Voluntary Qualified Importer Program (VQIP) Draft Guidance

July 20, 2015

UNITED FRESH
PRODUCE ASSOCIATION

Moderator:

- **Dr. David Gombas**
  SVP, Food Safety and Technology
  United Fresh Produce Association

Speaker:

- **Brian Pendleton**
  Senior Policy Advisor
  FDA Office of Policy and Planning

Instructions

- All phone lines are muted
- To ask questions, please type in the chat box and send

Voluntary Qualified Importer Program (VQIP)

Overview of Draft Guidance

Office of Foods and Veterinary Medicine
Food and Drug Administration

FDA FOOD SAFETY
MODERNIZATION ACT

THE FUTURE IS NOW

What Is VQIP?

- FDA required to establish a program to provide for the expedited review of food imported by voluntary participants.
- Eligibility is limited to importers who demonstrate a high level of control over the safety and security of their supply chains.

Definition of VQIP Importer

- Section 806(g) defines “importer” as “the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.”
  - Can include manufacturers, consignees and importers of record for food for humans and animals
  - May or may not be the FSVP importer

Draft VQIP Guidance Eligibility Criteria

- Quality Assurance Program (QAP)
- Assurance of compliance with the supplier verification and other importer responsibilities under the applicable FSVP or HACCP regulations.
- Current facility certification, including farms, issued under FDA's Accredited Third-Party Certification regulations for each foreign supplier of food in VQIP.

Draft VQIP Guidance Eligibility Criteria (con'd)

- 3+ year history of importing food to the United States.
- No ongoing FDA administrative or judicial action (e.g., import alert, injunction, recall), or other history of non-compliance with food safety regulations by the importer, other entities in the supply chain (e.g., foreign suppliers, filers/brokers, and FSVP and HACCP importers), or food

Draft Elements of a QAP

- Corporate Quality Policy Statement
- Organizational structure and individual responsibilities
- Policies and procedures to ensure food safety from source to entry (e.g., temperature and storage controls), including procedures regarding:
  - Compliance with supplier verification procedures in the FSVP or HACCP rules, if applicable, and maintenance of current facility certifications under FDA's Accredited Third-Party Certification Program,
  - Communication of information about potential health hazards to FDA and others
  - Corrective actions to address food and foreign supplier non-compliances that post a risk to public health

Draft Elements of a QAP (con'd)

- Food defense system to protect against intentional adulteration
- Experience and training requirements for employees responsible for implementing the QAP
- Written procedures for establishing and maintaining records relating to the structure and implementation of the QAP

Draft Benefits of VQIP

- Expedited entry into the U.S. for all foods included in an approved VQIP application
- Examination and/or sampling generally limited to “for cause” situations in which there is a potential threat to public health
- Any sampling or examination done at destination or another location chosen by the importer

Draft Benefits of VQIP (con'd)

- Expedited laboratory analysis of any samples
- VQIP Importers Help Desk
- Public posting on the FDA's VQIP web page of approved VQIP importers, if desired

Other Elements of the Draft Guidance

- Application Process (e.g., elements, timing, FDA review)
- Revocation Process
- Reinstatement Process
- FDA Oversight
- User Fees

Status of VQIP

- Notice of Availability published in Federal Register 6/5/15
  - Draft Guidance Document
  - Guidelines in Consideration of the Burden of the VQIP Fee on Small Business
  - 75 Day Comment Period

Key Questions

- Benefits
- QAP
- Fee Structure

Timing of VQIP Program

- Anticipate first applications January 1, 2018
- Anticipate first benefit period to begin October 1, 2018

Questions

- For more information, visit our website: http://www.fda.gov/fsma

Thank you for attending today's Webinar on Voluntary Qualified Importer Program (VQIP)!

- For more information on VQIP please contact Erin Grether at egrether@unitedfresh.org

UNITED FRESH PRODUCE ASSOCIATION