GRAS—Generally Recognized as Safe

“GRAS” is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

- Under sections 201(s) and 409 of the Act, and FDA’s implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

- Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.

- Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

Regardless of whether the use of a substance is a food additive use or is GRAS, there must be evidence that the substance is safe under the conditions of its intended use. FDA has defined “safe” (21 CFR 170.3) as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. The specific data and information that demonstrate safety depend on the characteristics of the substance, the estimated dietary intake, and the population that will consume the substance.

An ingredient may be considered GRAS for one use but may not necessarily be GRAS for all uses. Under section 201(s) of the Act, it is the use of a substance, rather than the substance itself, that is eligible for the GRAS exemption. A determination of the safety of the use of an ingredient includes information about the characteristics of the substance, the estimated dietary intake under the intended conditions of use, and the population that will consume the substance. Dietary intake of a substance depends on the food categories in which it will be used and the level of use in each of those food categories.

Source: FDA.gov

Lists of GRAS Substances

Because the use of a GRAS substance is not subject to premarket review and approval by FDA, it is impractical to list all ingredients whose use is generally recognized as safe. FDA has published several but partial lists of GRAS substances whose use is generally recognized as safe to aid the industry's understanding of what did not require approval. Importantly, these lists are not all-inclusive.

21 CFR Part 182 contains the remnants of a list, which FDA established in its regulations shortly after passage of the 1958 Food Additives Amendment. The list is organized according to the intended use of these substances. As part of the agency’s comprehensive review of GRAS substances in the 1970s, FDA affirmed that the use of some of the ingredients on this original GRAS list is GRAS, and moved the affirmed uses of the substance to 21 CFR Part 184.

21 CFR Part 184 contains a list of substances that FDA affirmed as GRAS as direct food ingredients for general or specific uses. This list derives from the agency’s 1970s comprehensive review of GRAS substances and from petitions that FDA received to affirm the GRAS status of particular uses of some food ingredients.

21 CFR Part 186 contains a list of substances that FDA affirmed as GRAS for certain indirect food uses. FDA’s Internet site also contains a list of substances that have been the subject of a notice to FDA – i.e., when a firm has notified FDA about its view that a particular use of a substance is GRAS. You can access this summary of GRAS notices, along with FDA’s response, from the GRAS Notification Program page.

The GRAS notification program is a voluntary procedure. The notification program is intended to replace the GRAS affirmation process by providing a mechanism whereby a person may inform FDA of a determination that the use of a substance is GRAS, rather than petition FDA to affirm that the use of a substance is GRAS. The submitted notice includes a “GRAS exemption claim” that includes a succinct description of the substance, the applicable conditions of use, and the statutory basis for the GRAS determination. A GRAS notice also includes information about the identity and properties of the notified substance and a discussion of the notifier’s reasons for concluding that the substance is GRAS for its intended use.
**United States Department of Agriculture Recalls (www.usda.gov)**

**Product:** Apple Slices  
**Incident:**  
Possible Health Risk—Listeria monocytogenes

A Richmond, BC, Canada firm is voluntarily recalling sliced apples and products containing sliced apples produced from its facility located in Brampton, ON, Canada because they have the potential to be contaminated with Listeria monocytogenes. The apple slices and products containing sliced apples were distributed to IL, IN, KY, MI, MN, MO, ND, OH, WI and WV through retail stores, distributors and food service establishments. The recall was the result of an abundance of caution by the company following a routine sampling program by the Canadian Food Inspection Agency (CFIA) which revealed that the finished products possibly contained the bacteria. Consumers who have purchased these items are urged to throw them out or return them to the place of purchase. Consumers with questions should contact the company directly for more information.

