



August 16, 2013

Ladies and Gentlemen:

Re: Invitation to Cooperating Agencies - EIS for Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Docket No. FDA-2011-N-0921

The U.S. Food and Drug Administration (FDA) will be preparing an Environmental Impact Statement (EIS) to evaluate the potential environmental effects of the "Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (hereafter referred to as "the produce safety rule" or "the proposed rule"). The EIS will be prepared in accordance with the National Environmental Policy Act (NEPA), U.S. Food and Drug Administration NEPA Implementing Regulations (21 CFR part 25), and the Council on Environmental Quality (CEQ) Regulations for implementing NEPA (40 CFR Parts 1500–1508). Information on the proposed rule may be accessed at the above-referenced Docket No.

To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the Food and Drug Administration (FDA) has published the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (hereafter referred to as "the produce safety rule" or "the proposed rule") to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption (78 FR 3504, Jan. 16, 2013). FDA has proposed these standards as part of our implementation of the FDA Food Safety Modernization Act (FSMA). These standards would not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance would be eligible for exemption from the requirements of this rule. The proposed rule would set forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. We expect that the proposed rule, if finalized as proposed, would reduce foodborne illness associated with the consumption of contaminated produce.

Issues that will be analyzed include possible effects from the rule on water resources, pesticide use, soil amendments, and other environmental effects.

As part of the process for determining the scope of issues to be addressed in the EIS and for identifying the important issues related to the proposed action, we request your comments on the above issues and any other issues that you can identify as important. We intend to use your comments to:

- Identify the range of alternatives and environmental impacts and important issues to be addressed in the EIS.
- Identify and eliminate from detailed study the issues which are not important or which have been covered by prior environmental review.
- Identify other environmental review and consultation requirements.

Because of your agency's expertise in related areas, we request your agency to be a cooperating agency.

We expect your agency's involvement to entail only those areas for which it has specific expertise and do not anticipate direct writing or analysis by your agency for the document's preparation. The activities we may take to maximize interagency cooperation include the following:

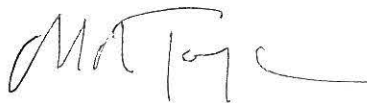
1. Invite you to participate in scoping meetings and other meetings;
2. Consult with you on any relevant technical studies that will be required for the project;
3. Provide you with project information, including study results;
4. Request your review of relevant sections of the draft EIS (DEIS) prior to its release for comment by the public and other agencies.
5. Encourage your agency to use the above documents to express your views on subjects within your jurisdiction or expertise; and
6. Include information in the project environmental documents that cooperating agencies need to discharge their National Environmental Policy Act (NEPA) responsibilities and any other requirements regarding jurisdictional approvals, permits, licenses, and/or clearances.

We look forward to your comments and response to this request and your role as a cooperating agency on this project. If you have any questions or would like to discuss in more detail the project or our agencies' respective roles and responsibilities during the preparation of this EIS, please contact:

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Please forward your comments and confirmation that you will be a cooperating agency to us by September 16, 2013.

Very truly yours,



Michael R. Taylor
Deputy Commissioner for Foods
and Veterinary Medicine