll working farmland in conservation programs to conserve and enhance the quality of our soil, water, air, and wildlife habitat.

FSMA, and the produce rule in particular, is guaranteed to impact the agricultural landscape. The agricultural landscape is inextricably linked to the environment. Throughout the legislative and rulemaking processes, NSAC has voiced concerns that the FSMA regulations may result in unnecessary adverse environmental impacts, particularly by discouraging farmers from maintaining and adopting beneficial conservation practices on their farms.

We also sought to ensure that the agency properly consider any other adverse impacts of the rule on air, soil, water, habitat, and human health. We are very pleased that the agency recognized that these rules – and this rule in particular – could have such environmental impacts, and that it agreed to conduct a full environmental review of the Produce Rule under NEPA.

NEPA's importance in the rulemaking process is two-fold: First, it ensures that the agency will have available, and will carefully consider, information necessary to determine whether its action could have significant environmental impacts. Second, and no less important, it provides the public with an opportunity to participate and weigh in on the agency's decision-making process. And so we commend the agency for undertaking this complex task, and for providing the public with significant opportunity to weigh in on the scope, and now content, of the DEIS.

It is our fervent hope that this process is not in vain, and that – court-imposed deadlines aside – the agency will seriously consider what modifications are needed to ensure the EIS provides a robust assessment of impacts as the Produce Rule is finalized. Given the short timeline, and the haste with which the agency had to complete this DEIS, we have some concerns about its adequacy. We will be providing written comments and recommendations on the DEIS once we have fully reviewed it.

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In the meantime, I provide the following initial concerns:

First, data. There are many instances throughout the DEIS where the agency acknowledges a lack of data necessary to fully assess any impacts. We recognize that data limitations are a significant problem, a problem that has plagued numerous aspects of this rulemaking. NEPA requires the agency take a hard look at the impacts, and perform the best analysis it can, with the best available data. Thus, the agency must do a careful, thorough search for all available data. If the data are not there, the agency must make its best, most reasoned estimates of impacts. The agency cannot simply choose not to consider important impacts just because the data is hard to locate or incomplete.

Second, cumulative impacts. NEPA requires FDA to consider the cumulative impacts of the rule together with other reasonably foreseeable impacts beyond the rule itself. This should include not only a consideration of the impacts of the Produce Rule in tandem with the rest of the FSMA rules, but also a consideration of the impacts associated with farms – particularly small and very small farms – that choose to stop growing covered produce, and the associated impacts on the economy and access to fresh fruits and vegetables. Unfortunately, the DEIS makes light of the effects to farmers that will be covered by multiple rules. We have consistently urged the agency to clearly identify and articulate the extent to which farms may be subject to multiple rules, without result, and the agency's failure to meaningfully discuss this scenario in the DEIS continues this troubling trend.

Finally, we are incredibly concerned by the agency's reliance on other laws, regulations, or voluntary compliance programs to mitigate the environmental impacts of the rule. The agency cannot abdicate its duty to analyze environmental impacts under NEPA; yet the agency consistently does just that - determining that there is no need to assess water quality impacts because of the Clean Water Act, or pesticide application impacts because of FIFRA. This strikes me as overly optimistic, if not downright naïve, and it runs counter to clear legal precedent, which says the agency cannot rely on compliance with another agency's requirements in a NEPA review. This issue is particularly troublesome where the agency defers to compliance with voluntary programs like NRCS conservation programs, or USDA GAPs. Both are which are *voluntary* programs, not to mention that the latter is not geared toward environmental health.

Again, we are very pleased with the opportunity to provide feedback on the DEIS. This was a massive undertaking, and an exceedingly important one. But the fact that the DEIS did not come out until after the rule's two comment periods ended and must now be hastily completed in time for the October deadline does give us some doubt that the agency will truly consider public input at this stage in the process. We hope that the agency will take this feedback and all the comments and suggestions received on the DEIS to improve the overall analysis, and consider the impacts of the rule *before* making any final decisions about the rule itself, as NEPA requires.

On all of these issues, we will follow up with specific recommendations in our comments to the docket, and we look forward to continuing to work with the agency to ensure that the regulations and their implementation are successful in meeting public health goals, and are supportive of sustainable agriculture and food systems.

Thank you,

Sophia Kruszewski, Policy Specialist
National Sustainable Agriculture Coalition