FDA Food Contact Fundamentals

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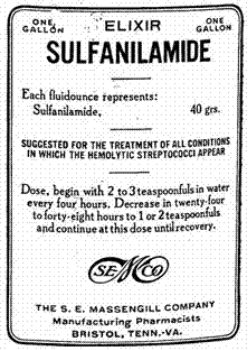
Legal Highlights for Food

1906:
Pure Food and Drug Act

1938:
Federal Food, Drug and Cosmetic Act



1958:
Food Additive Amendments

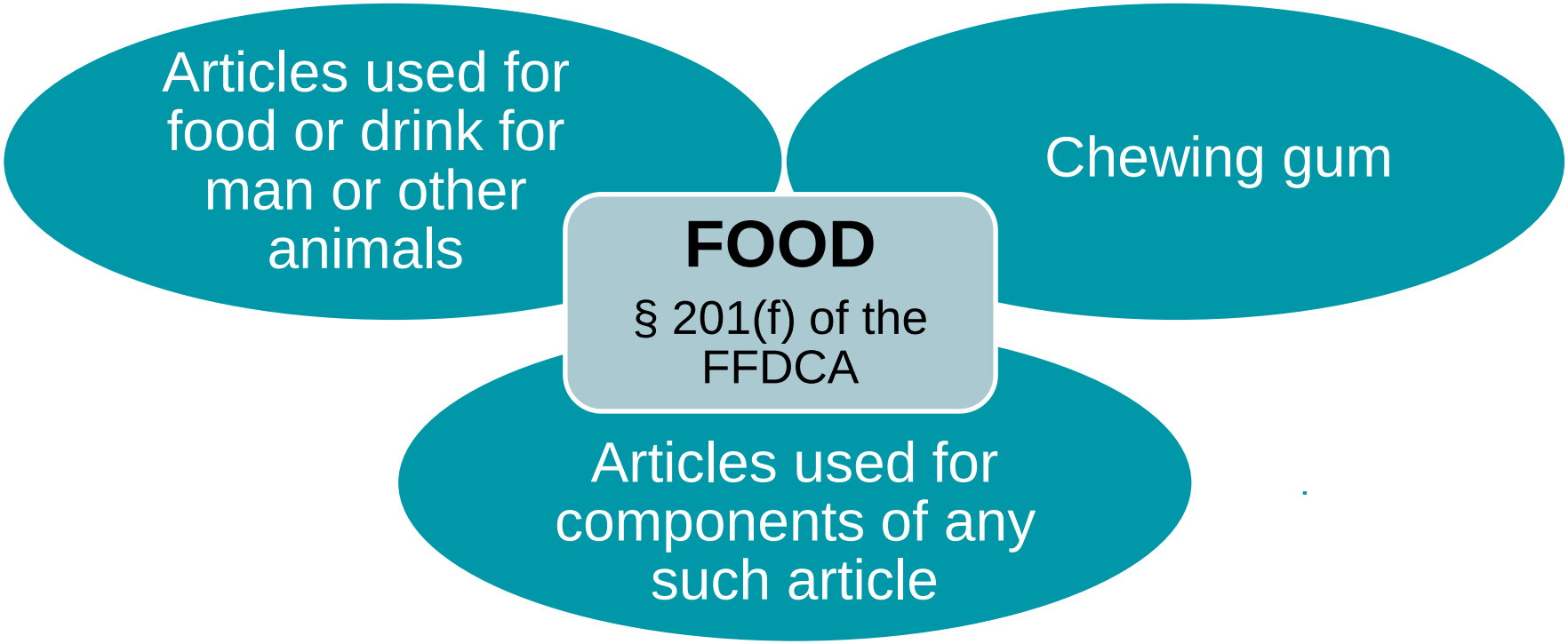
Rep. James Delaney

1997:
Food and Drug Administration Modernization Act

2011:
Food Safety Modernization Act

What is Food?

- 1906: “Food” shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound
- From 1938 on:



What is a Food Additive?

