[PERSPECTIVE]

by Eric F. Greenberg

GRAS: Leave Well Enough Alone

When it comes to regulatory compliance, it's all about you, as the young people say. While Americans commonly think that regulatory agencies such as the U.S. Food and Drug Administration (FDA) are responsible for assuring the safety of the food supply, really, it's on you—the food manufacturer.

As a member of the regulated industry, *you* must seek out the legal and regulatory responsibilities that fall upon your company, *you* must figure out how to meet them, and *you* must do it right the first time and every time. If you've ever been inspected by FDA and asked them to detail for you how to remedy a violation, you know that even FDA tells you that.

So it shouldn't come as a surprise that, in terms of food ingredients and additives, companies can make their own decisions about whether a substance they want to use in food is Generally Recognized As Safe (GRAS), and can do so without FDA's approval, concurrence, blessing, or even knowledge. If a use of a substance is GRAS, companies can use it on that basis, and don't even need to tell FDA what they're doing.

Why? It's an all-American regulatory framework, practically the free-market philosophy at work: leave companies on their own unless there's a good reason not to.

In recent years, however, private and public complaints have arisen about the current way GRAS ingredients in foods are regulated, and that high level of independence for companies has come under a lot of criticism. Certainly from the FDA point of view, the arrangement isn't optimal. The public expects FDA to keep foods safe, but FDA isn't aware of how and where all substances are being used in food.

Among the suggested alternatives is to require companies to give FDA notice of their uses of substances on the basis of GRAS determinations. Right now, companies can voluntarily send a GRAS Notification to the FDA, who will then let the company know if they have any serious questions about the company's GRAS conclusion. Then at least FDA will know what's happening, goes the argument.

The government oversight group, the U.S. Government Accountability Office (GAO), recommended in 2010 that notification be mandatory and that FDA make the information public, and also that FDA make rules to avoid conflicts of interest for GRAS experts, conduct random audits of company GRAS decisions, have FDA be more systematic in reconsidering product safety, and have FDA pay special attention to emerging nanoscale materials in food. FDA has said it agrees with some of the recommended changes.

Separately, the private Pew Health Group's 2012 report lamented that FDA isn't aware of many uses of substances in food because companies don't have to tell them, and raised concerns about FDA's lack of resources.

Are these groups' suggestions good ideas? Take the example of the simple-sounding idea of making companies notify FDA when they are using a food component on the strength of their own conclusion that the use is GRAS. A moment's reflection reveals, I think, that a mandatory notice program would be a complex, burdensome, voluminous data orgy. Lots of companies would be filing lots of new information with FDA about thousands of uses.

It's useful to ask whether the benefits outweigh the costs. FDA might have a better ability to monitor exposures to substances if they had a more complete picture of what was being used. But we are talking about exposures to substances that are both safe and generally recognized as such (at least in someone's opinion), and it's unlikely that even if a company's GRAS conclusion is incorrect that they would be wildly off-base, especially when any given use of a substance results in very, very low levels of dietary exposure.

Many of the hazards pointed to by the two groups, like conflicts of interest on the part of experts or the potential for poorly reasoned GRAS decisions, seem theoretical or rare, or both.

Do safety questions emerge about uses that were previously considered GRAS? Yes, but not too often. Even the excellent Flavor and Extract Manufacturers Association's GRAS review program for flavoring and related ingredients has, according to the GAO 2010 report, only removed 11 substances from its GRAS lists, which contain about 2,600 substances. GAO points to only four examples of FDA reconsiderations, though it also noted that since 2004, there have been 11 citizen petitions that requested FDA reconsiderations, and FDA has not acted on 10 of them. Still, the numbers are small.

And when issues do come up, the current system does allow for reconsideration, at least with respect to substances that are known to be in use.

The overall picture does not seem to cry out for dramatic action. The current GRAS system may not be perfect, but there doesn't seem to be a justification for turning it on its head and adding significant new burdens to industry and FDA. **FT**

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