CPMA ACDFL

Nov 22, 2013

Re: **FSMA Proposed Rule for Preventive Controls for Human Food:**
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Proposed rule

Docket Number: FDA-2011-N-0920

The Canadian Produce Marketing Association (CPMA) appreciates the opportunity to provide comments on the proposed regulation: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Proposed rule. Docket Number: FDA-2011-N-0920

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.

Specific comments to the Preventive Controls Rule
Comments on definitions:

1. ***Critical control point*** means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an **acceptable level**. **Comment:** There is no definition for "acceptable level" in this proposed rule. Recommend using the same definition from the produce rules "*Adequately reduce microorganisms of public health significance*, which means "reduce the presence of such microorganisms to an ~~extent sufficient to prevent illness~~", But would recommend replacing "**to an extent sufficient to prevent illness**" with "**minimize the risk of foodborne illness**."
2. We would seek clarification on the **differences in definition between "facility" and "plant";** if *holding and storage* are the same concept and if an operation holds product does that make it a ***facility*****? *(Holding*** means storage of food- Is there a time frame required here? **An example of a definition used in Canada: CanadaGAP definition-"Holding**: Keeping product in a non-temperature controlled (ambient) environment for a few minutes to a few days."**)**

3. The definition of "**lot"** (the food produced during a period of time indicated by a specific code) should not just be limited by time. We would recommend using the Canadian definition, which allows for lots to be defined by time **or** by a specific ID.
4. The definition of **Pest** refers to any objectionable animals or insects including birds, rodents, flies, and larvae. This definition of "pest" – needs clarity on how FDA defines "objectionable"? We feel **pest** is better defined in the Canadian *Pest Control Products Act:* "An animal, plant or other organism that is directly or indirectly injurious, noxious or troublesome, and an injurious, noxious or troublesome condition or organic function of an animal, a plant or other organism (e.g., rats, mice, birds, reptiles, beetles, weeds, disease, etc.).
5. **Qualified individual** means a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

   Comment: Requires clarity as to what criteria would be used to assess the equivalence of training to curriculum that would be recognized as adequate by FDA, such as curricula offered in international fora, as well as the criteria that will be used to recognize job experience in foreign countries/establishments exporting to the US.
6. **The definitions of "farm" and "mixed -type facility"** should be reviewed.

   The definition of **farm** ignores many activities that can also be included in farm activities (e.g. sorting, storing, waxing , packing ….) that result in no significant change in the product or the hazard analysis associated with the product and should be included in the activities consistent with the farm definition and the activities of these farms should be covered under the Produce Rule.

   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. Example: A packer packing fruit from more than one farm operation. 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 at the on farm-located facilities and the Produce Rule addresses these hazards. Additional preventative controls are not necessary.

   FSMA states that any facility that is required to register with the FDA Food Facility Registration program is to be regulated under the Preventive Controls Rule. This requirement has its origins in the Bioterrorism Act of 2002 and was intended to create a database for the FDA to track food suppliers globally and was not designed with any risk based criteria. Furthermore, this requirement is in conflict with FDA's original statements that registration was merely a means of identification.

   This requirement is overly simplistic and does not take into consideration facilities that pack only raw agricultural commodities (whole fresh produce.) These facilities and their production processes are clearly and comprehensively addressed in the Produce Safety Rule. Additionally, the food safety activities addressed in the Produce Safety Rule are well understood and therefore should not require validation or the same cGMP programs that are required in food processing and food manufacturing facilities.

   The benefits derived from the application of the Preventive Controls Rule to facilities that pack only raw agricultural commodities would likely be insignificant at best and it is extremely likely that the economic hardship posed on the fresh produce industry will be significant and will almost certainly affect family operated, small, and medium size operations the hardest. We strongly recommend that facilities that pack only raw agricultural commodities be regulated under the Produce Safety Rule.
7. **Sub part c Comment:** We would like FDA to use the "*Education and training"* terminology from the preventive controls rule to apply to the definition in the produce rule.

8. **Subpart (b) (3) Comment:** Need clarification from FDA on what is the definition of a "bulk vessel" (a bulk vessel should not include: lugs, totes, harvest container or other harvest containers, etc.)
9. **Subpart (b) (6)** – **Comment:** Add "where necessary" to the definition of adequate ventilation.
10. § 117.35 Sanitary Operations. **(3) Single-service articles**. (3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and **must** be handled, dispensed, used, and disposed of in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food packaging materials.
    Comment: Propose FDA uses the term "**should**" instead of "**must**".
11. **117.80 (b)(2):** "Raw materials and ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated."
    Comment: While fresh produce suppliers will follow practices to minimize the risk of contamination, growing produce is not risk free, and **fresh produce cannot be pasteurized nor is there any "kill step" available.**
12. **117.93 Warehousing and distribution –"**Storage and transportation of food must be under conditions that **will protect** against cross-contact and biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and the container".
    Comment: Even under the best conditions, produce will spoil/deteriorate. We suggest changing "will protect" to "will minimize to acceptable levels"
13. **117.130 Hazard analysis 2b Comment:** We suggest that FDA should include radiological hazards within "chemical". FDA has recognized the rarity of a radiological hazard reasonably likely to occur, and that frequency does not deserve a special category of consideration.
14. **In 117.150** "a) facility must validate that the preventive controls identified and implemented…are adequate to do so." **Comment:** FDA must provide clarification on expectations for a validation process. Sanitation and food safety practices in the packing and handling of whole fresh produce are well understood and clearly outlined in the Produce Safety Rule. Additionally, the costs associated and the experience required to properly validate even these basic processes are likely to pose severe economic hardship on all but the largest fresh produce producers and handlers.
15. **Subpart D** requires clarification that warehouses and operations that only hold food not exposed to the environment and not requiring temperature control for safety are exempt from Subpart C, and both Subparts B and C if only handling raw agricultural commodities, as described in the preamble.

    In **subpart D** there is insufficient information regarding the definition of "exposed".
    In 117.315(c) **Comment:** the requirement to keep records on site for 6 months should be deleted. The provision to provide required records within 24 hours of request should suffice

16. **Microbiological Testing. Comment:** CPMA agrees with the exclusion of mandatory microbiological testing of products from the rule, either as raw materials or finished products.
    - There is currently no scientific validity to any economically feasible sampling scheme to detect anything but gross contamination, attention to GAPs and GMPs are a more reliable approach to preventing gross contamination.
    - Raw materials that are raw agricultural commodities are individual entities; testing of one is not likely to be representative of others in the "lot".
    - Any raw material or finished product testing should remain a voluntary part of an operation's food safety plan.

17. **Environmental monitoring** should remain a voluntary part of the food safety plans of operations vulnerable to such routes of product contamination.
18. CPMA would strongly recommend that FDA release a revised proposed Preventive Control 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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