Insects' Protein in Animal Nutrition:
The Regulatory Landscape in the EU and US

In recent years, growing concerns around the sustainability and environmental impact of conventional protein sources, combined with the need to secure sufficient protein supply to meet the increasing demand in a growing global population have driven significant interest in alternative proteins.

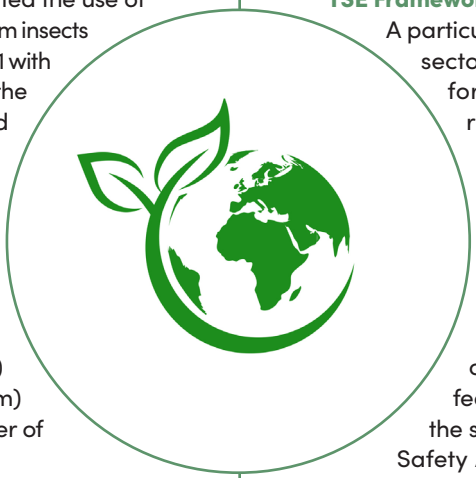
When it comes to animal feed, one protein source attracting great scientific and commercial interest is insect protein. Insects offer a combination of nutritional quality, production efficiency and environmental sustainability that sets them apart from other alternatives. From a nutritional standpoint, insects are a rich source of high-quality and digestible protein. From a production standpoint, insects are efficient converters of organic matter that require less land, water and feed than conventional livestock to produce an equivalent unit of protein.



The recognition of insect protein's potential has been reflected in policy over the past decade, with a series of regulations expanding the scope of its authorised use. Yet commercialisation of insect-derived ingredients in animal nutrition remains governed by a complex and still-evolving regulatory framework that varies considerably between jurisdictions. This article provides a structured overview of the current regulatory landscape in the two most relevant markets: the European Union (EU) and the United States (US).

Regulatory Context in the European Union

In the EU, the first insect-specific authorisation came in 2017 with Regulation (EU) No 2017/893 which permitted the use of processed animal proteins (PAPs) derived from insects in aquaculture feed.[1] This was followed in 2021 with Regulation (EU) 2021/1372 which extended the authorisation of insect PAPs to poultry and pig feed, covering seven species: Hermetia illucens (black soldier fly), Musca domestica (common housefly), Tenebrio molitor (yellow mealworm), Alphitobius diaperinus (lesser mealworm), Acheta domesticus (house cricket), Gryllodes sigillatus (banded cricket) and Gryllus assimilis (Jamaican field cricket).[2] Shortly after, Regulation (EU) 2021/1925 added Bombyx mori (silkworm) to the list, bringing to eight the total number of authorised species for insect PAPs.[3]



These authorisations finally opened the market for insect protein in animal feeds, but they do not stand alone. They are embedded within a broad regulatory architecture governing all animal feed in the EU that applies to insect PAPs directly and indirectly.

Other horizontal EU regulations are applicable to the insect feed sector. Regulation (EC) No 178/2002, the General Food Law, constitutes the overarching legal framework, establishing the fundamental principles and general requirements governing food and feed safety.4 The hygiene and safety standards for feed production are laid down in Regulation (EC) No 183/2005.[5] This regulation requires insect producers placing products on the feed market to be registered or approved as feed business operators and implement appropriate hygiene procedures. Furthermore, Regulation (EC) No 767/2009 governs the placing on the market and use of feed in the European Union, covering aspects such as labelling, presentation and claims made for insect-derived feed materials.[6]

TSE Framework

A particularly significant law for the insect protein sector is Regulation (EC) No 999/2001, which for many years represented the biggest regulatory barrier to the use of insect-derived ingredients in animal feed.[7] Originally adopted to prevent, control and eradicate transmissible spongiform encephalopathies (TSEs), this regulation established a broad feed ban on processed animal proteins (PAPs) for all farmed animals. Under this ban, insects along with other PAPs, were not permitted for use in feed for food-producing animals. Based on the scientific assessment of the European Food Safety Authority (EFSA) , which confirmed that insects do not present a TSEs risk, the restrictions were progressively lifted with the amendments to Reg. 999/2001, first lifting the ban for insect PAPs in aquaculture feed through Reg. 2017/893, and subsequently extending this derogation to poultry and pig feed through Reg. 2021/1372.8 The ban has not been fully lifted, as insect PAPs remain prohibited in feed for ruminants and the feeding of insects with blood products or proteins from ruminants continues to be prohibited by this regulation.

