

"Generally Recognized as Safe" Under Fire



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Friday, April 29, 2016

[Senator Markey sends letter to FDA criticizing GRAS review system.](#)

- As the food industry is well aware, consumer groups and others have been criticizing the “Generally Recognized as Safe” or “GRAS” exemption in the U.S. for the past several years. GRAS opponents criticize FDA’s alleged lack of oversight and direct involvement in the marketing of GRAS substances.
- On April 26, Senator Edward Markey (D-Massachusetts) sent a [letter](#) to FDA, characterizing the GRAS exemption as a “loophole” that “challenges the statutory intent of FDA’s assignment to protect the safety of the food supply.” The letter criticizes the “loose structure” of FDA’s voluntary GRAS Notification program and expresses concern about the marketing of “self-determined” GRAS substances and perceived conflicts of interest in the system. The letter concludes with Sen. Markey requesting FDA’s response to questions about: (1) the Agency’s authority to require labeling on self-determined GRAS substances (e.g., “The safety of some ingredients in this product has not been evaluated by the Food and Drug Administration.”); (2) the Agency’s authority to mandate requirements to minimize conflicts of interest in GRAS self-determinations; and (3) steps the Agency has planned to strengthen its oversight of GRAS substances.
- Because the GRAS exemption is expressly codified in law, it is not clear that FDA regulatory action alone would appease the opponents of GRAS. As part of a settlement of a lawsuit filed against FDA by the Center for Food Safety in 2014, FDA has agreed to issue a final rule on the GRAS review program by August 31,

2016. Thus, whether or not the Agency responds to Sen. Markey's entreaty, we anticipate concrete developments on the GRAS review front later this year.

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