



Nov 22, 2013

**Re: FSMA Proposed Rule for Produce Safety:**

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Docket No. FDA-2011-N-0921;

The Canadian Produce Marketing Association (CPMA) appreciates the opportunity to provide comments on the proposed regulation: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. Docket No. FDA-2011-N-0921;

Based in Ottawa, Ontario, the Canadian Produce Marketing Association (CPMA) is a not-for-profit organization that represents over 800 companies, both domestic and international, that are active in the marketing of fresh fruits and fresh vegetables in Canada. Our members include representation from all sectors of the fresh produce industry from the farm gate to the dinner plate. CPMA's vision is to enable and lead the produce industry by enhancing the market and facilitating trade of fresh fruits and vegetables for its members.

At CPMA we recognize that foodborne illness does not differentiate between small, medium or large operations. We are only as good as our weakest link and we must keep this in mind when applying exemptions for food safety. Safety is everyone's responsibility; the rule should equally apply to all applicable operations, regardless of size, source or growing methodology.

Regulations and rules must be flexible to adjust to science and industry solutions. The move to an outcome-based regulatory model is vital in the final proposed FSMA rules, specifically the Produce Safety and Preventive Control Rules which are presently being developed. Reliance on prescriptive regulatory tools that apply formalized metrics within regulations will hinder both industry and government's response to market change, advancing technologies and science-based innovative changes, both domestically and globally.

Additionally, every effort must be made by the USFDA to work with other jurisdictions to align regulations and policy with common outcomes in mind.

**Comments for consideration to the Produce Rule**

- That standards should apply to all produce, and variabilities should be addressed in Guidance documents or if more appropriate by incorporation by reference to standards.
- Quantitative metrics such as those suggested for water, and animal based soil amendments, quantitative standards and testing requirements should not be included in regulations and rather should be in guidance or industry standards which are subject to review and can be incorporated by reference. (If any metrics were to be included there must be a mechanism to facilitate rapid change and public comments)
- The Produce Safety Rule clearly addresses hazards present in the following areas: growing, harvesting, packing and holding of fresh produce. These hazards do not change when a packer includes produce from a farm separate from the packing facility. The same hazards are present in this scenario as would be present for packing directly on farm-located facilities. Additional preventative controls are not necessary. The definition for **mixed -type facility** included in the Preventive Controls Rule stipulates that mixed-type facilities would include many fresh produce packing operations **and fresh produce operations should be exempt from this definition and be should be regulated under the Produce Safety Rule.**
- Will FDA give consideration to recognition of industry-led and government recognized third-party audited food safety schemes, such as CanadaGAP and other GFSI schemes, along with international food safety standardization efforts or acceptance of equivalency? What would be the criteria to assess and recognize such schemes?

## Specific Comments

1. CPMA request clarification from FDA on the following
  - Allowances are proposed for alternatives to certain requirements based on provision of “adequate scientific data or information” demonstrating an equivalent outcome. It is not clear what the data or information would qualify to support such alternatives. It is recommended that FDA provide clear guidance on the information to be submitted to support the assessment and how the related decision making process will function.
  - Better definition for a *fruit*, some fruits do not have seeds, i.e. navel orange
  - Whether edible flowers that are used in various cuisines are going to be covered under scope of this rule
  - Whether seeds, example: sunflower seeds, would be considered in scope of the produce rule; seeds are mentioned only in terms of sprouting in the previous definition.
2. RE: “(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list— arrowhead, arrowroot, artichokes, asparagus ...and yams;”
  - Several of the items on this list are known to be eaten raw in salads and healthy drinks. Including lists of covered and non-covered produce in rules does not allow for easy amendment as dietary or cultural trends change, we would suggest this would be better addressed in guidance
  - There are products on the above list that are consumed raw (and increasingly so – in smoothies, salads etc. )
  - There should be no exemptions
3. Direct water application method
  - We would request FDA to provide clarifying examples of application methods that are not direct
4. The term “ownership” is problematic because a farm may have tenants or leases, etc. A definition of the responsible party should be included and a term such as “operator” would be preferable and would address industry practices and more properly assign liability.
5. We do not endorse the concept of certain facilities being exempted because they are selling directly to consumers.
6. 112.130 (d) “You may not use hand antiseptic/sanitizer or wipes as a substitute for soap and water” –  
**Comment:** we do not support this as it is hard for many growers to provide and keep water potable for hand washing. Other options may be more effective and a better alternative.
7. CPMA is opposed to exemptions to the rule based on size of an operation.
8. CPMA would strongly recommend that FDA release a revised proposed Produce Rule prior to issuing of a final rule, to allow all stakeholders an opportunity to review and provide comments to a modified proposed rule.

Respectfully submitted by

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On behalf of

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