- Section 201(s)

  "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 . . . if such substance is not:"

  – Generally recognized as safe (GRAS); OR
  – Prior sanctioned
    - FDA or USDA approval prior to 1958
    - 21 CFR Part 181

Food Additives For Humans and Animals

1. Direct Additives – food ingredients
2. Secondary Direct Additives
   - Technical effect during processing but not in in finished food
   - Boiler water additives, ion exchange resins
   - Some secondary directs meet definition of food contact substance – e.g. antimicrobials in food processing
3. Indirect additives
   - Includes substances that are in “direct” contact with food (e.g., can coating) or are used “indirectly” (e.g., buried film)
4. Radiation

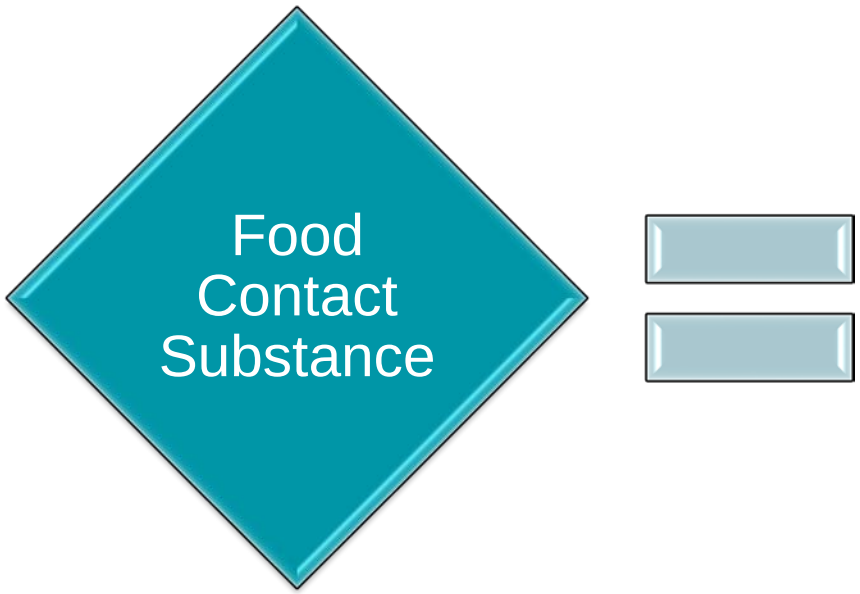
What's Not a Food Additive

Food additive does not include:	
	pesticide chemical residues in or on a raw agricultural commodity or processed food;
	pesticide chemical;
	color additive;
	prior sanctioned substance
	new animal drug; or
	"dietary ingredient" intended for use in a dietary supplement

When is Packaging Food?

- *U.S. v. Articles of Food 688 Cases of Pottery* (Cathy Rose), 370 F. Supp. 371 (E.D. Mi. 1974)
  - Lead-containing pottery seized by the government
  - Plaintiffs: Pottery is not "food" and lead is not a "food additive“
  - Court: “substances which are subject to being ingested by human beings because of migration are "food additives" and thus "foods" within the meaning of the Act.”
- *Natick Paperboard v. Weinberger*, 525 F.2d 1103 (1st Cir. 1975)
  - FDA seeks to seize paperboard containing >10 ppb PCBs as adulterated food
  - Plaintiffs: Food packaging is not “food” because packaging is not "used for components" of food and the PCB transfer is unintentional
  - Court: “unsafe food additives,” whether intentional or incidental, are “adulterated food”

What is a Food Contact Substance?



Any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in food (§409(h)(6), added by FDAMA)

