U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

U.S. FDA
Food Contact Regulatory Overview

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Office of Food Additive Safety (OFAS)
Division of Food Contact Substances (DFCS)

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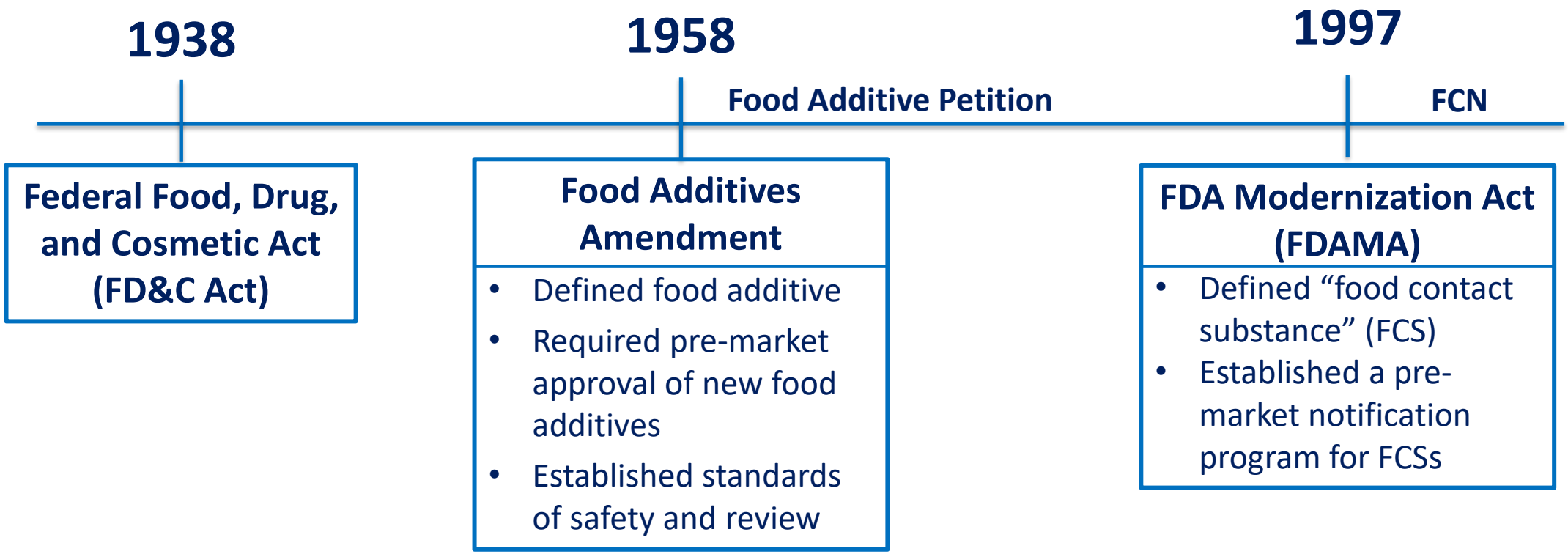
Outline

- FDA Mission
- Legal Authority
- Regulatory Mechanisms
  - Legal Definitions
  - FCN Submission and Review Process
- Additional Resources
- Conclusions

Food Safety at FDA

- FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
- FDA is involved in many aspects of food safety, including safety of food ingredients and food contact substances.
- CFSAN's **Office of Food Additive Safety (OFAS)** reviews safety information for food ingredients and food contact substances.

U.S. FDA Legal Authority



Food Additive

All substances, “the intended use of which results, or **may reasonably be expected** to result, directly or indirectly, in their **becoming a component of food** or otherwise affecting the characteristics of any food…”

– U.S. FD&C Act Section 201(s)

- Direct Food Additive
  - Directly added to food.
- Indirect Food Additive
  - Substances added to food as the result of food-contact use.
  - Not intended to have a technical effect in or on the food.

Food Contact Substance (FCS)

"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 any technical effect in such food."

– U.S. FD&C Act Section 409(h)

Food Contact Substance (FCS)

- FCSs are components of food contact materials.
- Review of discrete substances – not final packaging.

