Food Ingredients

Taylor C. Wallace, PhD, CFS, FACN, March 22, 2018

Disclosures

- Think Healthy Group, Inc.
- George Mason University, Department of Nutrition and Food Studies
- Journal of the American College of Nutrition
- Dr. Taylor Wallace – Food & Nutrition Blog
  - Additional information on conflicts of interest as well as a PDF of this presentation can be found at www.drtaylorwallace.com
A Few Clients…

Presentation Overview

- Definitions
- Food Ingredients (i.e., all substances added to food)
  - Food additives
  - GRAS substances
  - Color additives
  - Prior sanctioned substances
The Roles of Definitions

- There are three definitions of food in the Federal Food Drug and Cosmetic Act (FDCA):
  - Food
  - Food additive
  - Dietary supplement

1. Food

- 2 Section 201 (f) “food”
  - “food” means (1) articles used for food or dink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.
2. Food Additive

- 2 Section 201 (s) “food additive”
  - “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; and including any source of radiation intended for any such use), 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; except that such term does not include—…..

2. Food Additive Cont.

- except that such term does not include—
  1. a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
  2. a pesticide chemical; or
  3. a color additive; or
  4. any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph 4 pursuant to this Act [enacted Sept. 6, 1958], the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following);
  5. a new animal drug; or
  6. an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement
3. Dietary Supplement

2 Section 201 (ff) “Dietary Supplement”

1. Dietary supplement means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
   A. a vitamin;
   B. a mineral;
   C. an herb or other botanical;
   D. an amino acid;
   E. a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
   F. a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

2. means a product that—
   A. (i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or (ii) complies with section 411(c)(1)(B)(ii);
   B. is not represented for use as a conventional food or as a sole item of a meal or the diet; and
   C. is labeled as a dietary supplement; and

3. Talks about differences in dietary supplements versus drugs and biologics (its long).
One More Definition in FDCA…

- There is another definition that plays a role in classifying a food product. That is section 201(g)(1)(c), which contains part of the definition of a drug. It reads:
  - The term ‘drug’ means ... (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals...(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals.”
  - Often referred to as the “food exception.”

Introduction to Food Additives

- Food Additives Amendment of 1958
  - Added the definition of a food additive to the FDCA so that when determining adulteration the FDA could determine if the substance added met the applicable evidentiary standard for safety.
  - Did not repeal any part of the FDCA raising questions about how to interpret some original definitions. Congress had a clear intent to regulate components of food as food.
  - Definition covers landscape of both intentional direct additives which are functional to intentional indirect additives.
The Delaney Clause

- The Delaney Clause modifies the general safety standard for food and color additives.
  - It prohibits FDA approval for additives found to induce cancer.
  - The Delaney Clause will also follow a substance throughout its existence, with any new data potentially used to ban the additive.
  - The post-market enforcement under the Delaney Clause can be slow, often leading States to adopt its own standards.

Generally Recognized as Safe (GRAS)

- GRAS
  - The food additive definition provides a seemingly small exemption. The definition states the term “food additive” does not include a substance generally recognized to be safe under the conditions of its intended use. It provides qualifying criteria on what “safe” means for the exemption.
  - This exemption has experienced dramatic growth and popularity. If the exemption does not apply, the food additive approval criteria must be followed!
  - The FDA only applies the Food Additive approval process to those added substances that are not GRAS (i.e., GRAS substances are exempt from food additives provisions).
  - Exemption from the Food Additives Amendment does not represent FDA approval!
Generally Recognized as Safe (GRAS)

- **GRAS**
  - FDA regulations set a high-bar for scientific consensus. General recognition under the regulations requires "common knowledge" about the substance throughout the relevant scientific community. This immediately bars new or novel ingredients from the GRAS exemption.
  - GRAS approval depends on the substance and its intended use. The focus thus narrows to evidence demonstrating either a consensus among experts on safety or evidence of common use prior to 1958 that considers how the substance was used and in what amounts.
  - Evidence for one use or one level will not provide support for a different GRAS use or higher dietary intake.
  - Significant evidence of "common use prior to 1958 is also needed.