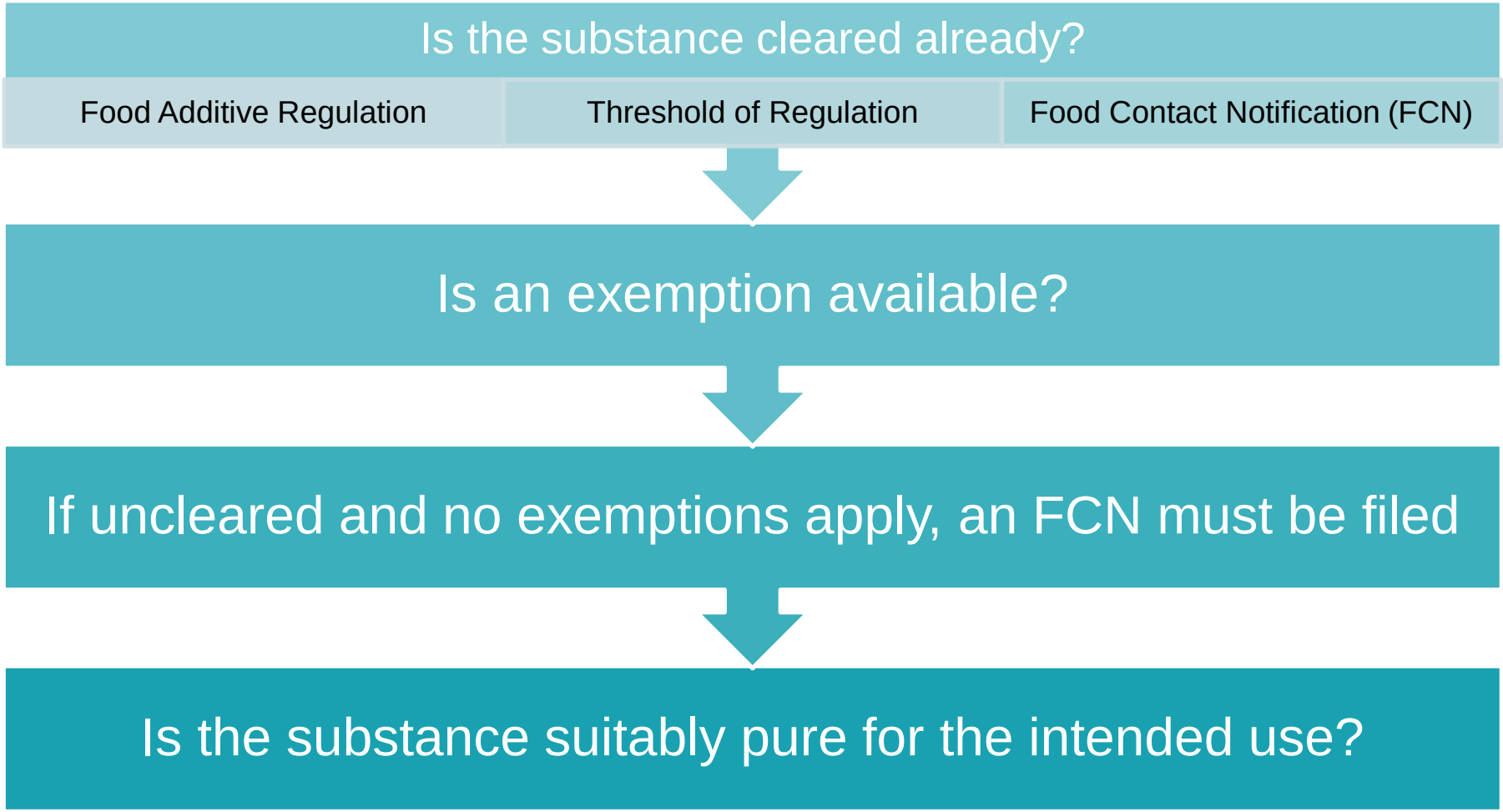
Fundamentals

Food additives require pre-market clearance from FDA

- Food is “adulterated” if it bears or contains any food additive that is unsafe within the meaning of section 409 (§ 402(a)(2))
- A food additive is “unsafe” if it is not used in accordance with a food additive regulation issued by FDA (§ 409)

Not all food contact substances are food additives

Evaluating the FDA Status



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Is it Cleared Already?

1. Check FDA's food additive regulations for indirect additives
   - 21 C.F.R. Parts 175-186
2. Check FDA's website for inventory of effective FCNs and TORs

- Clearances can be
  - Limited: does it covers your intended use?
  - Broad: some clearances are for groups of substances
    - E.g., Tall oil fatty acids, linoleic and oleic § 175.105)

FDA's Food Additive Regulations

- Food additive regulations are generic
- Some regulations are application-specific, others are material-specific
  - Application-specific: Adhesives (175.105), Can Coatings (175.300), Paper and paperboard (176.170/180)
  - Material-specific: Part 177 (polymers), Part 178 (Adjuvants, production aids)
- Direct food additive regulations not automatically cross-referenced into food contact applications

Extraction Testing

- Product must comply with any listed limitations and specifications or end tests
  - Compositional compliance alone not sufficient
  - End tests are extraction and/or solubility tests
  - Important note: They serve a different purpose than migration tests
- Who does the end-tests? Depends on the regulation.
  - §175.300: “The coating in the finished form in which it is to contact food”
  - §176.170
    - Only required if using substances cleared in paragraph (b)
    - “The food-contact surface of the paper and paperboard in the finished form in which it is to contact food”
  - §177.1380: “Extractives limitations are applicable to the basic resins in the form of pellets…”

Food Contact Notifications

Replaces Food Additive Petition process (CFR)

Inventory of effective FCNs found at FDA's website

Proprietary for the notifier and customers

Threshold of Regulation

- 1995 rule allows FDA to exempt a food-contact material from regulation if:
  - Either
    - Use results in dietary exposure of 0.5 ppb or less, or
    - Cleared as direct food additive and exposure from food-contact use is less than 1% of Acceptable Daily Intake (ADI)
  - And
    - Not a carcinogen and it does not have impurities that are potent carcinogens (TD50 < 6.25 mg/kg b.w./day)
  - 21 C.F.R. § 170.39
- TOR listings are not proprietary
- A TOR exemption must be confirmed by FDA

If uncleared, is an exemption available?

