

Current Issues and Outreach Committee Report/Minutes

2019 Midyear Meeting
Regency Ballroom
Hyatt Regency
Savannah, GA
Monday, January 21, 2019
10:00am –10:30am

Committee Recommendations

Committee recommendations summary or list
None

Board Recommendations

Board recommendation summary or list
None

Association Recommendations

Association recommendation summary or list
None

Committee Participants

Members Present: Jennifer Combs (KY), Tim Lyons (MI), Caitlin Price (NC), Richard Ten Eyck (OR), Shaness Thomas (FL), Kent Kitade (Life Member), Wendy Powell (MI) Ali Kashani (WA-Chair).

Advisors Present: Leah Wilkinson (AFIA), David Dzanis (APPA), David Fairfield (NGFA), David Meeker (NRA), Tomas Belloso (NGFA), Angela Mills (AFIA), Pat Tovey (PFI), Louise Calderwood (AFIA), Steve Younker (AFIA),

Committee Report

Committee Activities

ACTIONS:

Committee Minutes:

The meeting was called to order at 10:00 am EST by Chair, Ali Kashani

Modifications to Agenda:

Due to federal government shutdown no one represented from FDA at the meeting and no presentation on behalf of the agency was made.

Introduction of the Topic, GRAS:

The topic of Generally Recognized as Safe (GRAS) ingredients in animal feed to include pet food is one that AAFCO takes very seriously. Countless person-hours from states and industry have been devoted to discussions on an AAFCO process that results in state acceptance of an Independent Conclusion (ICG) of GRAS.

This morning, we are using this short time to present to you the AAFCO and industry viewpoints. Our intention is to introduce the audience to the perspectives AAFCO is working with. On Wednesday morning at 8:00 am, during the second IDC meeting, the discussion of the GOAL for the AAFCO GRAS Process will take place.

Discussion:

Mr. Doug Lueders, Commercial Feed Program Manager, Minnesota Department of Agriculture and the Chair of Model Bill and Regulations committee presented the following brief review:

Current and past terminology related to “Independent Conclusion of Generally Recognized as Safe (ICG)”, “GRAS Self-Conclusion”, “Self-Affirmed GRAS”, “Self-Determined GRAS” and “Self-GRAS”. It was noted that there might be other future terminologies that obviously we do not know presently. There are concerns about lack of regulator confidence that products made with ICG as ingredients are safe and effective for the intended use. ICG is an honor system without checks and balances, without any regulatory review of safety and efficacy data. State Feed control officials have expressed that there is a lack of transparency when distribution occurs without prior notification. Coupled with proprietary manufacturing processes without a required expert panel review have made states uncomfortable with the ICG. ICG is much less desirable than ingredient submissions via a Food Additive Petition, AAFCO Ingredient Definition or GRAS Notification.

Mr. Lueders noted that GRAS notification receives the least rigorous regulatory review by FDA. About 44% of GRAS notifications filed received FDA’s “no questions” letters, leaving 56% that are either withdrawn by submitter or declined by the FDA. The GRAS Notification success ratio for ingredients submitted for review is not good and states have no confidence that ICG ingredients would fare as well in a regulatory review process. The only possible conclusion is that there are ICG products in distribution that would not meet regulatory safety and efficacy review criteria. States are in precarious position, as they lack authority to require a safety and efficacy dossier or to deny ICG distribution. Most states, if not all, lack the required budget resources and technical expertise to review data, even if it were provided. ICG creates a state-by-state regulatory system that is contrary to the initial reasons for formation of AAFCO – to provide a regulatory framework for uniformity among states and jurisdictions. One resolution that would satisfy industry and state regulators is that FDA speeds up review and turn-around time on new ingredient petitions the agency receives in order to satisfy industry’s need to get an ingredient into distribution channels. To meet the needs of regulators, a centralized regulatory body is needed to review safety and efficacy data. Whether the above needs may be met within the current system or a new system that is built from the ground up, remains to be determined.

Mr. Richard TenEyck, Feed Safety Specialist, Oregon Department of Agriculture, and Chair of AAFCO Ingredient Definition Committee gave a brief history of IDC GRAS areas of agreements and challenges:

- Our newest acronym, ICG, stands for Independent Conclusion of Generally Recognized as Safe for an intended use. A firm making an ingredient gathers a data package demonstrating the same level of safety and utility as an FDA Food Additive Regulation. Data must be in the public domain.
- Standard of identity Monographs conceived at Bass Lake, CA in 2008?
- FDA had to push back on informal review process and ask CVM to establish GRAS status of OP defined materials
- AAFCO developed GRAS process whitepaper in 2016
- AAFCO formed GRAS Verification workgroup in 2017
- CVM review of AAFCO Definitions slow as firms file GRAS notices or FAP's
- In 2018 GRAS Verification workgroup refining acceptable process goal
- Consensus among states is that ICG does not provide the level of animal food safety we want.
- Board is ready to write a policy or SUIP that states should not accept un-reviewed self-conclusions.
- MBRC is ready to discuss removing the acceptance pathway from the model bill.
- IDC has an "AAFCO GRAS" pay to review system at an initial step as a white paper.
- Best Solution: CVM needs about 6-8 additional technical reviewers to process current workload volume within desired timelines.

***Ms. Emily Bulian Helmes**, Advisor, Global Regulatory Nutritional Health, Elanco Animal Health, and Co-Chair of the Enzyme Technical Association Feed Committee, provided the following industry perspectives on independent conclusions of GRAS (ICG):*

- GRAS is defined as a substance **G**enerally **R**ecognized **A**s **S**afe, among experts qualified by scientific training and experience, as having been adequately shown to be safe under the conditions of its intended use in animals.
- Marketing a GRAS substance without FDA premarket review and approval is acceptable according to federal law (21 U.S.C. 321, 341, 342, 346a, 348, 371) and according to state feed laws in nearly every US state.
- All GRAS conclusions are based on independently developed scientific dossiers, comprised of scientific data and information documenting all of the major components required by the FDA regulations (21 CFR 570.30 - 570.280) including publicly available information on the safety of the GRAS substance.
- Stakeholders (States, Industry, Public) need more education on what it means for a substance to be GRAS for an intended use. The requirements of the law are not well understood.

- Industry would use the FDA CVM GRAS notification process more if the FDA expectations did not exceed federal law (e.g., requirements for utility and pre-manufacturing data), and if the timing of the reviews were more predictable and shorter.
- Many firms would consider supporting an AAFCO GRAS review process if it would: (a) adhere to federal law, (b) result in acceptance of a GRAS substance in all US states, and (c) be an efficient process (timely and not too costly).
- All feed ingredients placed on the market must be safe for their intended use in animal feed.