Generally Recognized as Safe (GRAS)

- **FDA's GRAS List**
  - Prior to the passage of the Food Additives Amendment, the FDA established a partial list of GRAS substances. The list included familiar foods such as butter, coffee, cream, lard, and lemon juice.
  - Following the enactment of the Amendment, the FDA continued to list in its regulations additional GRAS ingredients. The list is now codified as Part 182 of the CFR.
  - Over 200 ingredients are listed (FDA considers this not exhaustive).
  - Deviating outside this limitation or for a substance with no limitations, a deviation outside the intended use voids the GRAS status provided in the list.
  - **GRAS is not a guarantee the substance will perpetually be exempt.** The FDA cautions a GRAS status may require reconsideration and potential revision or repeal.
FDA Approved GRAS

- When a substance is not listed in Part 182 (i.e., the FDA GRAS list), then a manufacturer may obtain GRAS status by applying to the FDA.
  - Under current procedures a manufacturer can voluntarily notify the Agency of its GRAS determination in an attempt to receive feedback or affirmation of the substance's GRAS status.
  - Submitting a GRAS notification to the FDA first involves preparing a GRAS affirmation. This provides the basis for claiming GRAS and its corresponding evidence. The notice will include information about the identity and properties of the substance, whether it GRAS based on common use or scientific analysis, and a discussion of meeting the GRAS criteria for the substance’s intended use.

FDA Approved GRAS

- FDA provides one of three responses to a GRAS notification:
  1. it does not question the basis for the notifier's GRAS determination (i.e., approval);
  2. the notice does not meet the GRAS requirements either because of insufficient data or the data raises questions about safety (i.e., rejection);
  3. Third type of letter follows a request from the notifier to cease evaluation, in which case the Agency responds to confirm the evaluation stopped (e.g., company goes bankrupt or dissolves).
Self Affirmed GRAS

- GRAS determinations also may be made without notifying the FDA.
  - All aspects of the GRAS process remain the same, but the GRAS determination is privately held.
  - FDA would only learn about the self-affirming determination during an inspection or other post-market authority. Thus, it is important to complete a notification-style GRAS determination even if not submitting under the voluntary notification program.

USDA – FSIS and Food Additives

- The FDA remains the primary agency for regulating the use of food additives even in meat and poultry.
  - The FDA and FSIS share responsibility for the safety of food additives used in meat, poultry, and egg products. Under the Food Additives Amendment, all the proposed additives are first evaluated by the FDA. A secondary review may be conducted by the Risk, Innovations and Management division of FSIS.
  - MOU spells out relationship.
  - List of allowable ingredients based on the joint Agency review/acceptance process since 2000.
Food Additive Approval Procedures

- If a food additive is not exempt it must gain approval through a food additive petition.
  - The petition process requires FDA involvement and can be resource intensive.
  - The FDA provides several Guidance Documents outlining the petition process.
  - Under Section 409(c) the FDA must issue a regulation approving the request for use of the food additive within 90 days of filing or provide the petitioner with the reasons for denial.
Irradiation

- Irradiation is a unique food additive.
  - A food is deemed adulterated if "has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to the Food Additives Amendment.
- Two ways for irradiation to gain FDA approval:
  1. The FDA can issue a food additive regulation;
  2. A petitioner can use the Food Additive Petition process. The FDA does not consider irradiation for any intended use or at any level GRAS.
- All irradiated foods must follow certain labeling requirements.
  - Radura symbol

Color Additives

- The Color Additive Amendment of 1960
  - Color additives are not food additives; although color additives are added to food to become a “component” the food additive definition expressly excludes the substances from its definition.
  - Applied globally to the FDA’s regulation of foods, drugs, cosmetics, and medical devices. It required the Agency to list all approved color additives and limited listing to only color additives that are “suitable and safe.”
  - Any use of a color additive outside the intended use of the listed color additive or deviation from the purity and identity specifications of the regulation cause a product to be adulterated.
Color Additives

- Two categories of color additives:
  - Color additives subject to FDA certification
    - Must gain approval for each batch manufactured
    - Primarily include dyes and lakes (e.g. FD&C Red No. 40)
  - Those exempt from certification
    - Primarily include dyes derived from plant or mineral sources (e.g., annatto extract or dehydrated beets)
  - FDA has a list of approved color additives (exempt and non-exempt).

Prior Sanctioned Substances

- Prior sanction provides a narrower and less common exemption from the Food Additives Amendment.
  - Excludes “any substance used in accordance with a sanction or approval granted prior to enactment of the Food Additives Amendment (i.e., prior to September 6, 1958).
  - Prior sanction can be any evidence of FDA or FSIS which is more likely its predecessors to the modern Agencies, that indicates official approval.
- FDA and USDA provide a list of known prior sanctions (e.g., nitrates).
  - Burden of proving a prior sanction rests solely on the party seeking the exemption.
  - Prior sanctions can NOT be expanded to new intended uses (e.g., potassium nitrate in meat to be included in beverages).
Helpful References


- Johnson R. The **Federal Food Safety System: A Primer.** Congressional Research Service. 7-5700 (RS22600).


Questions?

**Contact Information:**
Taylor C. Wallace, PhD, CFS, FACN
Think Healthy Group, Inc
George Mason University
P: 270.839.1776
E: taylor.Wallace@me.com
W: www.drtaylorwallace.com

*Slides available via website.*