FSMA, FSVP, and FCS

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Global Food Contact 2016

Global food contact USA
MAY 11-13 2016, BETHESDA, MD, USA

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Food Safety Modernization Act (FSMA)

- Became law in January 2011
- Improves safety and security of food supply through prevention, not response
- “Importer accountability” is a key component
- FDA is finalizing implementing regulations
- Industry has many questions and FDA guidance is expected

Highlights

- Biennial Facility Re-Registration (on even years)
- Hazard Analysis and Risk-Based Preventive Controls (human + animal)
- Foreign Supplier Verification Program
  - Voluntary Qualified Importer Program
  - 3rd Party Accreditation
- Produce Safety Rule
- Sanitary Transportation
- Intentional Adulteration
- Mandatory Recall

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FSMA Implementation

FSMA Component	Current Status
Biennial Re-Registration	Next registration period begins October 2016
HARPC – Human Food and Animal Food	Final rules published September 17, 2015, effective Nov. 16, 2015
FSVP, 3rd Party Accreditation, Produce Safety	Final rules published November 27, 2015, effective January 26, 2016
VQIP	Draft guidance published June 2015
Sanitary Transportation	Final rule published April 6, 2016
Mandatory Recall	Already effective
Intentional Adulteration	Final rule expected May 31, 2016

Applicability to Food Contact Substances

Applicable

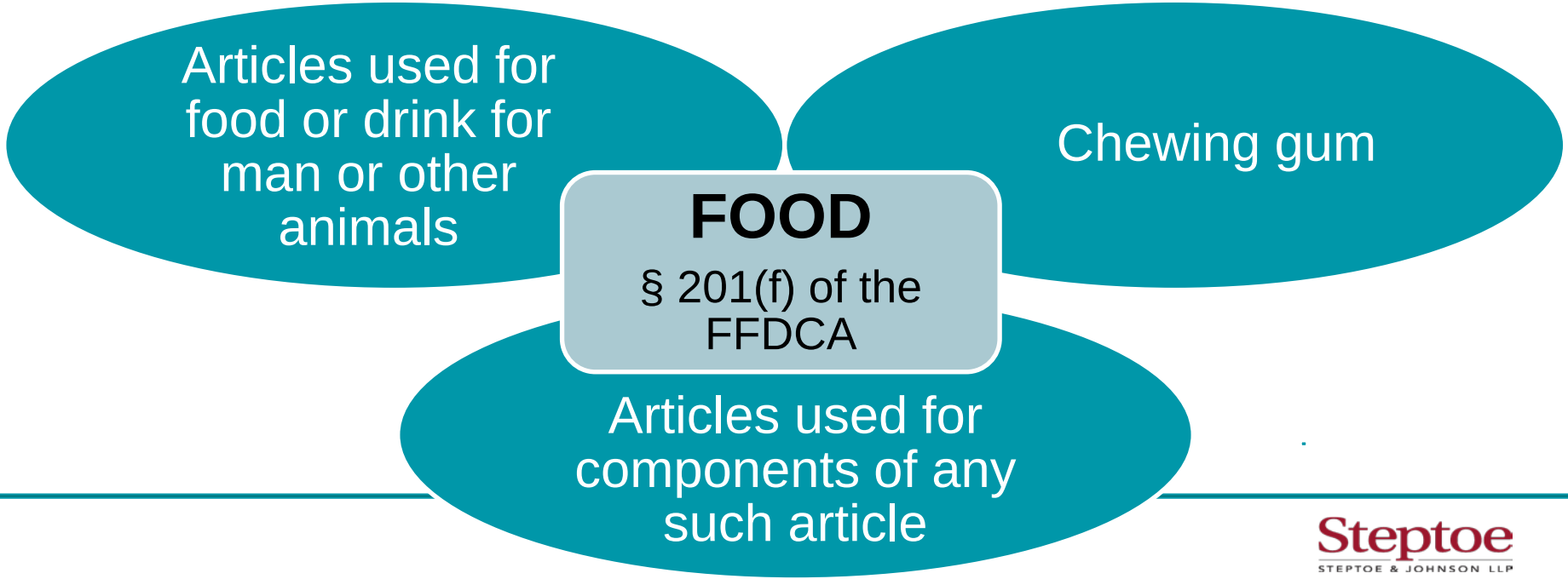
- Foreign Supplier Verification Program
- Mandatory recall

Inapplicable

- Hazard Analysis and Risk-Based Preventive Controls
- Sanitary transportation
- Intentional adulteration

FSVP

- Requires importers to perform certain risk-based activities to verify that **food** imported into the United States has been produced in a manner that meets applicable U.S. safety standards



