

Evaluation of Pre-Market Animal Food Ingredient Review Programs: Summary

Background

In [August 2024](#), FDA launched a comprehensive evaluation of two programs that govern how most new animal food ingredients reach the market: the animal Food Additive Petition (FAP) and Generally Recognized as Safe (GRAS) Notification programs.

FDA's goal: determine whether these programs were working as well as they could for industry, consumers, and public health, and identify solutions to address areas where there was room for improvement.

This summary marks the conclusion of that evaluation. What follows is an overview of what FDA heard, what FDA found, and the steps FDA is taking to strengthen these animal food programs.

How FDA Gathered Input

FDA cast a wide net to ensure this evaluation reflected the diverse perspectives of stakeholders with an interest in animal food.

Efforts included:

- **14 listening sessions** with participants spanning animal food industry associations, state regulatory partners, industry consultants, consumers, and animal food ingredient manufacturers.
- **A [public docket](#)** with targeted questions and information requests to guide input from stakeholders and other members of the public.
- An **internal staff assessment** to hear directly from reviewers and program staff who work within the programs every day.

The result was a robust body of feedback that gave FDA a clear picture of where the programs are working well, and where they need to evolve.

What FDA Heard

Stakeholders recognized meaningful strengths in both the animal food FAP and GRAS Notification programs. Commentors valued the regulatory certainty and intellectual property protections provided by the FAP review process. The GRAS notification process was praised for offering a faster path to market and greater marketing flexibility. Across both programs, the value of pre-submission consultations with FDA was consistently highlighted as an important resource.

Stakeholder concerns converged around four themes:

1. **Confidentiality and disclosure:** Uncertainty was expressed about what information would be disclosed, and when. Some stakeholders emphasized the importance of protecting confidential business information throughout the review process.

2. **Consistency:** Apparent inconsistencies between CVM and other FDA program areas created confusion about expectations.
3. **Predictability:** Long and unpredictable review timelines were among the most frequently cited frustrations.
4. **Data Requirements:** Unclear or shifting expectations about what data and information are needed added to submitter burden and uncertainty.

In addition, stakeholders also expressed strong interest in more structured, iterative engagement during the GRAS Notice review process and greater international harmonization. They also raised questions about market exclusivity, risk-based review, and recognition of foreign regulatory reviews for new animal food ingredients.

FDA Actions to Improve

FDA took the feedback seriously. We analyzed the underlying factors behind each area of concern and identified both new initiatives and improvements already underway. The goal throughout was to preserve the scientific rigor that makes FDA's animal food reviews internationally respected, while making the process more efficient, transparent, and engaging for submitters.

- ✓ **Provide clarity on disclosure and confidentiality requirements through plain-language communications in submitter meetings.**

Uncertainty about what information gets disclosed, and when, is a concern for firms investing in new ingredient submissions.

Worked with disclosure experts to translate complex disclosure requirements into clear, accessible language, so submitters know what to expect before they submit. This will help facilitate discussion and address questions during pre-submission conferences and other meetings.

- ✓ **Update internal best practices to improve consistency and reduce reviewer burden.**

Inconsistency across reviewers and submissions was a recurring frustration among submitters.

Updated internal best practice documents and streamlined review documentation to create a more uniform experience for submitters and free up reviewer capacity to help the program meet, and potentially exceed, target review timelines.

- ✓ **Implement earlier internal review timelines, allowing faster engagement with submitters.**

Rather than waiting until late in the review process to flag potential deficiencies, FDA is moving to identify issues earlier and reach out to submitters sooner.

This change is designed to reduce delays and give submitters a better opportunity to address concerns while there is still time to act.

✓ **Create a second amendment opportunity within the GRAS Notice evaluation process.**

Previously, submitters had limited opportunities to engage iteratively with FDA during a GRAS Notice review.

The addition of a second amendment opportunity makes the process more collaborative, increases the likelihood of successful outcomes within the evaluation window, and lays the groundwork for shorter timelines on well-prepared submissions.

✓ **Publish the GRAS Notice Evaluation Timeline as a formal Program Policy and Procedures Manual (PPM).**

Unpredictable timelines were among the most cited pain points in the evaluation.

Publishing CVM PPM 1244.3425: *Animal Food Generally Recognized as Safe (GRAS) Notice Evaluation Timeline* gives firms a transparent, documented benchmark for when to expect requests and responses from FDA. This turns an informal understanding into a publicly available commitment for targets throughout the submission review process.

✓ **Expand data flexibility to reduce submitter burden without compromising safety.**

Data requirements that feel unclear or excessive discourage innovation and can slow the path to market.

Where scientifically appropriate, FDA is expanding the use of extrapolation approaches (such as building safety arguments across species), ensuring utility data requirements are limited to situations where they are genuinely needed, and continuing to accept simplified Chemistry, Manufacturing, and Controls documentation, such as flow charts, narrative summaries, and reference tables, in place of more comprehensive submissions.

✓ **Advance international harmonization through collaboration with ICCF.**

Animal food is a global market, and duplicative regulatory requirements across jurisdictions create unnecessary burden for industry.

FDA's continued support for and collaboration with the International Cooperation for the Convergence of Technical Requirements for the Assessment of Feed Ingredients (ICCF) helps align standards internationally, making it easier for safe ingredients to move efficiently across borders.

FDA is Committed to Continuous Improvement

This evaluation required significant time and effort from the stakeholders who participated, the staff who conducted it, and the program teams who are now implementing its findings. We are grateful for that investment, and we take seriously the responsibility to act on what we heard.

Improving these programs is not a one-time exercise. We will continue to monitor outcomes, seek feedback, and refine our approach as the animal food ingredient landscape evolves. We look forward to continued collaboration with industry, state partners, international regulatory bodies, and consumers as we work to enhance the animal Food Additive Petition (FAP) and Generally Recognized as Safe (GRAS) Notification programs to be more efficient, transparent, and worthy of the trust placed in them.