CPMA ACDFL

DATE: January 27, 2014

Re: **Proposed Rule for Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals**
Docket No. FDA-2011-N-0143

The Canadian Produce Marketing Association (CPMA) appreciates the opportunity to provide comments on the proposed regulation for the Foreign Supplier Verification Program and we wish to thank the FDA for extending the deadline for the comment period.

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.

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

Issuance of Guidance and Support for Implementation Timeline
The FDA states that it intends to issue guidance to importers on interpreting and implementing FSVP. CPMA looks forward to the development of guidance material by the US FDA to assist industry in the interpretation and implementation of the requirements contained in the proposed rule. We hope that any guidance will provide flexibility to industry to implement rules in ways that are appropriate to their business practices while meeting the same high level of public health protection. CPMA would like to see this guidance released concurrently with the final rule to allow for effective implementation of FSVP measures.

Potential for rule overlap
In finalizing proposed rules under FSMA, the FDA should identify any areas where these rules overlap and/or require similar activities to meet those rules' objectives. For example, a very small foreign supplier could be subject to duplicative "modified requirements" under the provisions of the proposed rules on "*Food Supplier Verification Programs for Importers of Food for Humans and Animals*" (FDA-2011-N-0143) and "*Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food*" (FDA-2011-N-0920). Such a foreign facility/supplier would be required to provide two sets of documentation (which may vary) to two separate entities, the U.S. FDA under the first rule and the U.S. importer under the second rule, to meet the same objective of providing assurances that the food meets food safety requirements. Clear guidance from the FDA on whether activities performed to fulfill one rule's requirements will satisfy another rule's requirements should be made available to minimize burden on regulated industry.

FSVP Must Clarify "Comparability" Program and Fair Administration

CPMA requests that FDA focus on Canada as a priority in working towards comparability because of the close trade relationships between our two countries.

Definitions
CPMA suggests that definitions be aligned to the extent feasible with international standards and across rules to promote consistency and common understanding of terminology.

"Foreign supplier means*, for an article of food, the establishment that manufactures/processes the food, raises the animal, or harvests the food that is exported to the United States without further manufacturing/processing by another establishment; except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature."*
CPMA asks that FDA provide clarification of **de minimis** activities for fresh produce and should include activities as mentioned in our comments to the Preventive Control and Produce Safety Rules. (See below)
In the proposed definition of manufacturing/processing, FDA says that "*For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding".*

In our comments to The Preventive Control Rule and The Produce Safety Rule we felt 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.

CPMA also suggest that the definition for "foreign supplier" includes handlers who may aggregate produce from more than one grower.

"*Qualified individual *means a person who has the necessary education, training, and experience to perform the activities needed to meet the requirements of this subpart… a qualified individual must have 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 be otherwise qualified through job experience to develop and implement a food safety system."
As we provided in comments to the Preventive Control rules CPMA would like 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.

Modified requirements
Food safety hazards are independent of the size of an operation supplying or importing food and CPMA does not support an exemption or modified FSVP requirement based on the size of a company.

§ 1.502 What foreign supplier verification program (FSVP) must I have?
The FDA states, "*…for each food you import, you must develop, maintain, and follow an FSVP that provides*

adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g, 350h, 342, and 343(w)).”

CPMA requests clarity as to how the FDA will acknowledge processes and procedures that “provide the same level of public health protection”.

CPMA requests clarification as to the interpretation of “*for each food you import, you must develop, maintain, and follow an FSVP.”* Crop groupings should be considered under one FSVP, if the hazard analysis reveals similar practices and similar risks. CPMA believes that produce grown, harvested, and packed under the same conditions should be aggregated under one verification program.

§ 1.505 What hazard analysis must I conduct?
CPMA believes that the same requirements for hazard analysis should be required for both domestic and imported products, to ensure fair and equal treatment among all suppliers and across all rules. In the FSVP rule, FDA proposes to require importers’ hazard analyses to go beyond microbiological risks to include chemical, physical and radiological. For products covered under the Produce Safety Rules and meeting its requirements no further hazard analysis (for physical, chemical or radiological) should be required of the importer.
§ **1.506 What foreign supplier verification and related activities must I conduct?**
§ **1.506(g) Hazard Controlled or Verified by the Foreign Supplier**
The CPMA supports the proposal to use FDA accredited third-parties for compliance with FSVP. We also support the proposal that certification of food under section 801(q) required as a condition of granting admission to certain high-risk foods be allowed as a valid audit for FSVP purposes. Audits conducted for the purpose of enrolling in the Voluntary Qualified Importer Program should also satisfy audit measures under the verification methods for FSVP. Aligning audit requirements, industry resources, and government resources are all crucial in ensuring that resources are used effectively to enhance food safety.

Importers should also be permitted to use non-accredited auditors for FSVP verification audits that do not participate in FDA’s Third Party Accreditation activities, so long as foreign government inspection is used as a substitute and provided the foreign country’s food safety system compares favourably with the U.S., as determined by country-to-country systems recognition.

1.506 (g) (3) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority.
CPMA supports that an inspection by FDA or an officially recognized or equivalent food safety authority, provided the scope is comparable, could be relied upon by an importer as part of their verification steps.

1.507 What investigations and corrective actions must I conduct under my FSVP?
In 1.507(b) and 1.507(c), *FDA proposes that the importer must investigate the cause or causes of adulteration or misbranding and take appropriate corrective actions if it determines that one of its foreign suppliers did not produce the food in compliance with processes and procedures that provide the same level of public health protection as required under the FD&C.*

CPMA agrees that the importer has a role in investigating the cause or causes of adulteration or misbranding, and in taking appropriate corrective actions. CPMA believes that such actions do not necessarily require a physical visit to the foreign supplier, but could include actions such as written and/or verbal inquiries, as well as written and/or verbal instructions toward corrective actions.

1.512 What FSVP may I have if I am a very small importer or I am importing from a very small foreign supplier?
CPMA does not support modifications or exemptions to the FSVP requirements based on a company's size or description.

1.513 What FSVP may I have if I am importing a food from a country with an officially recognized or equivalent food safety system?
CPMA believes that food imported from a country whose food safety system has been formally recognized by FDA as comparable should be considered compliant under FSVP requirements.

Respectfully submitted by
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On behalf of Ron Lemaire
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