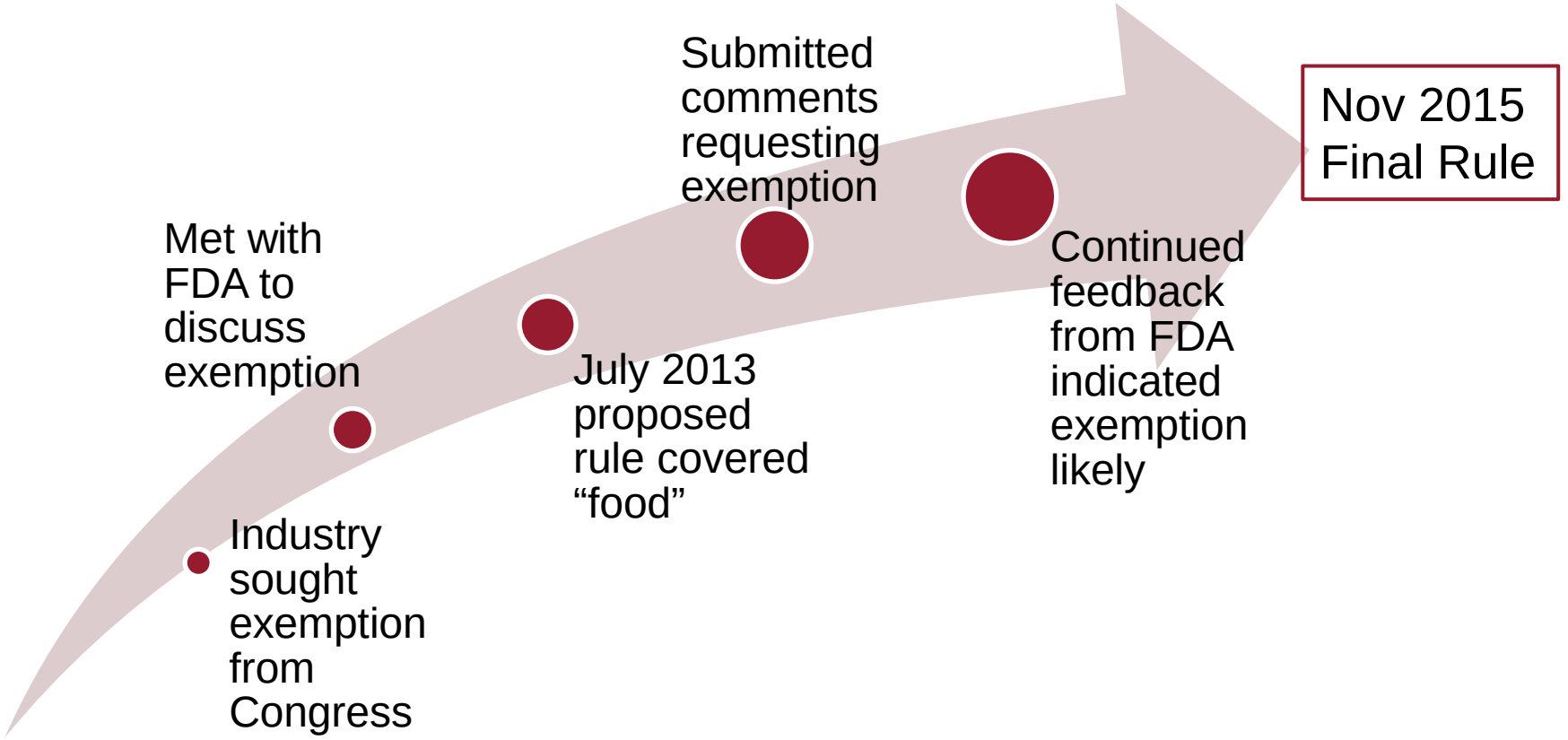
Applicability to “Food”

§ 201(s) “Food additive”
Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (unless GRAS or Prior Sanctioned)

Scope

1. Direct Additives – Food Ingredients
2. Secondary Direct Additives
   - Technical effect during processing, not in finished food
   - Some are food contact substances
   - Boiler water additives, ion exchange resins, some antimicrobials (no continuing effect on food)
3. Indirect Additives – Food Packaging and Other Food-Contact Materials

How Did We Get Here?



