REGULATORY AFFAIRS • ANIMAL NUTRITION & FEED INNOVATION

Feed Innovation at a Regulatory Inflection Point: FDA's 2026 GRAS Reset, the Post-AAFCO Transition and the Emerging Global Dossier Model

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EXECUTIVE ABSTRACT

The regulatory architecture governing innovative animal-feed ingredients is undergoing one of its most consequential restructurings in decades. In the United States, FDA has proposed converting the historically voluntary GRAS notification system into a mandatory notification framework for many human and animal food substances, while simultaneously reforming its animal Food Additive Petition and GRAS review processes to improve predictability, scientific interaction and data flexibility. These developments follow the end of the long-standing FDA–AAFCO ingredient-review memorandum and the creation of the interim Animal Food Ingredient Consultation pathway. At the same time, the European Union continues to operate a formal pre-market authorisation system under Regulation (EC) No 1831/2003, Great Britain is simplifying its regulated-product authorisation architecture, and ICCF is progressively constructing internationally convergent technical guidance. Together, these changes point toward a new competitive paradigm: successful feed innovation will increasingly depend not merely on ingredient efficacy, but on designing regulatory evidence packages that are modular, internationally transferable and scientifically defensible from the earliest stages of product development.

Keywords: *animal feed ingredients; GRAS; FDA; feed additives; EFSA; ICCF; regulatory convergence; animal nutrition*

Meta description: FDA's 2026 GRAS reforms could reshape global feed innovation, evidence requirements and market access across the US, EU and Great Britain.

1. A Regulatory Change That Is Larger Than a Procedural Reform

Innovation in animal nutrition increasingly depends on sophisticated ingredients: fermentation-derived compounds, enzymes, microbial preparations, mineral systems, phytogenic substances, functional fibres, metabolites, precision-fermentation products and technologies intended to influence feed stability, digestibility, animal performance or the characteristics of animal-derived foods.

The scientific possibilities are expanding considerably faster than many regulatory systems were originally designed to accommodate.

In September 2026, the U.S. Food and Drug Administration's Center for Veterinary Medicine completed a two-year evaluation of its principal pre-market animal-food ingredient review pathways: the Food Additive Petition (FAP) and Generally Recognized as Safe (GRAS) Notification programs. FDA reported recurring stakeholder

concerns relating to confidentiality, inconsistent expectations, unpredictable review times and unclear or changing data requirements.

FDA's response is not simply administrative streamlining. It includes:

- earlier scientific interaction with applicants;
- a second opportunity to amend GRAS submissions;
- formal publication of review milestones;
- greater acceptance of scientifically justified extrapolation between species;
- more targeted requirements for efficacy or utility data;
- simplified Chemistry, Manufacturing and Controls documentation where appropriate; and
- stronger engagement in international technical harmonisation through ICCF.

These measures arrive only weeks after an even more fundamental proposal: converting much of the American GRAS notification system from voluntary disclosure to mandatory notification.

The interaction between these two reforms is potentially transformational.

2. Understanding the Existing U.S. Architecture

Under the Federal Food, Drug, and Cosmetic Act, an intentionally added substance is generally considered a food additive requiring FDA approval unless an exclusion applies. One major exclusion concerns substances that are Generally Recognized as Safe under their intended conditions of use.

Historically, a manufacturer could reach an independent GRAS conclusion without necessarily submitting that conclusion to FDA.

The FDA notification procedure therefore provided regulatory visibility but was not universally compulsory.

That distinction has frequently been described as the difference between a GRAS conclusion and a GRAS notification.

FDA's August 2026 proposal would substantially narrow that distinction. The agency proposes that persons introducing qualifying substances into interstate commerce under the GRAS provision notify FDA of the basis for the GRAS conclusion, subject to defined exceptions.

This point requires precision.

FDA is not proposing to convert GRAS into the European-style feed-additive authorisation system.

