CR ConsumerReports™

FACT SHEET: The Generally Recognized as Safe (GRAS) Process

What is GRAS?

- Substances added to food are required to go under premarket review under the Food Additives Amendment of 1958. However, this law excluded from the definition of "food additive" any "substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety, as having been adequately shown through scientific procedures to be safe under the conditions of their intended use."

Who Makes GRAS Determinations? (Hint: It's Not Really the FDA?)

- Initially, the FDA put out the first list of GRAS substances back in 1958. In October 1969, the Nixon Administration directed the FDA to make a critical evaluation of the safety of GRAS food substances. This led to the formation of the Select Committee on GRAS Substances (SCOGS). By 1982, SCOGS had produced 151 detailed reports covering over 400 substances.
- In addition to the government reviews, a company could make their own determination that a substance was GRAS. To do that, they would submit a GRAS affirmation petition which would lay out the science demonstrating that the particular substance meets the GRAS definition. The GRAS affirmation petition would usually have been developed by a panel of "qualified experts" put together by the company. The FDA would review these petitions and then grant them, ask for more information or reject them.
- In 1997, FDA proposed dropping the GRAS affirmation petition process and simply put a notification process in its place, whereby a company could send a notice to the FDA saying they had determined that a particular substance was GRAS. The FDA could review the notice and agree the substance was GRAS, ask for more information, or reject it.
- However, companies were not required to submit GRAS notices; they could simply make the GRAS determination themselves and not notify the FDA that the determination was made. Furthermore, the "qualified experts" that were supposed to make a GRAS determination could all be employed by the company that was making the GRAS determination.
- **In other words, it is a demonstration of how broken the system is that companies could make their own determination of the GRAS status of a food substance, using scientists employed by the company, and fail to inform the FDA of the determination, essentially taking away FDA's ability to even review the GRAS decision.**

Consumer Reports Position

We support legislation that would keep dangerous chemicals out of the food supply and make the industry's chemical food additives subject to FDA approval.

- **The Toxic Free Food Act (H.R. 3699).** This bill would close the GRAS loophole and require chemical food additives to be approved by the FDA.
- **The Food Chemical Reassessment Act (H.R. 4694)**.This bill would require the FDA to regularly study and reassess chemicals used in food.