GRAS Overview

Conventional foods are foods that are not dietary supplements. A dietary supplement is a product taken by mouth that is intended to supplement the diet and that contains one or more “dietary ingredients.” The “dietary ingredients” in the products may include vitamins, minerals, herbs or other botanicals, amino acids, and other substances found in the human diet, such as enzymes.

Dietary supplements must be labeled as such and must not be represented for use as a conventional food or as the sole item of a meal or the diet. Conventional foods must have a “Nutrition Facts” panel on their labels, but dietary supplements must have a “Supplement Facts” panel.

Conventional Foods

If a substance is not generally recognized as safe (GRAS) by qualified experts for its intended use in conventional food and does not qualify for any of the other exemptions from the food additive definition, it is a food additive. Under section 201(s) of the FD&C Act (21 U.S.C. sec. 321(s)), the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food; (2) pesticide chemicals; (3) color additives; (4) substances in accordance with a “prior sanction” (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958; (5) new animal drugs; and (6) dietary ingredients in or intended for use in a dietary supplement. Any unapproved food additive used in a conventional food causes the food to be adulterated under section 402(a)(2)(C) of the FD&C Act (21 U.S.C. 342(a)(2)(C). Adulterated foods cannot be legally imported or marketed in the U.S.

Food additives require pre-market approval based on data demonstrating safety. The 1958 Food Additives Amendment to the Federal Food Drug & Cosmetic Act (FFDCA), provided an exemption for common food ingredients, such as oil and vinegar, when their use is “generally recognized as safe,” or GRAS. GRAS ingredients are excluded from the food additive definition; therefore, not requiring pre-market approval by the FDA as a food additive. Specifically, GRAS substances are defined as “generally recognized, among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through scientific procedures” to be safe for their intended purpose. 21 U.S.C. sec. 321(s).

The food industry is currently using a 1997 proposed rule which allows companies to determine that a substance is GRAS without submitting a GRAS notice to the FDA.

Dietary Supplements and New Dietary Ingredient (NDI)

A New Dietary Ingredient (NDI) is any substance that was not marketed as a dietary supplement ingredient in the U.S. prior to October 15, 1994. 21 U.S.C. 350(b). A manufacturer
intending to market a NDI must submit to the FDA documented evidence establishing that the NDI is reasonably expected to be safe as used in the dietary supplement at least 75 days before the introduction of the product into commerce.

An NDI notification is not required “for a dietary ingredient that has been listed or affirmed by FDA as GRAS for direct addition to food, self-affirmed as GRAS for direct addition to food, or approved as a direct food additive in the U.S.,” if the ingredient has been used in the food supply and will not be chemically altered. See “Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredients” at

(www.fda.gov/Food/GuidanceComplianceRegulatorInformation/GuidanceDocuments/DietarySupplements/ucm257563.htm). Although an NDI notification is not required for such an ingredient, the NDI Draft Guidance states that the NDI adulteration standard will still apply if the ingredient was not marketed in the U.S. prior to October 15, 1994. Under the NDI adulteration standard, a dietary supplement containing a direct food additive or GRAS NDI is adulterated unless there is sufficient information to provide reasonable assurance that it does not present a significant or unreasonable risk of illness or injury. 21 U.S.C. sec. 342(f)(1).

FDA discussed its position on NDI related issues in the above noted draft guidance. One Q&A in the FDA’s guidance speaks directly to whether a NDI Notification would be required for a NDI that also has a GRAS food ingredient use. FDA noted that a substance legally marketed as a food ingredient in conventional food would be exempt from the NDI notification requirement because it has been present in the food supply chain as an article used for food in a form in which the food is not chemically altered. Submission of a GRAS Notification will establish a basis for a NDI to be legally marketed as a food ingredient. See “Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredients.”

Food Additives Regulatory Background (from the ‘Center for Food Safety’ case)

1958 Food Additives Amendments


A substance is generally considered a food additive: “if such substance is not generally recognized 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. 21 U.S.C. sec 321(s) (emphasis added). The GRAS concept emerged: excluding GRAS substances (common food ingredients, such as oil and vinegar) from the definition of a “food additive,” thus exempting them from compliance with the corresponding burdensome food additive regulations. 62 Fed. Reg. at 18938; 21 U.S.C. sec. 321(s). A substance that is GRAS for a particular use may be marketed for that use without a formal FDA review and pre-market approval required for food additives. 62 Fed. Reg. at 18939.

Under the 1958 amendment, the FDA is required to initiate a formal review process when a manufacturer petitioned to approve a new food additive. The petition process requires FDA to notify the public; provide an opportunity for comment; and, if FDA deems the additive’s intended use to be safe, issue a regulation allowing the use. 21 U.S.C. sec 348; 21 C.F.R. sec. 170.35(c)(4)-(c)(6) (emphasis added).

The Petition process

In the 1970’s, the FDA established criteria for determining when a substance was eligible to be classified as GRAS, and developed the process by which it could affirm a substance’s GRAS status. 21 C.F.R. sec. 170.35. The regulations provided that a substance is eligible for GRAS status only if there is both “technical evidence” and “common knowledge” of its safety. 62 Fed. Reg. at 18940.

Establishing “technical evidence” requires either scientific evidence or proof that the substance was commonly used in food prior to 1958. 21 C.F.R. sec. 170.30(a); 62 Fed. Reg. at 18940. “Common knowledge” requires satisfaction of a two-prong test: the technical evidence must (1) be generally available, and (2) show consensus among qualified experts that the substance is safe for its intended use. 62 Fed. Reg. at 18940. The first prong is often satisfied if the information is published in a peer-reviewed scientific journal. Id. The second prong is often satisfied by an opinion of an expert scientific panel. Id. At 18940-41.

The FDA may affirm the GRAS status of substances either on its own initiative or by petition. Id. at 170.35(a). In order to receive FDA affirmation that a substance is GRAS by petition, the petitioner must demonstrate that the substance satisfies the eligibility requirements, including general scientific agreement about its safety, and provide FDA with all backup information supporting the petition. Id. Sec 170.35(c)(1).

The Notification process

In 1997, the FDA proposed a GRAS notification program to replace the 1972 petition process. Id. at 18,941. The FDA proposed a notification program whereby a person simply notifies the Agency of its GRAS determination (self-affirmation GRAS). Id. at 18,941. Like the petition process, the notification procedure was also completely voluntary. Id. (emphasis added). Each notification had to include “a succinct description of the ‘notified substance’ (i.e., the substance that is the subject of the notice), the applicable conditions of use, and the basis for the
GRAS determination (i.e., through scientific procedures or through experience based on common
use in food),” as well as the notifier’s signature and date. Id.

The FDA has never promulgated a final rule regarding the procedures for the notification
program and the procedure remains voluntary. 62 Fed. Reg. at 18954. A manufacturer can make
a self-determination GRAS and then choose whether or not to notify the FDA of its GRAS
determination.

The pressure to change the GRAS system is increasing. The impact of social and
mainstream media in the food industry as well as consumer groups is challenging the lack of
transparency with the GRAS process.