Certain exemptions from FDA pre-clearance authority stem from the food additive definition

A substance which, when used as intended, is reasonably expected to become a component of food, except GRAS and prior sanctioned substances (§ 201(s))

- No Migration
- Prior Sanction
- GRAS

“No” Migration

A substance not reasonably expected to become a component of food is not a food additive

Monsanto v. Kennedy (1979): a substance must migrated in more than insignificant amounts to consider it a food additive

What does “no” mean?

Functional barrier

Depends on toxicity and potential exposure

Default? 50 ppb (1969 Ramsey Proposal)

- Never formally adopted by FDA

TTC provides a more current and flexible scientific basis for setting a no migration standard

Prior Sanction

- Letters issued by FDA or USDA prior to 1958
  - 21 C.F.R. Part 181
  - A.J. Lehman's 1956 article "Food Packaging Materials"
  - Private company letters
- Prior sanctions viewed narrowly–limitations matter
  - Apply to specific use of a substance delineating level(s), condition(s), and product(s) set forth by explicit pre-1958 FDA/USDA approval
- Caveat: New safety concerns may impact prior sanctions
- Narrowly interpreted

What is GRAS?

. . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use . . .

What is GRAS?

What
- General recognition of safety

Who
- Experts qualified by scientific training and experience to evaluate its safety

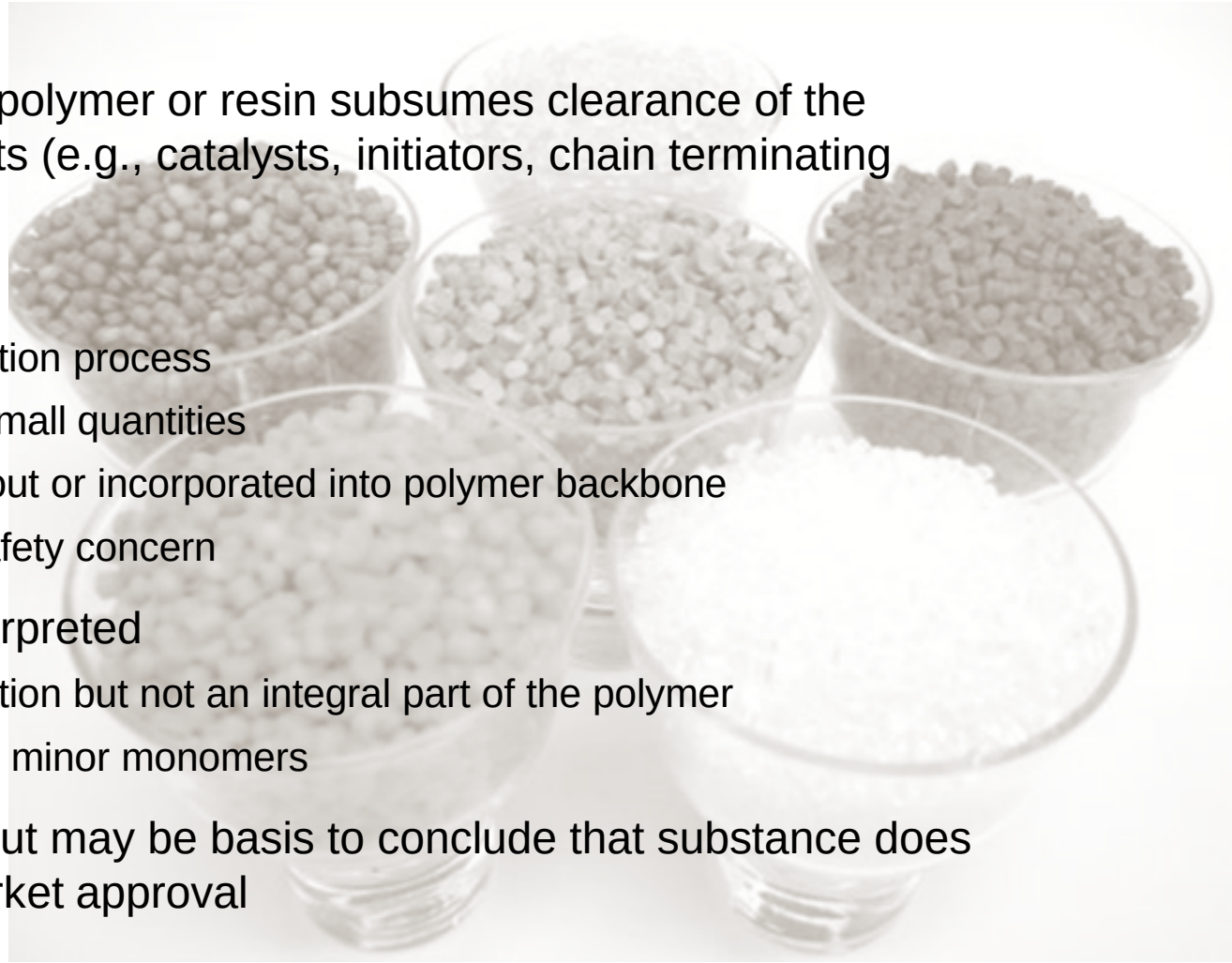
When
- Under the conditions of its intended use