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FDA's Response

- "We do not agree that it is appropriate to exclude food contact substances (including food packaging), as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)), from the definition of "food" for FSVP purposes."
- Cites to:
  - *Natick Paperboard v. Weinberger*, 525 F.2d 1103 (1st Cir. 1975) (paperboard containing PCBs intended for food use is adulterated food)
  - *U.S. v. Articles of Food 688 Cases of Pottery* (Cathy Rose), 370 F. Supp. 371 (E.D. Mi. 1974) (ceramic pottery that leaches lead is adulterated food)

Summary

- Requires importers to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards
- FDA has indicated that “food” includes food contact materials
- Is currently considered to be broadly applicable to cover not only finished packaging (e.g., containers, cans, bottles, etc.) but all components (e.g., polymers, additives, paper) and processing aids (e.g., antimicrobials, boiler water additives)
- Industry is currently in discussions with FDA regarding the scope of the program as applied to food contact products and whether the agency will continue to consider FSVP relevant for these products

Who?

Importers

- The U.S. owner or consignee
- If none, U.S. agent or representative of the foreign owner or consignee

Exemptions

- For certain foods already subject to other regulatory programs
- Food for consumption, transshipment, import for export, returned U.S. food

Modified requirements

- “Very small importer” – Averaging <$ 1 million (human food)/ <$2.5 million (animal food) in sales over the prior 3 years

What's Required for the FSVP?

Importers must develop, maintain, and follow an FSVP

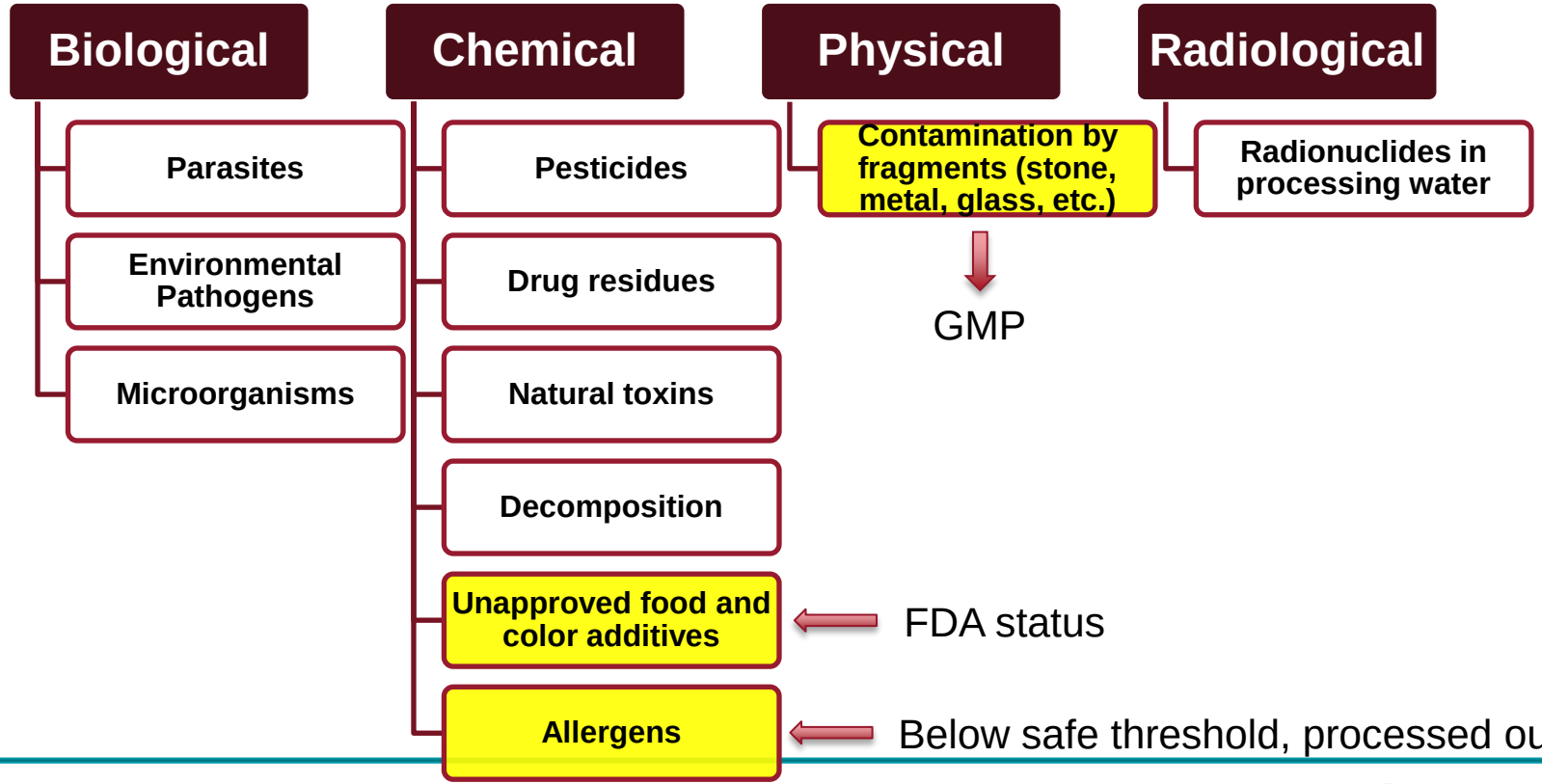
For each imported food, the importer must:

Conduct a hazard analysis	Evaluate the risk posed by each hazard and determine the need to establish preventive controls

What Might Be Needed for the FSVP?