Examples of Food Contact Substances

Monomer	Antimicrobial agent
Catalyst	Oxygen scavenger
Polymer	Stabilizer
Polymer modifier	Epoxy resin
Antioxidant	Formulation component
Filler	Colorant
Processing aid	Paper additive

Food Contact Articles

Food Packaging

Bottles

Cans

Paperboard

Plastic Bags

Food Processing

Conveyor belts

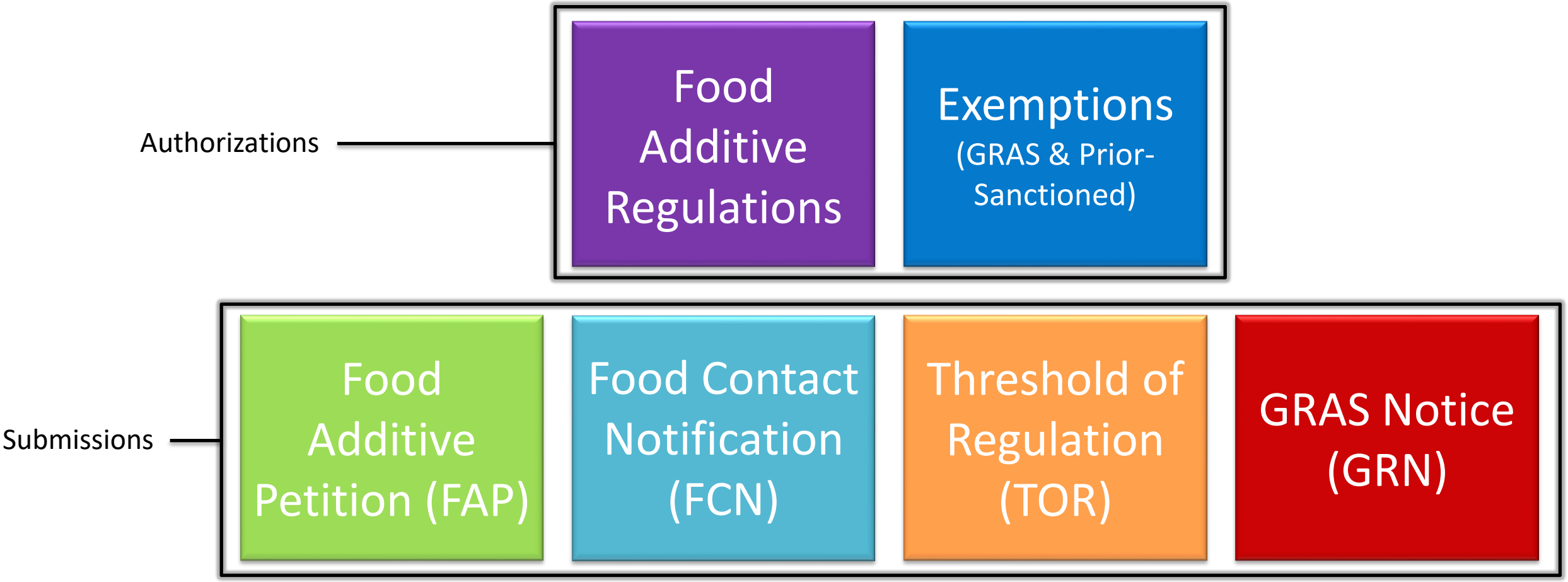
Blenders

Production Machines

Trays

FDA Regulatory Mechanisms

If an FCS migrates to food, its use must be authorized by the FDA.

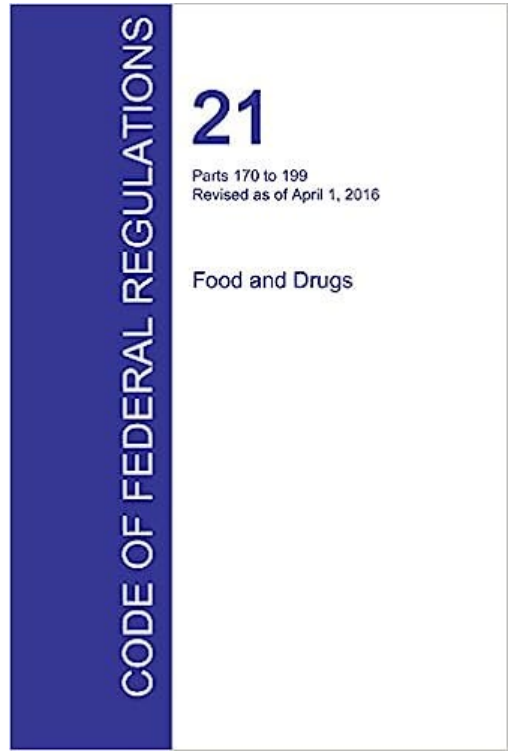


Standard of Safety

- Based on Safety only (no risk/benefit analysis).
- Requires "Reasonable Certainty of No Harm"
  - "*a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.*" (21 CFR 170.3)
  - "*It does not – and cannot – require proof beyond any possible doubt that no harm will result under any conceivable circumstance.*" *(H.R. report No. 2284, 85th Congress, 1958)*
- Safety is determined by intended use.