A GRAS substance would still derive its legal status from the statutory GRAS exemption rather than from an affirmative FDA authorisation.

The proposal instead introduces mandatory regulatory visibility.

Indeed, the current framework does not require a company to await an FDA response before introducing a notified GRAS substance into interstate commerce.

That distinction is fundamental.

> ***"mandatory regulatory notification without universal pre-market approval"***

rather than:

> ***"mandatory pre-market authorisation"***

3. The Proposed End of Invisible GRAS Conclusions

On 10–11 August 2026, HHS and FDA published proposals that would require GRAS notifications for many uses of substances added to human or animal foods. The stated objective is to give FDA greater visibility over ingredients entering the food supply and enable more systematic post-market oversight.

The proposed rule is currently not final law.

Comments remain open through 9 December 2026.

If the rule is adopted substantially in its proposed form, manufacturers relying on GRAS status would need to reconsider regulatory strategy much earlier in product development.

This has several consequences.

3.1 Regulatory affairs moves upstream

A company could no longer treat a GRAS assessment simply as an internal safety file prepared near commercial launch.

Regulatory classification, intended uses, target species, use levels, manufacturing specifications and safety evidence would increasingly need to be designed during product development.

3.2 Ingredient identity becomes commercially strategic

An apparently small change in:

- manufacturing process,
- source organism,
- purity profile,
- carrier,
- particle characteristics,
- residual processing material,
- target species,
- dosage,

may change the regulatory analysis.

The commercial product and the substance described in the regulatory dossier must therefore be scientifically congruent.

3.3 Regulatory transparency becomes part of IP strategy

Greater disclosure improves public accountability but creates an obvious tension with proprietary know-how.

FDA itself identified confidentiality and disclosure uncertainty as a major stakeholder concern during its program review.

Companies will therefore need to distinguish rigorously between:

- information required to establish identity and safety;
- confidential manufacturing know-how;
- patentable technology;
- trade secrets; and
- information likely to enter the public regulatory record.

Regulatory affairs and intellectual-property strategy can no longer operate independently.

4. The Legacy Ingredient Problem

Perhaps the most underestimated component of the proposed rule concerns substances that are already being marketed on the basis of historical independent GRAS conclusions.

FDA proposes a time-limited streamlined pathway allowing qualifying legacy substances already in interstate commerce to be identified to the agency.

For animal food, the proposal contemplates submission within one year after the effective date of a future final rule.

The proposal also envisages an 18-month compliance date for the principal mandatory-notification provisions after the final rule becomes effective.

These dates are therefore prospective and contingent: no final rule has yet established them.

Nevertheless, companies selling feed ingredients in the United States should already begin asking a deceptively simple question:

> *"What exactly is the legal basis under which each ingredient is currently marketed?"*

For international manufacturers this can become surprisingly complex.

A portfolio may contain products marketed through different historical mechanisms:

- FDA-reviewed GRAS notices;
- independent GRAS conclusions;
- Food Additive Petitions;
- AAFCO ingredient definitions;
- substances recognised in regulations;
- ingredients marketed under enforcement discretion;
- or substances whose regulatory status depends on their specific intended use.

A future mandatory-notification system could expose inconsistencies that have remained commercially invisible for years.

5. The Post-AAFCO Transition

For approximately 17 years, FDA and the Association of American Feed Control Officials collaborated under a memorandum governing the scientific review of ingredient-definition submissions.

That memorandum expired on 1 October 2024 and was not renewed.

FDA subsequently introduced the Animal Food Ingredient Consultation (AFIC) process as an interim voluntary mechanism for ingredients that might previously have moved through the AAFCO definition process.

AFIC allows FDA to evaluate whether it has questions regarding the safe use of a proposed animal-food ingredient.

FDA envisaged an initial approximately 30-day screening to determine whether a submission is suitable for consultation and sufficiently complete.

The interaction among FAP, GRAS, AFIC, legacy AAFCO definitions and state feed law creates an architecture more complicated than the common phrase "US feed approval" suggests.