Animal By-Product Legislation

Another central element of the regulatory framework for insects are the laws on Animal by-products (ABPs), Regulation (EC) No 1069/2009 and its implementing Regulation (EU) No 142/2011, which establishes the health rules regarding ABPs and derived products.[9,10] These regulations directly affect insect production: Article 3(5) of Reg.1069/2009 defines any vertebrate or invertebrate as an 'animal,' and Article 3(6) establishes that a 'farmed animal,' includes any animal kept for food production or other farming purposes, thereby formally bringing insect producers within the scope of EU farm animal legislation. Under this framework, insect-derived products are treated as ABPs, subject to processing, traceability and establishment approval requirements.

In the case of using insects for pets, animals raised for fur and zoo animals, since these animals do not enter the human food chain, the biosafety concern is removed. For pet food, Article 35 defines the eligible materials from which pet food may be derived, within which Article 10(l) insect-derived ingredients fall as 'products of terrestrial invertebrates.' For fur and zoo animals, Article 18(1) of the same regulation provides a derogation from the standard rules of ABPs in farmed animal feed.

A regulatory constraint for insect production is the substrates that may be used for insect rearing. On one hand, Reg. 767/2009 requires that feed must not consist of any material prohibited under the list provided in the Annex III of the same regulation. On the other hand, Reg. 142/2011 establishes the raw material requirements for PAPs derived from farmed insects, including the permitted substrate list and the explicit prohibition on manure, catering waste and other waste.11 These restrictions, while based on biosafety principles, reduce the practical implementation of circular economy models in insect production. It is worth noting that these substrates rules apply to insects reared for PAPs, but no equivalent list exists for use as live insects, which are approved feed materials as specified in the next section.

Catalogue of Feed Materials

The formal inclusion of insect-derived ingredients as feed materials is stablished in Regulation (EU) No 68/2013 the EU Feed Material Catalogue. This catalogue is the official reference list of ingredients that are legally recognised for use in animal feed in the European Union. Four entries are directly relevant to insects and one specific to insect PAPs:

- **Entry No 9.16.1 –** Terrestrial invertebrates, live: Live terrestrial invertebrates, in all their life stages, other than species having adverse effects on plant, animals and human health.
- **Entry No 9.16.2 –** Terrestrial invertebrates, dead: Dead terrestrial invertebrates, other than species having adverse effects on plant, animals and human health, in all their life stages, with or without treatment but not processed as referred to in Regulation (EC) No 1069/2009.
- **Entry No 9.4.1 –** Processed animal protein: Product obtained by heating, drying and grinding whole or parts of land animals, including invertebrates in all their life stages from which the fat may have been partially extracted or physically removed.
- **Entry No 9.2.1 – Animal fat:** Product composed of fat from land animals, including invertebrates other than species pathogenic to humans and animals in all their life stages.

Regulatory Context in the US

The regulatory context in the US differs greatly from that of the EU, both in the structure of the legal framework and in the routes available to obtain market authorisation for new feed ingredients.

Under the Federal Food, Drug and Cosmetic Act (FD&C Act) animal feeds are classified as food and any ingredient must meet one of the three conditions: approval as a food additive under a Food Additive Petition (FAP), the recognition as Generally Recognised as Safe (GRAS) under 21 CFR Part 570 and 582, or the listing as a defined ingredient in the official publication (OP) of the Association of American Feed Control Officials (AAFCO).[12,13,14] AAFCO is a voluntary membership organisation that has maintained the AAFCO OP since 1920. The OP contains a comprehensive list of animal food ingredients. Most states adopt the ingredient definitions under their state laws, facilitating the marketing of animal food ingredients.

Another relevant regulation is the Food Safety Modernisation Act, a milestone in the preventive approach towards food safety in the US.[16] Its section 21 CFR Part 507 on current good manufacturing practice, hazard analysis and risk-based preventive controls for food for animals, requires all food and feed manufacturers, including insect producers, to proactively identify hazards and implement preventive controls.[17]

The first approved insect-ingredient arrived in 2016, with the AAFCO definition of Hermetia illucens (dried black soldier fly larvae - BSFL) as a feed ingredient for feeding of salmonid fish. In 2018 the definition was reviewed to include poultry, in 2019 to include swine and in 2021 to include adult dogs. In 2022, three new definitions were incorporated such as dried whole BSFL, partially defatted BSFL meal, and BSFL oil for use in finfish, poultry, swine, adult dogs and adult cats. Only in 2024 the AAFCO approved a new insect species with the definition for dried Tenebrio molitor (yellow mealworm) meal for adult dogs, the second to receive an AAFCO definition.

