

FEMA Launches GRAS 24, Celebrates 50th Anniversary of the GRAS Process

As the latest GRAS list comes online, FEMA examines the past, present and future of the safety assessment of flavor materials.

The Flavor and Extract Manufacturers Association (FEMA) has launched GRAS 24 online (www.femaflavor.org), featuring materials 4430 through 4666. The publication also includes updated average use levels and average maximum use levels for citral (FEMA# 2303), parsley oil (FEMA# 2836), jambu oleoresin (FEMA# 3783), N-gluconyl ethanolamine (FEMA# 4254), N-lactoyl ethanolamine (FEMA# 4256) and *cis*-3-nonen-1-ol (FEMA# 4412). The list's publication comes on the heels of the organization's symposium celebrating 50 years of the GRAS process, which provided an opportunity for the industry to reflect on the safety assessment of flavor materials.

Flavor Modifiers: New Materials Demand New Expertise

The food and beverage industry's response to the growing obesity epidemic in the United States and elsewhere is just one of the factors that have led to the increased application of flavor modifiers in flavors and foods. Many of these novel flavor modifiers have been developed based on the protein structure of taste receptors. This category has grown exponentially in recent years, presenting key challenges to the FEMA Expert Panel, which evaluates the safety of substances for use in flavor formulations. In comments during the organization's symposium, Tim Adams, the scientific director of FEMA, noted that the panel has experienced an increase in the number of GRAS applications for flavor modifiers.

"[The panel] evaluates sensory testing data so that they can actually characterize the modification," he explained. "They're also careful to differentiate between flavor modification properties and other food functions such as sweetness and sour." A number of times, he added, the panel has had to differentiate the levels at which a flavor modifier could be used based on the modification properties versus its sweetener properties. "And of course it's not GRAS as a sweetener—it's GRAS for use as a flavor modifier at a particular level," Adams clarified. The pattern of use, together with metabolism and toxicity data, are key components of the GRAS evaluation.



Tim Adams

Adams also explained that, because the structure of a receptor-designed flavor modifier is often uniquely complex compared to materials of previous eras, the expert panel requires more metabolism and toxicity data than would be required for a simple naturally occurring food flavor such as ethyl butyrate. The overall goal, however, remains: assessing substances used in preparations of flavors for GRAS status. "GRAS substances are considered GRAS only under conditions of intended use," Adams reiterated. Whether the substances are flavors, flavor modifiers, emulsifiers, antioxidants, etc., the panel continues to keep expanding its expertise in order to do the most careful safety evaluation of flavoring substances. "No known aspect of safety evaluation goes unconsidered by the expert panel," Adams concluded.

The Evolution of GRAS

A subsequent presentation by Sean Taylor, FEMA's assistant scientific director, and Christie Gavin, FEMA's health and safety director, further outlined the ongoing evolution of GRAS. Established one year after the 1958 "Food Additives Amendment" to the US Federal Food, Drug and Cosmetic Act that established the GRAS concept, the GRAS process netted its first expert panel publication, *GRAS 3*, in 1965. The list contained more than 1,100 flavor materials. While the organization's contemporary electronic database allows for flexible data outputs for different regulatory bodies depending upon need, with calculations done automatically, the original system required data entry on an IBM 716 punch card machine. In all, said Gavin, there have been 22 GRAS



Sean Taylor and Christie Gavin

publications covering more than 2,500 flavor ingredients. That pace has only increased with time. As Adams noted, since 1995 the panel has almost doubled the GRAS list.

Taylor pointed out that the GRAS opinions and safety data that support GRAS findings under intended use are published in peer-reviewed literature. There are at least two such publications slated for this year. These publications, he concluded, illustrated the “dynamic, ongoing” nature of FEMA’s GRAS program.

Yet the favored methods for measuring exposure could be shifting. Gavin noted that maximized survey-derived daily intake (MSDI) is the current standard used by the FEMA Expert Panel and several international regulatory bodies. MSDI results from a simple calculation, based on the volume of a flavoring substance going into the marketplace, by the FEMA Expert Panel and several other international regulatory bodies, but groups such as the Joint Expert Committee on Food Additives (JECFA) of the United Nation’s Food and Agricultural Organization/World Health Organization are looking to more time-consuming and resource-intensive methods that require use-level surveys for flavors, specifically the single-portion evaluation technique (SPET), which is based on the daily consumption of a single portion of food containing the flavoring agent. Given the popularity of MSDI, Taylor asked, why is SPET gaining ease and general acceptance? He answered that question with another: what if a consumer likes to eat a specific food on an exceedingly regular basis? Taylor cited the example of Don Gorske, perhaps America’s biggest fan of McDonalds’ Big Mac sandwich. Gorske has claimed

to eat two-plus sandwiches every day, for a grand total of more than 23,000 Big Macs. “Could the intake be higher for a very small part of the population that has very serious brand loyalty to a specific product in which [a] specific flavoring substance is used?” Taylor asked. This sort of scenario of course represents an extreme look at intake, but some international regulatory bodies are raising these issues: is the margin of safety still sufficient for the extreme food product loyalty of some consumers? “They suggest that there may be a role for use levels to play here,” Taylor added. The JECFA has concluded that SPET provides complementary information and has requested that SPET be calculated in addition to MSDI for all future evaluations of flavoring substances. Taylor concluded that it is likely SPET will be considered by more and more regulatory authorities in the future.

NEXT MEETING:

FEMA 100th Anniversary/Annual Meeting; May 3–6, 2009, Palm Beach, Florida; details at www.femaflavor.org.

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