Moreover, FDA's 2026 GRAS proposal recognises this history explicitly. The proposal would provide certain exceptions for animal-feed ingredients listed and used consistently with Chapter 6 of the 2024 AAFCO Official Publication, provided FDA has not publicly expressed concerns regarding the GRAS status of the use.

This preserves some continuity while moving regulatory visibility increasingly toward FDA.

6. FDA Is Also Trying to Make Regulation Faster

More oversight does not necessarily mean slower regulation.

This is arguably the most interesting aspect of the September 2026 reforms.

FDA simultaneously proposes greater transparency and reduced friction.

Its review identified unpredictable timelines as one of industry's principal complaints. FDA has therefore issued CVM PPM 1244.3425, which establishes public target milestones for animal-food GRAS evaluations.

Stage	Target
GRAS notice filed	Day 1
Internal reviewer meeting	Day 75
First FDA questions	Day 90
First applicant amendment	Day 104
Possible second FDA questions	Day 134
Second applicant amendment	Day 148
Extension decision	Day 180
Potential response without second amendment	Day 215
Potential response with second amendment	Day 270

These are internal process goals, not statutory guarantees, except for the regulatory review framework described in 21 CFR 570.265. FDA expressly notes that operational circumstances can affect target dates.

Nevertheless, publication of these milestones is important because regulatory uncertainty itself has economic cost.

Companies can now structure toxicology work, production scale-up, customer qualification, distributor agreements, launch inventories and financing milestones against a more transparent regulatory clock.

7. A Scientifically More Interesting Change: Evidence Flexibility

One of the most consequential passages in FDA's September assessment concerns data requirements.

FDA states that, where scientifically appropriate, it intends to expand the use of extrapolation across species, reduce unnecessary utility-data requirements and continue accepting simplified CMC presentations such as flow diagrams, narrative summaries and reference tables.

This deserves considerably more attention than it has received.

Traditional regulatory systems frequently evolve into checklists in which additional studies are commissioned not because they resolve meaningful uncertainty but because applicants fear that omitting them might delay review.

That can create three problems:

1. unnecessary cost;
2. unnecessary animal experimentation;
3. regulatory duplication between jurisdictions.

A genuinely risk-based approach should instead ask:

> ***"What uncertainty actually prevents a scientifically defensible conclusion?"***

Species extrapolation, read-across, weight-of-evidence approaches, in-vitro methods and computational modelling can sometimes answer that question more efficiently than repeating similar experiments across multiple species.

ICCF has been moving in the same direction.

Its guidance on ADME assessment explicitly supports a weight-of-evidence hierarchy involving read-across, in-silico and in-vitro approaches before progressing to in-vivo studies where necessary.

This is regulatory science moving toward evidence proportionality.

8. ICCF May Become More Important Than Many Companies Realise

The International Cooperation for the Convergence of Technical Requirements for the Assessment of Feed Ingredients brings together regulatory and industry organisations including FDA, the European Commission, the Canadian Food Inspection Agency, FEFANA, AFIA and others.

Its purpose is not to create a global authorisation.

It is more subtle and potentially more powerful:

> ***"to make the scientific evidence required by different jurisdictions more compatible"***

ICCF has progressively produced guidance covering:

- ingredient identification and characterisation;
- manufacturing and specifications;
- environmental risk;
- ADME;
- analytical methods;
- and effectiveness assessment.

In January 2026 it published guidance concerning analytical methods for feed ingredients, including method validation and transferability.

In July 2026 it published general recommendations for feed-ingredient effectiveness assessments.

FDA's September reform specifically identifies continued ICCF collaboration as an instrument for international harmonisation.

The long-term implication is important.

The future competitive advantage may not belong to companies capable of preparing a U.S. dossier, an EU dossier and a Canadian dossier independently.

It may belong to companies that create one scientifically robust global evidence architecture from which jurisdiction-specific applications can be generated.

