



U.S. FOOD SAFETY MODERNIZATION ACT (“FSMA”)

OVERVIEW AND IMPLICATIONS

**CONFERENCIA INT’L BERRIES - TALCA
1-SEPTEMBER-2016**

1. OBJECTIVES

- **High-Level Overview of FSMA**
- **The Major Rules**
- **Implications**
- **Practical Impact on Chilean Berry Industry**

2. FSMA BRIEF OVERVIEW

- **Enacted January 4, 2011**
- **Amends FDCA (Federal Food, Drug, and Cosmetic Act) of 1938**
- **Supplements: Bioterrorism Preparedness Act of 2002; 2008 Farm Bill**
 - **Same Framework but Fundamental Changes; 70+ Year Reform**
- **“Reactive” vs. “Preventive”**
- **FSMA did not include funding**
- **Final Rules Issued 2015-16**
- **No “one-size-fits-all”**

3. MAJOR ELEMENTS

- **Preventive Controls (HARPC)**
- **Enhanced Safety Standards**
- **Inspection and Compliance**
- **Imported Food Safety**
 - **Ensure that imported foods meet U.S. safety standards.**
 - **Importers must verify adequate foreign supplier preventive controls. (FSVP)**
- **Response**
 - **Mandatory recall authority. Expanded administrative detention. Suspend food facility's registration.**
- **Enhanced Partnerships**
- **Equal Application: U.S. and Foreign Suppliers**

4. Rulemaking: “Foundational Rules”

- **Preventive Controls for Human Food (Sept. 10, 2015)**
- **Produce Safety (Nov. 13, 2015)**
- **Foreign Supplier Verification Program (Nov. 13, 2015)**
- **Third Party Certification (Nov. 13, 2015)**
- **Sanitary Transportation (April 5, 2016)**
- **Intentional Adulteration (May 27, 2016)**

5. Implementation Status

RULE	FINAL ISSUED	DESCRIPTION	COMPLIANCE DEADLINES
Preventive Controls for Human Food (HARPC)	9/10/2015	Requires that food facilities have safety plans that set forth how they will identify and minimize hazards.	Safety Plans/Record-Keeping: Sept. 19, 2016 (+ 1-2 years for small businesses) Supply-Chain: March/Sept. 2017
Produce Safety	11/13/2015	Establishes science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms.	Jan. 26, 2018 (+ 1-2 years for smaller farms)
Foreign Supplier Verification Program (FSVP)	11/13/2015	Importers will be required to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of U.S. food producers.	May 29, 2017 (or 6 mos. after foreign supplier compliance)

6. OVERVIEW OF HARPC RULE

- **“Hazard Analysis and Risk-Based Preventative Controls”**
 - **Compare to HACCP (“Hazard Analysis and Critical Control Point”)**
- **Applies to Registered FDA Food Facilities**
 - **Manufacturing, Processing, Packing or Holding of Food**
 - **Some exemptions**
- **Science-Based. Product and Situation Specific.**

7. ELEMENTS OF HARPC RULE

- **Written Food Safety Plan**
- **Hazard Analysis**
- **Preventative Controls**
- **Recall Plan**
- **Monitoring**
- **Corrective Actions**
- **Verification Activities**
- **Supply Chain Program**
- **Record-Keeping**

8. OVERVIEW OF PRODUCE SAFETY RULE

- **Standards for agricultural water, biological soil additions, worker training and hygiene, equipment, etc.**
- **Exemptions:**
 - **Farms with annual revenues \leq USD 25,000**
 - **Produce that is not a raw agricultural commodity (RAC)**
 - **Produce that subsequently is processed to eliminate harmful micro-organisms**
 - **Juice**
 - **Processes must be validated**

9. FSVP Elements

The importers shall:

- **Conduct written hazard analysis (HARPC) for each type of food.**
 - **Must evaluate biological, chemical and physical hazards.**
- **Evaluate and approve foreign suppliers based on hazard analysis, supply chain, and foreign supplier performance**
 - **Re-evaluation at least once every three years**
- **Conduct on-going supplier verification activities**
 - **Document appropriate verification activities: onsite audits, sampling and testing food, review of foreign supplier's food safety records, etc.**
 - **Review & assess results of verification activities, modify FSVP as needed**

10. FSVP Elements, continued

The importers shall:

- **Use qualified individuals (training, experience) to perform all required FSVP tasks**
 - **Note: Use of Third-Party Determinations**
- **Take corrective actions**
- **Maintain signed & dated records of ALL required FSVP tasks**
 - **Must make records available promptly upon request by FDA**
 - **Retain records for at least 2 years**
 - **Offsite storage of records is allowed if records can be retrieved within 24 hours of request**

11. FSVP (cont.)

- **Applies to All Importers**
 - **U.S. Owner or Consignee (or their U.S. Agent) of Food at Time of U.S. Entry**
- **Exemptions allowing for less stringent FSVP requirements (must document eligibility for exemption)**
 - **Importers with < \$1 million annual sales**
 - **Produce from farms with < \$25,000 sales**
 - **No hazard analysis required and may generally rely on written assurances from foreign suppliers**

12. Compliance Conclusions

- **No “one-size-fits-all” solution to comply with FSMA Requirements**
- **Product / Facility / Situation Specific**
- **Qualified / Trained individuals must design and implement strategies**

13. Penalties

- **Administrative Detention: “appears” to be adulterated or misbranded**
- **Refusal of Admission: appearance of importer FSVP non-compliance**
- **Mandatory Recall Authority**
- **Suspension of Facility Registration**
- **Failure to Comply = “Prohibited Act”**
- **Civil/Criminal Liability for “Prohibited Acts”: 1-3 years prison + fines (up to \$100K/\$250K)**
- **The Park Doctrine: Senior corporate officer criminal strict liability (e.g., regardless of knowledge).**

14. Foreign Enforcement

- **Testing**
- **Administrative Detention Authority: “credible evidence” vs. “reasonable belief”**
- **Inspections**
 - **19,200 inspections by 2017**

15. Foreign Enforcement: Challenges and Realities

- **Limited Testing: < 2%**
- **Practical / Legal Limitations**
 - “[W]e expect to have a far less robust system of direct public oversight of foreign food facilities and farms We have less ability to physically inspect and take enforcement actions against [such facilities/farms] due to legal and practical limitations.” Unannounced inspections are complicated or impossible abroad. Also we do not have the same access to the courts. 80 Fed. Reg. 74225 (Nov. 27, 2015)
 - > 200,000 Foreign Registrations (2015 Imports: >130,000)
- **Other Uncertainties: Budgetary**

16. FSMA Reliance on Importers

“Given the difficulties in conducting direct FDA regulatory oversight of foreign producers, FSMA requires importers to share responsibility for verifying the safety of imported food. . . . [by taking actions to ensure safety] by taking risk-based supplier verification activities.” 80 Fed. Reg. 74225 (Nov. 27, 2015)

Impact:

Importers → Exporters/Processors → Farms

Thank You