Food and Drug Administration Regulation of Food Ingredients, Additives and Colors

International Association of Color Manufacturers

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CONSUMER BRANDS ASSOCIATION

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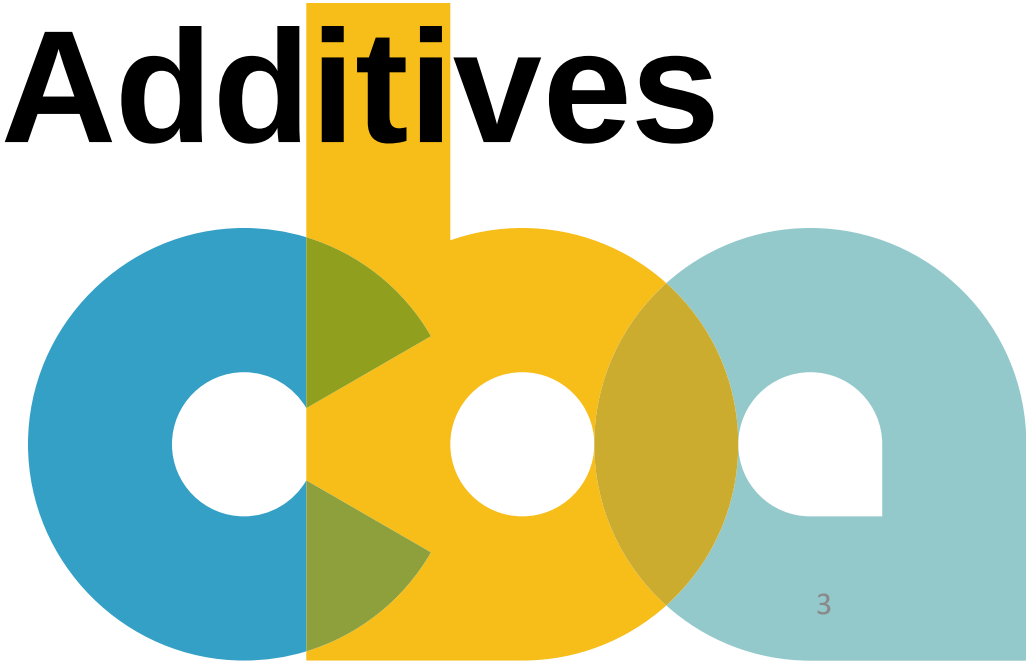
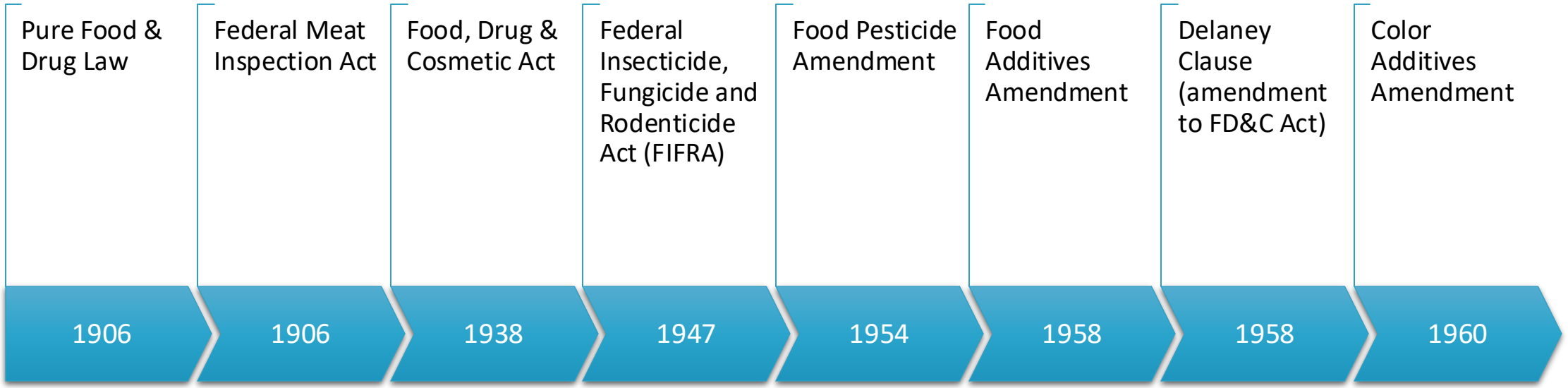
Consumer Brands Association

