GRAS: Time-Tested, and Trusted, Food Ingredients

By Carol Rados

If Marco Polo were to attempt to bring back spices from the Orient today, he would have more to worry about than pirates. The 13th century explorer now would be required to prove that his cargo is not toxic, does not cause birth defects, and will not interfere with nutrition or affect individuals with allergies—unless the flavorings already are “generally recognized as safe” (GRAS) by the Food and Drug Administration.
GRAS is one of four legal categories set up by Congress under the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (FD&C Act). At the time, knowledge about food science and the potential long-term harmful effects of food chemicals on health were beginning to surface. Congress decided it was not necessary for the food industry to prove the safety of substances such as salt, sugar, and spices intentionally added to foods if they were already generally regarded as safe by qualified scientists.

New Food Additives
The FDA approves new ingredients for use in the food supply based on reviews of extensive scientific research on safety. To market a new food additive, a manufacturer must first petition the FDA for its approval. The petition must provide convincing evidence that the proposed additive performs as it is intended. Animal studies using large doses of the additive for long periods often are needed to show that the substance would not cause harmful effects in people when eaten in expected amounts. Studies of

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A GRAS substance, therefore, is one that has a long, safe history of common use in foods, or that is determined to be safe based on proven science. If, however, new evidence suggests that a GRAS substance may no longer be safe, the FDA can prohibit its use or require further studies to determine its safety.

Some substances may be GRAS for one use, but not for others. For example, some uses of a food substance are intended for a narrowly defined population, such as newborn infants who consume infant formula as the sole item of the diet. In this case, there may be special considerations associated with that population, but not with general use of the food substance.

Manufacturers add substances to foods to prevent spoilage or to enhance appearance, taste, texture, or nutritive value. Without them, cakes wouldn't rise, salt would lump, bread would mold more easily, ice cream would separate into ice crystals, and marshmallows would harden into bite-sized rocks. Food additives allow us to enjoy a variety of safe, wholesome, and tasty foods all year round. They also help make convenience foods readily available.

For More Information
The FDA Center for Food Safety and Applied Nutrition
www.cfsan.fda.gov/~lrdl/foodadd.html

"Everything Added to Food in the U.S."
www.cfsan.fda.gov/~dms/eafus.html

Regulatory Categories for Substances Added to Foods
Other than pesticides and animal drugs, substances added to foods fall into four legal categories.

• Food additives—substances that have no proven track record of safety and must be approved by the FDA before they can be used.

• Generally recognized as safe (GRAS)—substances for which use in food has a proven track record of safety based either on a history of use before 1958 or on published scientific evidence, and that need not be approved by the FDA prior to being used.

• Prior-sanctioned—substances that were assumed to be safe by either the FDA or the U.S. Department of Agriculture before 1958, to be used in a specific food. (For example, while the preservative nitrate can be used in meat because it was sanctioned before 1958, it cannot be used on vegetables because they were not covered by the prior sanction.)

• Color additives—dyes that are used in foods, drugs, cosmetics and medical devices and must be approved by the FDA before they can be used.

GRAS or prior-sanctioned status does not guarantee a substance’s safety. Sometimes new evidence shows that a substance may not be as safe as it was commonly thought to be. If new data suggests that a substance under either of these categories may be unsafe, the FDA may take action to remove the substance from food products or require the manufacturer to conduct studies to evaluate the newly raised concern.