9. The European Union: More Formal, but Also Changing

The European regulatory philosophy remains structurally different.

Under Regulation (EC) No 1831/2003, a feed additive cannot be placed on the EU market unless it has been authorised following scientific assessment.

EFSA evaluates safety for target animals, consumers of foods of animal origin, users/workers and the environment, as well as efficacy where relevant.

Applications must include information on identity, manufacturing, intended use, safety, efficacy and analytical methods.

The European Union Reference Laboratory evaluates methods used to determine the additive in feed and, where relevant, residues.

Authorisations under the current EU framework are generally valid for ten years and subject to renewal.

Yet the system itself is under evaluation. The European Commission has completed an evaluation of Regulation 1831/2003 and indicates that an impact assessment is planned in connection with its revision.

Therefore the EU model should not be treated as static.

10. Microbial and Fermentation-Derived Ingredients Raise the Evidentiary Bar

Feed innovation is increasingly biological.

Microorganisms may be the active ingredient, production organisms, fermentation systems, enzyme producers, probiotic strains or platforms generating functional metabolites.

EFSA's updated microorganism-characterisation guidance became fully applicable to relevant feed-additive dossiers from 1 April 2026.

Its practical implementation includes issues such as antimicrobial resistance, viable production organisms, residual DNA, whole-genome sequencing, strain identity and genetic modification.

This illustrates an important paradox.

Regulators may become more flexible regarding the quantity of studies while becoming more demanding regarding the quality and molecular resolution of evidence.

Less data does not necessarily mean weaker regulation. It may mean better-targeted evidence.

11. Great Britain Is Developing a Third Model

Post-Brexit Great Britain provides an increasingly interesting comparator.

Feed additives remain subject to pre-market authorisation under assimilated Regulation 1831/2003.

However, reforms taking effect from 1 April 2025 removed periodic renewal requirements for certain regulated-product authorisations, including feed additives, and allowed authorisations to take effect following ministerial decision and publication in an official register rather than requiring an individual statutory instrument.

The official GB feed-additive register contained more than 1,600 entries when updated in July 2026.

FSA and Food Standards Scotland also published updated feed-additive application recommendations in June 2026 based on recurrent dossier deficiencies observed since 2021.

Thus three regulatory philosophies are increasingly visible:

United States: notification/risk-based architecture with several legal pathways.

European Union: centralised scientific assessment followed by formal authorisation.

Great Britain: EU-derived authorisation architecture undergoing procedural simplification.

These systems are not converging legally.

But their scientific dossiers increasingly can.

12. The Real Innovation Opportunity: Regulatory-by-Design

Most companies still develop ingredients in the following order:

> ***"idea → formulation → testing → commercial interest → regulatory assessment"***

That sequence is becoming obsolete.

A better model is:

> ***"regulatory classification → intended function → target species → exposure → identity → manufacturing architecture → evidence plan → product development"***

This can be called regulatory-by-design.

The concept is analogous to Quality by Design in pharmaceutical development.

Instead of asking at the end:

> ***"What studies do regulators require for this product?"***

the development team asks at the beginning:

> ***"What product architecture allows us to demonstrate safety, efficacy and reproducibility most efficiently across our priority jurisdictions****?"*

This affects even apparently simple formulation decisions.

A change in carrier, production microorganism, mineral composition, fermentation process or intended technological function can radically change the evidentiary burden.

Regulation therefore becomes a design variable.

13. Research & Innovation Opportunity

The Global Feed Ingredient Evidence Architecture

Unresolved problem

International feed-ingredient developers frequently create separate regulatory packages for different jurisdictions.

This produces:

- duplicated testing;
- inconsistent specifications;
- incompatible study designs;
- repeated analytical validation;
- delayed market entry;
- and unnecessary regulatory cost.

