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Generally Recognized as Safe

February 6, 2018

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Food Additives

- A food is adulterated:
  - **FD&C Act § 402(a)(1)(C):** if it is or if it bears or contains any "food additive that is unsafe within the meaning of Section 409"
  - **FD&C Act § 409:** a food additive is *per se* unsafe unless its use is in conformity with a regulation (or an FCN if it is a food contact substance)

Food Additive

- Thus, if a substance is a *food additive* and is not the subject of a clearance, the government can establish that food is adulterated simply by establishing that the substance falls within the definition of a food additive
- But, what is a “food additive”?

Definition of a Food Additive

- **FD&C Act § 201(s):** The term "**food additive**" means 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 (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food…"

Definition of a Food Additive (con't)

Unless the substance is "…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."

GRAS Exemption

- Thus, a substance is not a food additive by definition and not subject to Section 409 if the substance is Generally Recognized as Safe (GRAS) based on either
  - General recognition by experts that the substance is safe for its intended use or
  - Common use in food prior to 1958

GRAS

- Fundamental Conditions for GRAS status:
  (1) General recognition among experts that substance is safe for its intended use;
  (2) Experts must be qualified by scientific training and experience; and
  (3) Experts must have based their safety judgment either on scientific procedures or the fact that the substance was commonly used in foods prior to January 1, 1958.

GRAS (con't)

- Same quality and quantity of evidence/safety data needed in food additive petition
- "Key/Pivotal" safety data must "ordinarily" be published (e.g., in peer-reviewed scientific literature)
- There must be general recognition about the conclusion, i.e., consensus

GRAS Recognition by FDA

- FDA has recognized that some substances are GRAS:
  - Lists of substances recognized by FDA as GRAS appear at 21 C.F.R. Parts 182, 184, and 186
  - Many of these regulations impose maximum use levels and specify the functional role the ingredient must serve in the finished food

GRAS Recognition by FDA

- Some manufacturers submit GRAS Notifications or Notices to FDA
  - Positive response is not an "approval," but simply a statement that FDA does not object to the marketing of the ingredient for the condition and uses specified
- Voluntary program in place since 1997 proposal

GRAS Recognition by FDA

- FDA publishes the submission and their correspondence on the Agency's website
  - https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices
- As of February 2018, around 750 GRAS notices have been submitted to FDA

GRAS Final Rule

- On August 17, 2016 FDA publishes final rule on GRAS substances
  - 81 Fed. Reg. 54960
- Clarifies GRAS criteria
- Sets forth details of the GRAS Notifications process
- FDA no longer accepting GRAS affirmation petitions

GRAS Self Determinations

- Once GRAS determination has been reached, there is no requirement that FDA approve the conclusion
- Manufacturers may develop “self-determined” GRAS opinions without consulting FDA
- These self-determinations must meet all the GRAS eligibility criteria
- GRAS self determinations should be documented

GRAS Guidance Documents

- On November 16, 2017, FDA released two guidance documents related to GRAS:
  - Best Practices for Convening a GRAS Panel, available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM584930.pdf
    - Comments due March 15, 2018 (81 Fed. Reg. 53433 (Nov. 16, 2017))
  - Regulatory Framework for Substances Intended for Use in Human Food or Animal Food on the Basis of the Generally Recognized as Safe (GRAS) Provision of the Federal Food, Drug, and Cosmetic Act https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM585027.pdf