FDA Food Additive Regulations

- 21 CFR 170-199
- These regulations are not manufacturer specific.
- The regulation is based on intended use of the food contact substance.
  - It must also comply with all specifications and limitations listed in the regulation.
    - *i.e*. Temperature conditions, use levels, food type restrictions, etc.
- FCS must also comply with any “end test” specifications listed in the regulation.



FDA's Food Types

Table 1—Types of Raw and Processed Foods

I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).

II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.

III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.

IV. Dairy products and modifications:

- A. Water-in-oil emulsions, high- or low-fat.
- B. Oil-in-water emulsions, high- or low-fat.

V. Low-moisture fats and oil.

VI. Beverages:

- A. Containing up to 8 percent of alcohol.
- B. Nonalcoholic.
- C. Containing more than 8 percent alcohol.

VII. Bakery products other than those included under Types VIII or IX of this table:

- A. Moist bakery products with surface containing free fat or oil.
- B. Moist bakery products with surface containing no free fat or oil.

VIII. Dry solids with the surface containing no free fat or oil (no end test required).

IX. Dry solids with the surface containing free fat or oil.

FDA's Conditions of Use

Table 2--Conditions of Use

A. High temperature heat-sterilized (*e.g.*, over 212 deg. F).

B. Boiling water sterilized.

C. Hot filled or pasteurized above 150 deg. F.

D. Hot filled or pasteurized below 150 deg. F.

E. Room temperature filled and stored (no thermal treatment in the container).

F. Refrigerated storage (no thermal treatment in the container).

G. Frozen storage (no thermal treatment in the container).

H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:

   1. Aqueous or oil-in-water emulsion of high- or low-fat.
   2. Aqueous, high- or low-free oil or fat.

I. Irradiation.

J. Cooking at temperatures exceeding 250 deg. F.

Exemptions

- **Generally Recognized as Safe (GRAS)**
  - 21 CFR 182-186
  - GRAS Inventory
- **Prior-Sanctioned**
  - Subject of a letter issued by FDA or USDA prior to 1958 offering no objection to its use.
  - 21 CFR 181

Comparison of Regulatory Mechanisms

	FAP	FCN	TOR
Allowed Exposure	Dietary Concentration: > 1 ppm	Dietary Concentration: < 1 ppm	Dietary Concentration: < 0.5 ppb
Required Safety Data	Case-by-case (Always > than FCN requirement)	Specific requirements based on exposure tiers (See Guidance)	Carcinogenicity only
Are study reports provided?	Required	Required	Literature search only
Environmental Review?	Required	Required	Required
Is submission to FDA required before marketing the product?	Required	Required	Required
Who can utilize the result?	Any manufacturer	Listed manufacturer only	Any manufacturer

