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Introduction to US Food Contact Regulations

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Agenda

- Definitions
- Regulatory Authority with examples
- Agency engagement



What is food?



Food Additives § 201(s) of the FFDCA

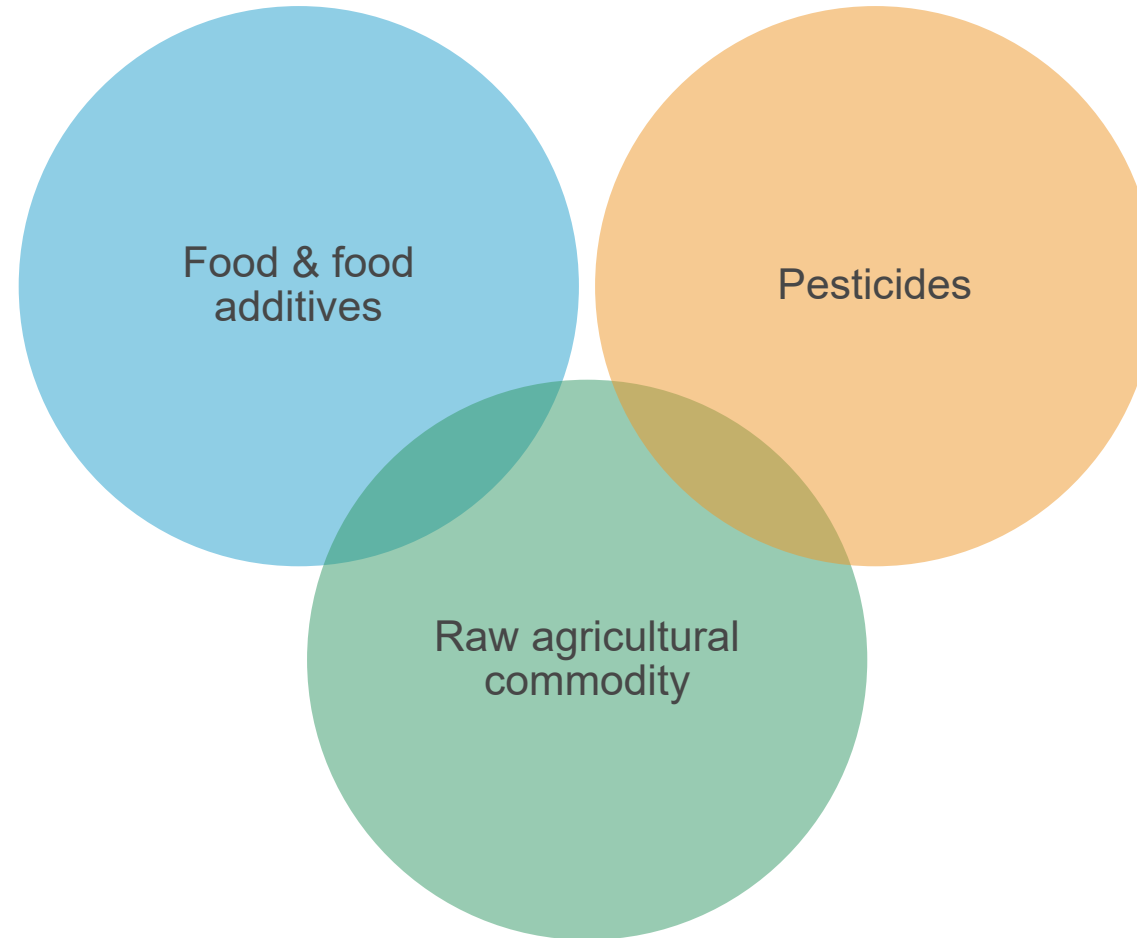
“Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not:”

