



Overview of the regulatory system for food and feed safety: EU

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1. Regulatory system for alternative proteins in food

Alternative proteins: Definition

- ✓ No definition at EU level
- ✓ Good Food Institute: meat made from plants, cultivated from animal cells, or produced via fermentation—are designed to taste the same as or better than conventional animal products while costing the same or less.
- ✓ European Parliament: plant-based and alternative proteins from four sources (algae, insects, microbial fermentation and cultured meat).
- ✓ Melbourne University: Alternative proteins are plant-based and food-technology alternatives to animal protein. They include food products made from plants, fungus, algae, insects and even cultured (lab-grown) meat.

Farm to Fork (F2F) Strategy

Research and innovation (R&I) are key drivers in accelerating the transition to sustainable, healthy and inclusive food systems:

- ✓ The F2F highlighted that the research should focus on increasing the availability and source of **alternative proteins** such as **plant, microbial, marine** and **insect-based proteins** and **meat substitutes**.

Regulatory framework for alternative proteins

- ✓ Regulation (EU) 2015/2283 on Novel Foods
- ✓ Regulation (EC) No 1829/2003 on genetically modified food and feed

The Novel Food Regulation

The purpose of novel food Regulation is to ensure the effective functioning of **the internal market** while providing a **high level of protection of human health and consumers' interests.**“

Definition: Food not used for human consumption to a significant degree before 15 May 1997 and that falls under at least one of 10 specified categories.



10 categories in total. Relevant categories ref alternative proteins

- (ii) food consisting of, isolated from or produced from microorganisms, fungi or algae;*
- (iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of.....;*
- (v) food consisting of, isolated from or produced from animals or their parts, except.....;*
- (vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;*
- (vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances.*

Novel Foods Regulation (EU) 2015/2283 (Article 7)

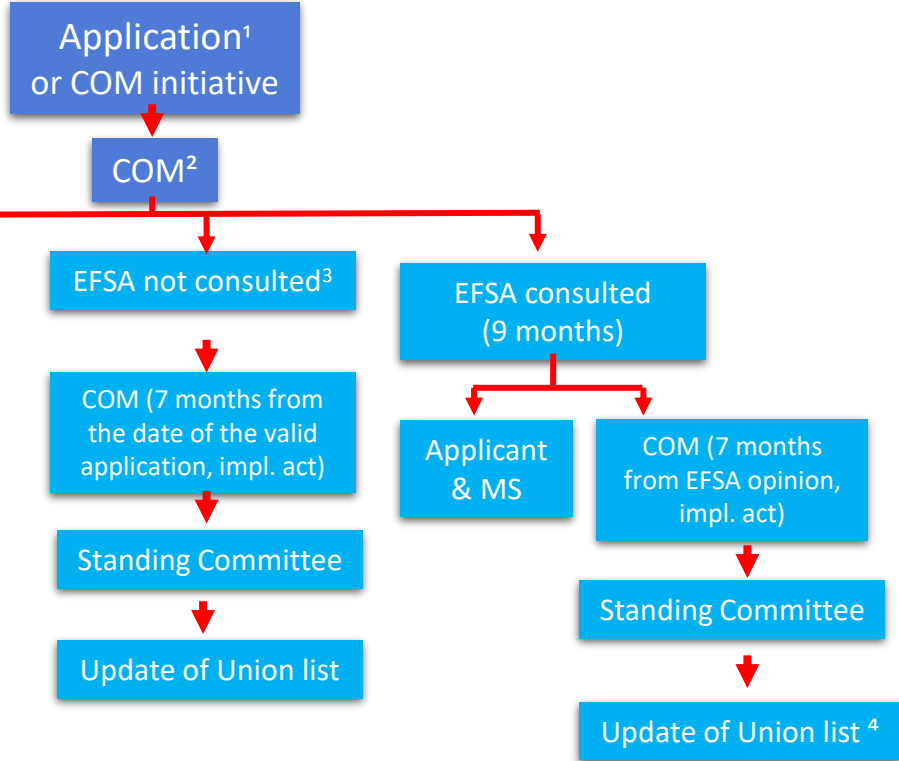
Main requirements - novel foods must:

- *Be **safe***
- *Not **mislead the consumer**, especially when the novel food is intended to replace another food*
- *Not be **nutritionally disadvantageous** where it is intended to replace another food*



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Authorisation process Novel food - Article 10



¹ Applicant may withdraw its application at any time

² COM may terminate the procedure at any stage

³ When the update is not liable to have an effect on human health

⁴ Generic authorisation, except if authorisation based on protected data

Confidentiality

- ✓ Amended by Regulation 2019/1381 (TR)
- ✓ On request by applicant
- ✓ Confidentiality may only be granted to a limited list of elements (list in Article 39 GFL and complemented in the NF regulation) and only if disclosure is demonstrated to potentially harm the applicant's interests to a significant degree.
- ✓ Assessments to be performed by EFSA – in accordance with its Practical Arrangements
- ✓ Except where EFSA is not consulted (novel food applications without EFSA opinion), assessment to be performed by the Commission – in accordance with the NF regulation.