- If preventive controls are needed, then for each foreign supplier of that food the importer must:
  - Evaluate supplier's performance
    - Procedures, processes and practices
    - Food safety history
    - Compliance with FDA regulations (i.e., import alerts, recalls, etc.)
  - Determine and conduct appropriate supplier verification activities
    - Use only approved suppliers
    - On-going verification of compliance (audits, testing, records review)
  - Take corrective actions when supplier is out of compliance

What Hazards?



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Example Hazard Analysis

ANIMAL FOOD SAFETY PLAN FOR COMPLETE SWINE, POULTRY, CATTLE AND SHEEP FEED TABLE 1. HAZARD ANALYSIS & PREVENTIVE CONTROLS										
Identification			**Evaluation**					**Prevention**		
(1)	(2)		(3)	(4)	(5)	(6)	(7)	(8)	(9)	
Ingredient or Processing Step	**Identify known or reasonably foreseeable animal food safety hazards (B, C, P)**		**What is the severity for the animal food safety hazard?**	**What is the probability for the animal food safety hazard?**	**What is the risk assessment for the animal food safety hazard?**	**Does the hazard require preventive controls?**	**Justify the response in column 6**	**What are the preventive controls for the hazard?**	**Hazard Preventive Control Number**	
Processing: Storage after Blending	B	None								
	C	Medication or nutrient Carryover	High (I)	Very Low (D)	Moderate (I-D)	No	1) As a registered medicated feed manufacturing facility, procedures are maintained to ensure compliance with CFR21 Part 225 CGMP Requirements for Medicated Feed. 2) Facilty maintains a history of no incidences of drug cross-contamination.			
	P	None								
Processing: Pelleting	B	None								
	C	Medication or nutrient Carryover	High (I)	Very Low (D)	Moderate (I-D)	No	1) As a registered medicated feed manufacturing facility, procedures are maintained to ensure compliance with CFR21 Part 225 CGMP Requirements for Medicated Feed. 2) Facilty maintains a history of no incidences of drug cross-contamination.			

Example Risk Assessment

RISK ASSESSMENT CHART				
PROBABILITY / SEVERITY	HIGH (A) Immediate danger to health and safety of the animal or humans.	MEDIUM (B) Probably will occur in time if not corrected, or probably will occur one or more times.	LOW (C) Possible to occur in time if not corrected.	VERY LOW (D) Unlikely to occur; may assume hazard will not occur.
HIGH (I) Imminent and immediate danger of death or severe sickness.	I-A	I-B	I-C	I-D
MEDIUM (II) Danger and sickness may be severe, but it is not imminent or immediate.	II-A	II-B	II-C	II-D
LOW (III) Sickness or injury may occur, but impact is reversible.	III-A	III-B	III-C	III-D
VERY LOW (IV) Sickness or injury is minor.	IV-A	IV-B	IV-C	IV-D

FSVP Considerations for FCM Manufacturers

- If the hazard analysis/risk evaluation determines that no controls are necessary, then no foreign supplier approval and verification activities are needed
  - Still have to conduct the hazard analysis/risk evaluation to reach this determination!
- Premarket review for FDA compliance *may* be sufficient to conclude no controls are needed
- The hazard analysis/risk evaluation must be conducted by a "qualified individual" with the training, education, or experience (or some combination) necessary to undertake the FSVP activities

What Can I Outsource?

- May rely upon another entity to conduct the hazard analysis, but must review and assess
- May rely on another entity (except the supplier) to do the risk evaluation, but must review and assess

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- Must evaluate the entity minimizing or preventing controls
- Must review supplier's procedures, processes and practices related to food safety

When Does My FSVP Have to Be In Place?

- The later of…
  - 18 months after publication of the final rule (May 27, 2017)
  - If supplier is subject to the HARPC rules, six months after the supplier must be in compliance with HARPC
  - If importer is a manufacturer or processor subject to the HARPC supply-chain program, FSVP compliance date is the same as the HARPC compliance date
- The written hazard analysis/risk evaluation records must be kept for two years

Final FSMA Thoughts

- Can conclude there are no hazards needing controls
- Can use existing documentation and procedures
- Merely a recordkeeping issue?
- FDA has indicated that it will not recognize foreign systems (e.g. EU) as equivalent

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Thank You!

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