Submitting an FCN

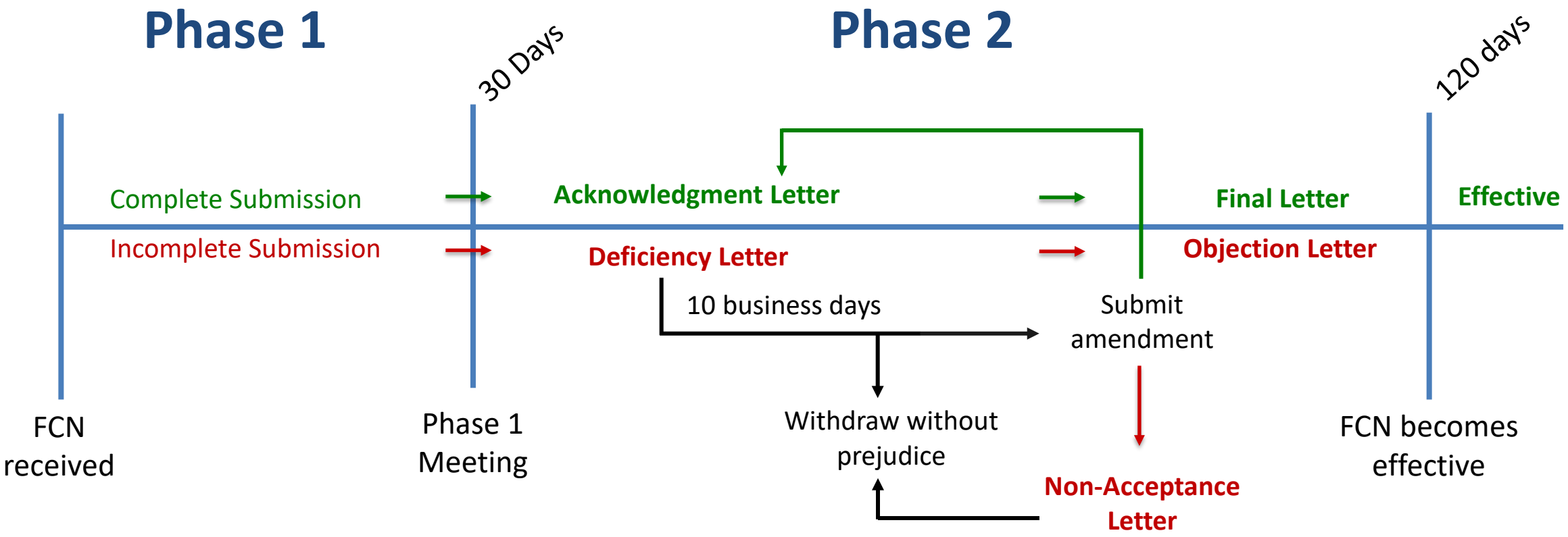
- The subject of an FCN is the intended use of a food contact substance (FCS).
- The submission includes information necessary to support the conclusion that a reasonable certainty of no harm will result from the intended use of the FCS.
  - Burden to demonstrate safety lies with notifier (21 CFR 170.3).
- The FCN is reviewed by an interdisciplinary technical review team at FDA.
  - Chemistry
  - Toxicology
  - Environmental
  - Microbiology (depending on the intended use)

Submitting an FCN

- Withdrawal of a submission by the manufacturer allowed during review of submission.
  - Effective submissions may only be removed by FDA based on safety determination (21 CFR 170.105).
  - Proposed rule to amend §170.105 to allow FCNs to no longer be effective for other reasons.
- FCNs are manufacturer/supplier specific.

FCN Timeline

- Statutory 120-day review period.
  - If 120-day period passes, products can enter market without FDA response.