What is already known

ICCF has established an expanding set of technical convergence documents covering major components of feed-ingredient evaluation. FDA is explicitly supporting ICCF harmonisation, while EFSA and other regulatory authorities participate in its scientific work.

What remains unresolved

There is still no widely adopted commercial framework that maps a single feed-ingredient evidence package simultaneously against FDA GRAS, FDA FAP, AFIC, EU Regulation 1831/2003, EFSA FEEDAP requirements, GB feed-additive authorisation and ICCF technical guidance.

Proposed development pathway

A modular regulatory platform could structure evidence into reusable components:

4. Identity and characterisation module
5. Manufacturing and specifications module
6. Analytical-method validation module
7. Target-animal safety module
8. Consumer-safety/residue module
9. User-safety module
10. Environmental module
11. Efficacy module
12. Exposure/use-condition module
13. Jurisdiction-specific legal module

An AI-assisted layer could then identify gaps between the master evidence package and specific jurisdictional requirements.

The objective would not be automated regulatory approval.

It would be regulatory evidence interoperability.

For ingredient companies operating internationally, this could shorten development timelines considerably.

14. Practical Implications for Ingredient Manufacturers

The immediate consequences are operational.

Companies intending to market animal-nutrition ingredients internationally should begin constructing a regulatory identity file for every significant product containing at least:

- exact substance identity;
- manufacturing description;
- composition and specifications;
- impurities and contaminants;
- analytical methods;
- stability;
- intended target species;
- dose;
- technical or nutritional function;
- historical market status;
- safety rationale;
- existing regulatory determinations;
- and jurisdiction-by-jurisdiction legal basis.

For U.S. portfolios, particular attention should be paid to products historically relying on independent GRAS conclusions.

For EU portfolios, companies should verify that the actual commercial product continues to match the authorised additive specification and conditions of use.

For microbial and fermentation-derived products, genomic characterisation and production-organism documentation increasingly need to be incorporated during R&D rather than generated retrospectively.

For globally marketed products, ICCF-compatible study design should increasingly become the default rather than an afterthought.

15. A Critical Caveat: Faster Regulation Is Not Automatically Better Regulation

Regulatory simplification has obvious commercial appeal.

However, there is an important scientific risk.

Greater use of read-across, species extrapolation, simplified CMC, computational evidence and reduced efficacy requirements is only defensible when uncertainty is genuinely controlled.

Poorly justified extrapolation can transform regulatory efficiency into evidence dilution.

The correct principle is therefore not:

> ***"fewer studies"***

It is:

> ***"fewer unnecessary studies, combined with stronger scientific reasoning"***

That distinction should guide future regulatory reform.

Conclusions

The 2026 U.S. feed-ingredient reforms represent more than administrative modernisation.

They reveal a broader restructuring of food and feed regulatory science.

Three movements are occurring simultaneously:

greater transparency, through proposed mandatory GRAS notification;

greater regulatory predictability, through formalised FDA review timelines and iterative interaction;

and greater scientific flexibility, through risk-based data requirements and international convergence.

The European Union continues to maintain a more formal authorisation model, while Great Britain is progressively simplifying the machinery inherited from EU law.

The most important development may ultimately occur between these legal systems rather than within any single one.

ICCF and related regulatory-science initiatives are beginning to create the possibility that the same underlying scientific evidence can serve multiple markets.

For innovative ingredient companies, the strategic conclusion is clear:

> ***"the future regulatory asset will not merely be an authorised product. It will be a transferable, modular and scientifically robust evidence architecture capable of supporting that product across jurisdictions."***

That may become one of the decisive competitive advantages in next-generation animal nutrition.

Related INTABIOTECH Knowledge Areas

Animal Nutrition · Regulatory Affairs · Functional Ingredients · Biotechnology · Food Safety · AI & Food · Mineral Technologies · Emerging Research

Suggested Internal Tags

Animal Nutrition · Feed Additives · FDA · GRAS · EFSA · ICCF · Regulatory Science · Global Market Access

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