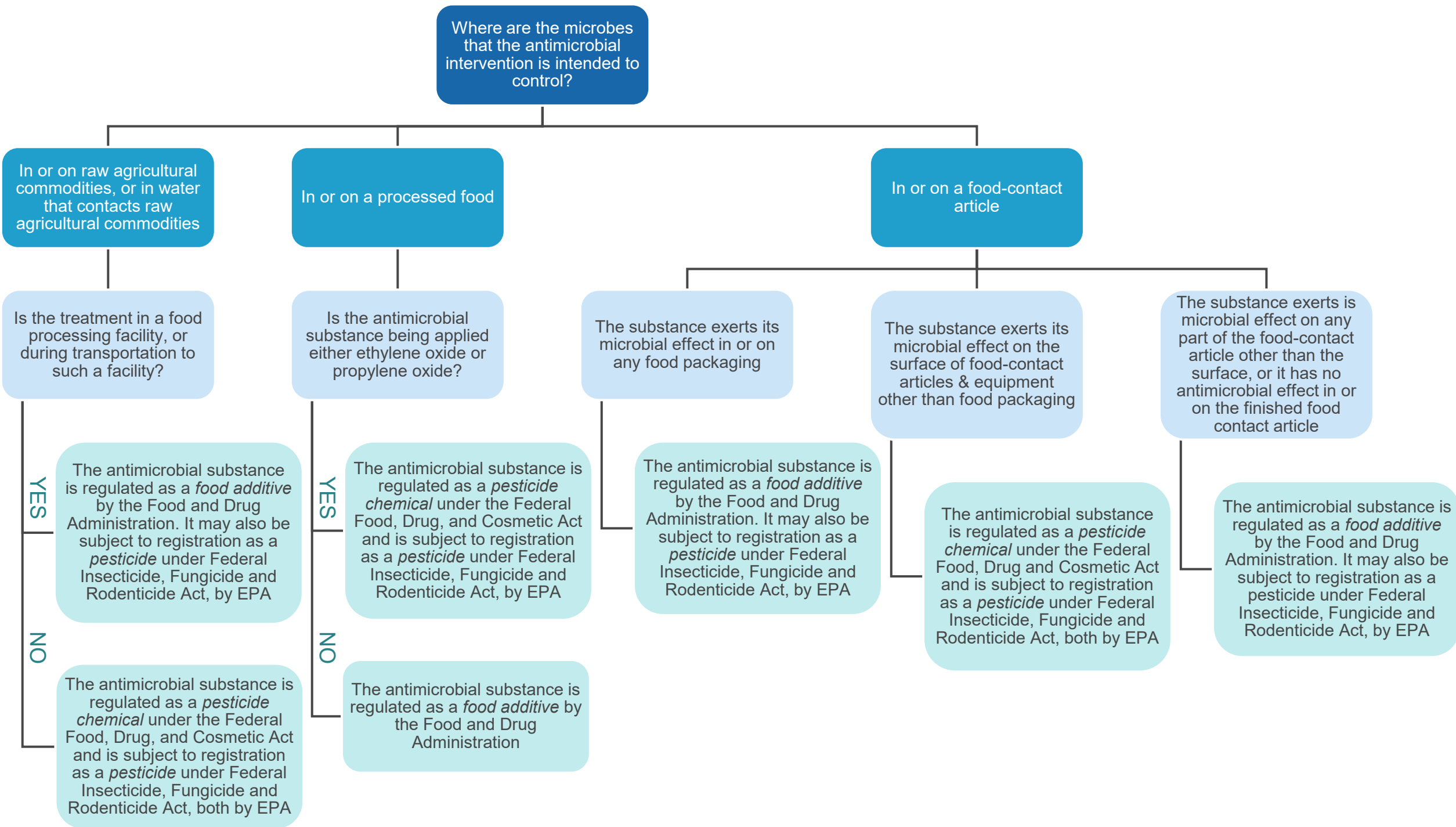
- Generally recognized as safe (GRAS); OR
- Sanctioned by FDA or USDA prior to the Food Additives Amendment of 1958
- Per § 409 of FFDCA, all food additives must be subject to a food additive regulation or an effective food contact substance notification (FCN)
- FDA also issues exemptions on a case-by-case basis under the “Threshold of Regulation” (ToR) rule (21 CFR § 170.39)



Who regulates what?

- FDA?
- EPA?
- FDA & EPA?





Example 1: Pesticide chemical

Use area

- Cutting board

Technical effect

- Antimicrobial effect on surface of a food contact article other than packaging

Determination

- Pesticide chemical subject to registration with EPA



Example 2: Food additive

Use area

- Cutting board

Technical effect

- Chemical for hardening cutting board surface to reduce scoring

Determination

- Food additive subject to registration with FDA



Example 3: Food additive and pesticide chemical

Use area

- Cutting board

Technical effect

- Preserves the cutting board from contamination

Determination

- Food additive subject to registration with FDA
- Pesticide chemical subject to registration with EPA



Agency engagement

- Data requirements
- Resources
- Example filing process



Data requirements

Rigorous review of scientific data to ensure the safety of the FCS (FDA) and the protection of human health and the environment (EPA):

FDA – FCN, FAP, ToR

- Proprietary and public
- Chemistry (product specific only)
- Product performance
- Migration of FCS
- Exposure
- Safety
- Environmental

FDA GRAS

- Publicly available information
- Decided on by outside government experts

EPA – PRIA Action

- Proprietary and public
- Generic data (active ingredient)
- Chemistry (product specific and active ingredient)
- Product performance (public health)
- Toxicology (product specific and active ingredient)
- Environmental and ecological data (product specific and active ingredient)

Beneficial resources for review

FDA

- FFDCA 21 USC § 301-399i
- 21 CFR § 100-199
- Numerous databases
 - Food ingredient and packaging inventories, FCN inventories, GRAS inventories, etc.
- FDA guidance documents
 - Administrative, chemistry, toxicology, regulatory, recycled plastics, infant formula and human milk, TOR
- Pre-notification consultation meeting

EPA

- FIFRA 7 USC § 136-136y
- 40 CFR § 150-189
- Numerous databases
 - PPLS, APPRIL, Pesticide Chemical Search, Inert Finder
- EPA guidance documents
 - OPPTS guidelines
 - Decision documents
- Pre-submission meeting

Example filing process – new food use

Scenario: an existing chemical is used as a preservative for use in making a cutting board

FDA – FCN

New FCS outside scope of 21 CFR

- 120 day review
 - If no response allowable for use
- \$0 filing fee
- Comprehensive review of data
- Possible request for additional data or clarifications
 - Could impact decision timeline

EPA – PRIA A440

New use, indirect food use

- 21-60 day administrative review + 23 months review
 - Possibility of missing deadline and asking for extension
- \$45,737 filing fee
- Comprehensive review of data
- Possible request for additional data or clarifications
 - Could impact decision timeline

Key takeaways



Maximize chemical product portfolio across multiple regulatory bodies



Extensive regulatory texts and databases available



Identify creative solutions for innovation challenges



Leverage business driven support



Questions?

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