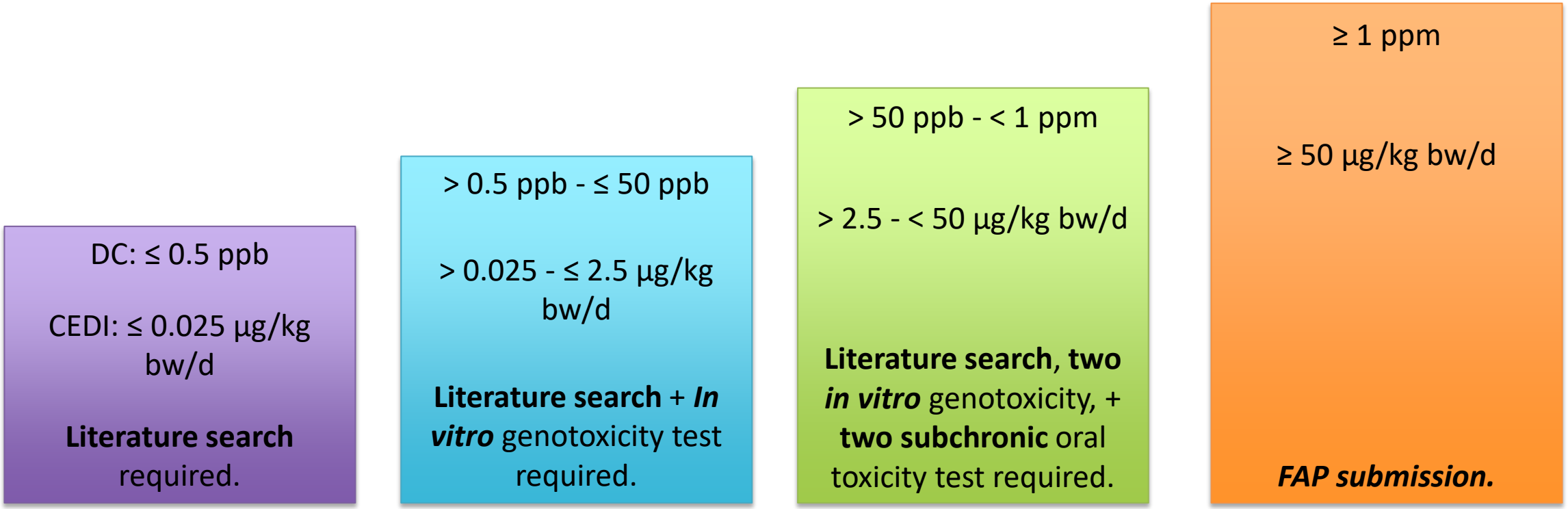
FCN Chemistry Information

• Identity • Physical/chemical specifications • Manufacturing Information • Impurities • Conditions of Use • Technical Effect • Stability	***What is the FCS?*** ***What has the potential to migrate?***
• Migration Levels in Food	***How much is migrating?***
• Exposure Estimates	***How much is being consumed?***

Establish identity of the FCS (and impurities) and assess potential **consumer exposure**.

FCN Toxicology Information

FDA has an exposure-driven tiered approach for safety testing.



FCN Toxicology Information

- Safety data is discussed in the following attachments:
  - Safety Narrative (SN)
    - Describes the scientific basis of the notifier's safety determination.
  - Comprehensive Toxicology Profile (CTP)
    - Includes all unpublished and published safety studies and related information relevant to the safety assessment.

FCN Environmental Information

- **Environmental Assessment (EA)**
  - A public document that is "stand alone."
  - Required if use does not qualify for a CATEX or if extraordinary circumstances apply.
    - No applicable Categorical Exclusions (CATEX).
- FDA's current National Environmental Policy Act (NEPA) regulations are listed in 21 CFR 25.

Joint Jurisdiction

Depending on the intended use, the use of a substance may be regulated by any combination of FDA, USDA, and EPA.

- **USDA/FSIS: U.S. Department of Agriculture/Food Safety Inspection Service**
  - Substances used in processing meat, poultry, egg products, or *Siluriformes* fish (catfish)
- **EPA: U.S. Environmental Protection Agency**
  - Substances intended to prevent, destroy, repel, or mitigate pests (including microorganisms)
    - Antimicrobials

Pre-Notification Consultation (PNC)

Tool to assist notifiers through the regulatory process

- Clarification and interpretation of regulatory status.
- Request for Cumulative Estimated Daily Intake (CEDI), Acceptable Daily Intake (ADI), and Unit Cancer Risk (UCR) values.
- Pre-submission review of safety package.
- Discussion of alternative approaches to determining exposure and/or safety.
- Questions related to U.S. food contact applications.

Email: premarkt@fda.hhs.gov

PNC - Abbreviated Reviews

- In the past, FDA has granted expediated, abbreviated reviews for “implant trials.”
  - Typically, in response to other agency’s needs.
- Temporary authorizations granted on a case-by-case basis.
- Based on incremental dietary exposure.

Email: premarkt@fda.hhs.gov

Online Resources

- Packaging & Food Contact Substances Guidance
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm
- How to Determine the Regulatory Status of a Food Additive
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm228269.htm
- Threshold of Regulation Exemptions
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ThresholdRegulationExemptions/default.htm
- Inventory of Effective FCNs – list of currently authorized FCNs
  - https://www.accessdata.fda.gov/scripts/fdcc/?set=fcn

Online Resources

- Inventory of Environmental Impact Decisions for FCNs
  - https://www.accessdata.fda.gov/scripts/fdcc/?set=ENV-FCN
- CEDI Database
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/CEDI/ucm2006857.htm
- Recycled Plastics in Food Packaging
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RecycledPlastics/default.htm
- Video Presentation on FDA's Food Contact Notification Program
  - https://www.youtube.com/watch?v=i6vswVzDuxM

Conclusions

- Determining whether a food contact material is authorized for a particular use is complicated, but we're here to help.
  - premarkt@fda.hhs.gov
- FDA is a science-based agency committed to keeping the food supply safe, protecting the confidential business information with which we've been entrusted, and making the review process as smooth as possible.

Questions

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