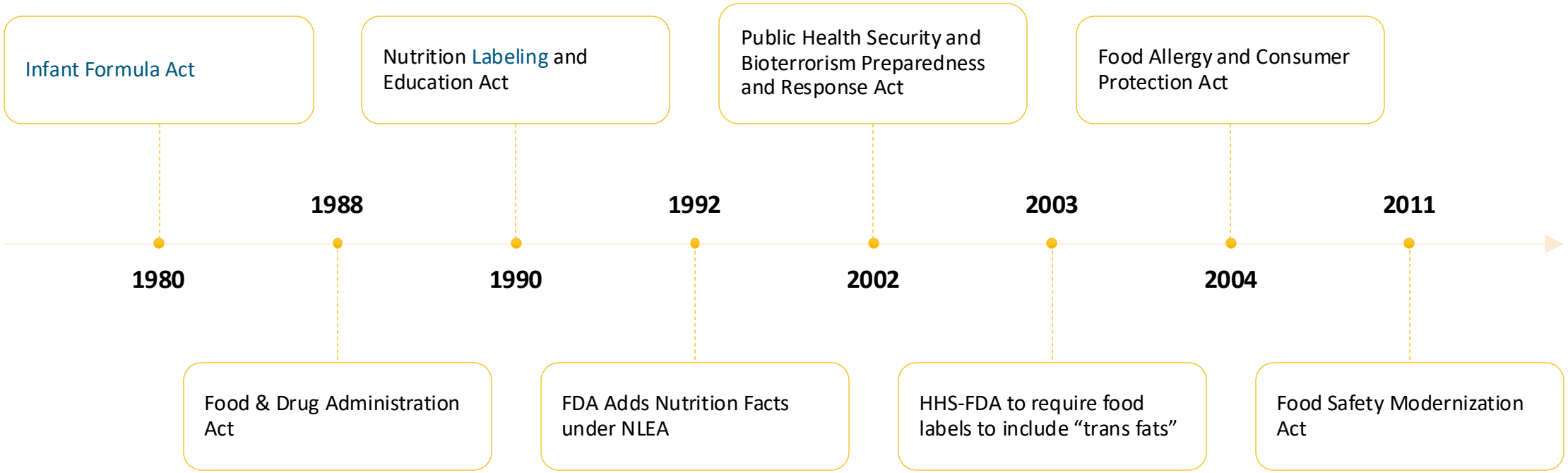
FDA Regulates Food Ingredients and Additives



Food Safety Laws in the United States 1906-1960



Food Safety Laws in the United States 1980-2011



FDA Regulates

- Food Additives and color additives
- Food Ingredients
- Food Contact Chemicals
- GRAS (generally recognized as safe)

Food Additive - A food additive is defined in Section 201(s) of the FD&C Act as 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 characteristic of any food;

. . . if such substance is not GRAS or sanctioned prior to 1958 or otherwise excluded from the definition of food additives[1].

FDA Pre-market approval for ingredients and additives

- Food Contact Chemicals
- Food Additive and Color Additive Petitions
- GRAS uses in Food
- Novel Infant Formula Ingredients
- Food Innovations

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FDA Regulates Color Additives

- **Color Additive** - A color additive is a dye, pigment or other substance, which is capable of imparting color when added or applied to a food, drug, cosmetic, or to the human body. The legal definition can be found in Section 201(t) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provides exclusions as well. Color additives for use in food, drugs, and cosmetics require premarket approval.

- FDA has regulatory oversight for color additives used in foods, drugs, cosmetics, and medical devices. FDA lists new color additives or new uses for listed color additives that have been shown to be safe for their intended uses in the *Code of Federal Regulations* (CFR), conducts a certification program for batches of color additives that are required to be certified before sale, and monitors the use of color additives in products in the U.S., including product labeling.

FDA Pre-Market Approval Process for Color Additives

- Any interested person may petition FDA for the use of a new color additive or to amend the listing of a color additive for a new use. The petitioner for a new color additive must provide information on the following:
- Identity of the proposed color additive
- Physical, chemical, and biological properties
- Chemical specifications
- Manufacturing process description
- Stability data
- Intended uses and restrictions
- Labeling
- Tolerances and limitations
- Analytical methods for enforcing chemical specifications
- Analytical methods for determination of the color additive in products
- Identification and determination of any substance formed in or on products because of the use of the color additive
- Safety studies
- Estimate of probable exposure
- Proposed regulation
- Proposed exemption from batch certification
- An environmental assessment or claim for categorical exclusion
- The petitioner must submit data demonstrating the safety and suitability of the new color additive or new use. FDA will then evaluate the data in the petition, public comments to the petition, and other relevant data in FDA's files.

FDA Enhancing its Post-Market Review Process (proposal)

- Food Chemical Signal Monitoring, Triage, Fit for Purpose Decision
- Increased Transparency
- Public Engagement
- Focused Assessments (FDA experts conduct cursory review to determine whether additional review is warranted).

- Comprehensive Assessments (complex and resource intensive – years to complete)
- Post-Market assessment of prioritization of risk process – science-based, data-driven, systematic, and reproducible.
- Multi-Criteria Decision Analysis method.

FDA Needs Resources

- FDA needs more resources for its scientific research, safety analysis and regulatory engagement/enforcement activities.
- Congress needs to provide more funding to FDA to increase its human and other resources.
- FDA and State Regulators need to continue to engage and expand their collaboration.
- Needs to be more public education on the industry-FDA partnership to protect consumer safety.

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Why are state legislators trying to regulate food additives?

- Interest Groups promoting incomplete, inaccurate or misleading information about FDA's ability to regulate.

- Interest Groups telling state legislators that FDA is broken and unable to regulate.

- Interest Groups telling state legislators that FDA is absent and doing nothing to ensure safe food in U.S. markets.

What does industry need to do?

- Talk about the importance of FDA's regulatory authority and its purpose to provide a single entity with a single set of rules for food safety in the U.S. market. Consumers in every state can be confident in the safety of their food.

- Engage with state legislatures and individual legislators to provide truthful, accurate and complete information about our industry and how it is regulated and our record of safety and compliance.

- Embrace the work industry does to ensure the safety of its products, especially food.
- We don't talk enough about how companies work tirelessly to ensure the safety of food.

Thank You!


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Questions?

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