How
- Through scientific procedures
- Common use in food prior to January 1, 1958

When all other options are exhausted…

- It will be necessary to file with FDA
  - Likely an FCN will be needed, but possibly a TOR request or a Food Additive Petition (only in special cases)
- It also could be helpful to file an FCN for marketing reasons

Basic Resin Doctrine



- Clearance of a basic polymer or resin subsumes clearance of the reaction control agents (e.g., catalysts, initiators, chain terminating agents)
- Four criteria:
  - Integral to polymerization process
  - Substances used in small quantities
  - Substances washed out or incorporated into polymer backbone
  - Must not present a safety concern
- Must be narrowly interpreted
  - Facilitates polymerization but not an integral part of the polymer
  - E.g., not applicable to minor monomers
- NOT an exemption, but may be basis to conclude that substance does not need FDA premarket approval

Housewares

- Products used as consumer articles or in commercial food-service establishments to prepare or serve food
- Legislative and agency statements support position that pre-market clearance not necessary, provided product is safe
  - How safe is safe?
  - Strongest case is GRAS
- Our position: Use narrowly
  - Easier case: metal utensils, ceramic plates
  - Harder case: Paper towels, disposable cups and plates
- FDA has pulled products from the shelf for testing

Good Manufacturing Practice

- Help determine whether food is potentially “adulterated”
- Manufactured under such conditions that it is “unfit for food”
- Prepared, packed, or held under insanitary conditions whereby it may have:
  - become contaminated with filth, or
  - rendered injurious to health
- 21 C.F.R. Part 117:
  - Detailed regulations for the production and packaging of actual food
  - Previously Part 110, revised under Food Safety Modernization Act

GMP for Packaging

- No formal cGMP program for food contact substances
- Formal GMP Standard: 21 C.F.R. §174.5
  - Should not use more than reasonably required to accomplish the intended physical or technical effect in the food-contact article
  - Any substance . . . shall be of a purity suitable for its intended use.
- Material must not be contaminated so as to cause food to be:
  - Unsafe, or
  - Unfit for consumption (taste or odor)
- Applies even if all components are covered by regulations or FCNs

Suitable Purity

- What procedures should be followed to assure suitable purity?
  - Standard industry practice
    - Unless that practice has clear deficiencies
  - Reasonable care
    - Heroic measures not required
    - Technical and economic feasibility/limitations
- Food GMPs at 21 C.F.R. Part 117 can be a guide
  - Caveat: Food standards are *not* applicable to the production of food contact materials in every detail
- GMP procedures should be in writing

Bioterrorism Act

- Facility registration – not required for food contact facilities
- Prior notice of imports – not required for food contact substances
- Administrative detention – food contact substances could be detained if FDA has a reason to believe the product ("food") is adulterated or misbranded
- Recordkeeping
  - Don't have to keep specific records
  - Required to produce the records you have

Food Safety Modernization Act (FSMA)

Applicability

Food for Consumption	All "Food"

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

FSMA and Packaging

- FSVP
  - 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 substances and materials
  - Does not apply to filled packaging
  - FDA has extended the compliance dates, from May 20, 2017 to May 28, 2019, while it considers “feasibility concerns”
- Sanitary transportation
  - Food contact substances are excluded from the “transportation operations” covered by the rule

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Thank You

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