**Product:** Soybean Sprouts & Bean Sprouts  
**Incident:**  
Possible Health Risk—Listeria monocytogenes

A Springfield, VA firm is recalling all packages of soybean sprouts and bean sprouts because they have the potential to be contaminated with Listeria monocytogenes. The recall includes 1-lb, 2-lb, and 10-lb bags of soybean and bean sprouts distributed to retail stores in VA, MD, NJ and NC. The potential for contamination was discovered after sampling by the Virginia Department of Agriculture and Consumer Services Food Safety Program and subsequent analysis by the Virginia Division of Consolidated Laboratory Services revealed the presence of Listeria monocytogenes. Consumers who have purchased any of these products are urged to dispose of or return them to the place of purchase for a full refund. Consumers with questions should contact the company directly for more information.

**Consumer Product Safety Commission Recalls (www.cpsc.gov)**

**Product:** Toy Vehicles  
**Incident:**  
Possible Risk—Choking Hazard

A Rowley, MA importer is recalling approximately 13,200 units of toy vehicles (2,100 units in Canada). The recall involves white plastic toy cars that have a painted dark blue hood and trunk, light blue windshield with black eyes and mouth painted on the front of the car. There is a police head coming out of the roof of the car wearing a blue police hat with a green star on the center of the hat. When the police head is pressed down it winds up the motor and the car moves forward. The hat can detach from the policeman’s head and pose a choking hazard to young children. The company has received one report of the police hat detaching from the toy. No injuries have been reported. The product was manufactured in China and sold at toy and gift stores nationwide from April 2010 through April 2015. Consumers should contact the company directly or visit their website for more information.

**Product:** Pressure-Mounted Safety Gates  
**Incident:**  
Possible Risk—Fall Hazard

A Conshohocken, PA importer is recalling approximately 58,000 units of safety gates (17,000 units in Canada) manufactured in Denmark. The recall involves white safety gates made of steel and plastic. The gate has a spring mechanism that fits between the two sides of the door frame to hold the gate in place. The friction between the wall and the pressure-mounted safety gate is insufficient to hold the gate in its intended position, posing a fall hazard. There have been 18 incidents worldwide, including three incidents in which children have been injured as a result of falling down stairs. No injuries have been reported in the U.S. The gates were sold at a retailer nationwide and online from Aug. 1995 through Feb. 2015. Consumers should immediately stop using the recalled safety gates and return them to the store for a full refund. Contact the company for more information.

**Food and Drug Administration Recalls (www.fda.gov)**

**Product:** Chicken Noodle Soup Products  
**Incident:**  
Possible Health Risk—Non-Inspection

A Toronto, ON, Canada firm is recalling approximately 4,672 pounds of chicken noodle soup products that contain chicken from a country that is not eligible to send product to the U.S. The poultry ingredients were sourced from Thailand, and were formulated using poultry ingredients that were not produced under equivalent inspection. The frozen chicken noodle soup items were produced on Feb. 5, 2014, April 1, 2014 and Sept. 11, 2014. These products were exported to Sharjah, United Arab Emirates and were not distributed in the U.S. The problem was discovered when a FSIS import inspector observed a shipment certified by CFIA as formulated with poultry ingredients sourced from Thailand while verifying new foreign inspection certification requirements for source country and establishment. This shipment was refused entry by FSIS. Consumers and media should contact the company directly for more information.

**Product:** Boneless Veal Trim Products  
**Incident:**  
Possible Health Risk—E. coli O157:H7

A Duvall, WA establishment is recalling approximately 2,522 pounds of boneless veal trim and whole veal muscle cut products that may be contaminated with E. coli O157:H7. The boneless veal trim and whole veal muscle cuts were produced from Jan. 2-23, 2015 and were sold in various size bulk boxes ranging from 22 to 63-lbs. The problem was discovered by FSIS personnel while reviewing records following a positive test for E. coli O157:H7 in May 2015. A subsequent review of test results indicated that the company failed to report positive tests in Jan. 2015. Product from those lots was shipped for further processing to wholesale establishments in CA, MA and WA. FSIS has received no reports of injury or illness from consumption of these products. Media and consumers with questions in regard to the recall should directly contact the company.