AFIC and SRIS: New Pathways

Insect-derived ingredients have been introduced in the US via AAFCO listing so far, however a significant structural change occurred in October 2024, when the memorandum of understanding (MOU) between FDA and AAFCO, under which FDA provided scientific review support for the AAFCO ingredient definition process, expired ending so the most common route that the industry had to bring insects to the market.

In October 2024, the FDA published the Guidance for Industry (GFI) #293 confirming they do not intend to initiate enforcement action with respect to the food additive approval requirements of the FD&C Act for ingredients listed in chapter six of the 2024 AAFCO Official Publication.18 This meant that BSFL and mealworm definitions in the 2024 OP retain their regulatory standing under federal law. As an alternative to the previous MOU, in January 2025 the FDA published GFI #294 stablishing the Animal Food Ingredient Consultation (AFIC) as the new interim pathway for companies seeking FDA input on novel



animal food ingredients, this is therefore the primary route for new insect species seeking regulatory recognition in the US.[19]

In parallel, AAFCO established a new independent review pathway through a partnership with Kansas State University's Olathe Innovation Campus. This new pathway was introduced to offer a fast and accurate scientific assessment of new animal food ingredients, currently known as the Scientific Review of Ingredient Submissions (SRIS).[20] Submissions are evaluated by experts specifically recruited across the country, according to the FDA GRAS framework, and approved definitions are incorporated into the AAFCO Official Publication. SRIS represents a practical pathway for insect companies seeking to introduce new species or products into the US market.

Both pathways end in the listing of a non-proprietary AAFCO definition, but each of them offers advantages and limitations. AFIC represents a recognition at the federal level, with direct FDA involvement and does not require pivotal safety data to be in the public domain. SRIS, on the other hand, does not incorporate an FDA review, operates on the basis of an independent GRAS conclusion, which requires that peer-reviewed safety data is available in the public domain, delaying the process if the information has not already gone through the publishing step and potentially limiting the ability of companies to protect sensitive information. The treatment of information also differs: AFIC publishes a public notice of the consultation filing, containing the company name, substance, date and intended use, while SRIS dossiers are not subject to Freedom of Information requests, providing greater confidentiality during the process (a summary of the expert panel findings will be published only towards the end of the process, when scheduled for discussion by the AAFCO Ingredient Definitions Committee). Finally, the two pathways differ in terms of cost and timeline. SRIS operates on a fee-based model and offers a defined review timeline of approximately nine months. The AFIC consultation does not involve a fee but does not provide a fixed review timeline. The choice between these pathways therefore depends on the nature of the data, the tolerance for public disclosure and the need for timing certainty.

Conclusion

The regulatory framework governing the use of insects in animal nutrition has evolved considerably over the past decade in both the EU and the US, yet the two systems remain structurally different. The EU has built a more comprehensive, species-specific that requires legislative action for the addition of new species, while the US has relied on a submission-driven, ingredient-by-ingredient process that delivered an earlier feed approval in 2016, but that currently only covers two fully authorised species while undergoing significant changes following the establishment of two new review pathways SRIS and AFIC.

The market for insects is opening and it comes with uncertainty and opportunities, however they could become a new staple ingredient in sustainable in animal nutrition. Understanding these frameworks will be essential for industry and feed formulators seeking to navigate the opportunities of this emerging sector.

REFERENCES

1. http://data.europa.eu/eli/reg/2017/893/oj
2. http://data.europa.eu/eli/reg/2021/1372/oj
3. https://eur-lex.europa.eu/eli/reg/2021/1925
4. http://data.europa.eu/eli/reg/2002/178/2026-01-01
5. http://data.europa.eu/eli/reg/2005/183/oj
6. http://data.europa.eu/eli/reg/2009/767/oj
7. http://data.europa.eu/eli/reg/2001/999/oj
8. Risk profile related to production and consumption of insects as food and feed https://doi.org/10.2903/j.efsa.2015.4257
9. http://data.europa.eu/eli/reg/2009/1069/oj
10. http://data.europa.eu/eli/reg/2011/142/2025-10-29
11. Regulation (EU) No 142/2011, Annex X, Chapter II, Section 1
12. https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act
13. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-570
14. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-582
15. https://www.aafco.org/
16. https://www.fda.gov/food/food-safety-modernization-act-fsma/full-text-food-safety-modernization-act-fsma
17. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-507
18. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-293-fda-enforcement-policy-aafco-defined-animal-feed-ingredients
19. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-294-animal-food-ingredient-consultation-afic
20. https://sris.k-state.edu/

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