Data Protection

- On request by applicant
- Conditions for data protection:
 - a) the newly developed scientific evidence or scientific data was designated as proprietary;
 - b) the initial applicant had exclusive right of reference to the evidence or data; and
 - c) the novel food could not have been assessed by EFSA without the submission of the proprietary scientific evidence or scientific data.
- COM can grant the individual authorization for 5 years
- Authorization holder indicated in the Union list

Examples of alternative proteins as novel foods

- Plant-based novel proteins
- Novel foods from microorganisms, algae or yeasts
- Insects and products thereof
- Cell-based food isolated from plants or animals



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Authorised plant-based novel proteins

- ✓ Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)
- ✓ Mung bean (*Vigna radiata*) protein
- ✓ Partially defatted chia seed (*Salvia hispanica*) powders
- ✓ Partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L.
- ✓ Rapeseed Protein
- ✓ Pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia
- ✓ Potato proteins (coagulated) and hydrolysates thereof
- ✓ Protein concentrate from *Lemna gibba* and *Lemna minor*



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Authorised novel foods from algae, yeasts or microorganisms

Microalgae:

- ✓ Dried *Tetraselmis chuii* microalgae

Yeasts:

- ✓ *Yarrowia lipolytica* yeast biomass



Authorised insects

4 insect species and products thereof :



Locusta migratoria – frozen, dried and powder



Acheta domesticus – frozen, dried and powder



Tenebrio molitor - frozen, dried and powder



Alphitobius diaperinus – frozen, paste, dried and powder

Cell-based food isolated from plants or animals

From plants:

- ✓ Apple fruit cell culture biomass. Authorised

From animals

- ✓ First application (duck cells from cell culture) submitted in July 2024. Ongoing.



Challenges and expectations

Food innovation can be seen as both

- Creative : shift to more sustainable, 'green' food production and consumption systems
- Disruptive : may challenge some well embedded traditional, cultural and for some ethical codes

Carry high expectations and challenges for and from civil society, food businesses, and regulators

2. Regulatory system for alternative proteins in feed

Legislative framework applying to alternative proteins for feed

- ✓ Regulation (EC) No 1831/2003 on feed hygiene and
- ✓ Regulation (EC) No 767/2009 on the placing on the market and use of feed

The notion of “**Novel feed**” does not exist in the legislative framework on feed

Regulation (EC) No 183/2005 on feed hygiene

Lays down that:

- ✓ Good hygiene practices and feed safety requirements are under the responsibility of business operators over the whole chain of feed production
- ✓ Procedures must be based on HACCP principles, except primary production and associated operations
- ✓ Provides for the registration and, where required by the Regulation, approval of establishments.



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Proteins for feed should be considered as feed materials.

Article 3 of Regulation (EC) 767/2009 on the placing on the market and use of feed

'Feed materials' means products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures



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Regulation (EC) No 767/2009

➤ Lays down that:

- *Feed may only be placed on the market and used if it is safe, and it does not have a direct adverse effect on the environment or animal welfare.*
- *Feed business operators placing feed on the market shall ensure that the feed is sound, genuine, unadulterated, fit for its purpose and of merchantable quality.*
- *Does not lay down a pre-market authorisation procedure for feed materials*
- *But provides for an obligation for all feed materials to be either listed in the EU Catalogue of feed materials (Regulation (EU) No 68/2013), or to be listed in the Feed Materials Register (notification by the person who, for the first time, places on the market the feed material (<https://www.feedmaterialsregister.eu/register>))*

Regulation (EC) 767/2009

➤ Provides in Annex III for a list of materials prohibited or restricted for feed use ("negative list"), including:

5. All waste obtained from the various phases of the treatment of the urban, domestic and industrial wastewater, as defined in Article 2 of Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment, irrespective of any further processing of that waste and irrespective of the origin of the waste waters.

...

8. Protein products obtained from yeasts of the *Candida* variety cultivated on *n*-alkanes.

Other legislation to consider:

- ✓ *Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*
- ✓ *Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies*
- ✓ *Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption*

Thank you for your attention

Useful links:

European Commission, DG Health and Food Safety website
https://ec.europa.eu/food/safety/novel_food_en

Functional mailbox: SANTE-NOVELFOODS@ec.europa.eu



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