

FAQ

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Lupins, insects or lab-grown meat: what is the current state of health risk assessment for alternative protein sources?

From legumes that to date have rarely been used, insects or meat derived from cell cultures: alternative protein sources are the subject of increasing focus in the food and feed domain. In order to sustainably meet the growing global demand for protein, alternative protein sources may supplement or even replace conventional sources in the future. While plant-based proteins from soya and peas are already established, new sources such as insects, algae or microorganisms as well as cell culture-based meat substitutes have not yet been fully researched. The same is true for consumer acceptance.

Health risks can arise from potentially harmful substances that occur as contaminants in the raw materials or that are created during the manufacturing process or are introduced into the product. In addition, health problems due to allergic reactions or certain viruses and bacteria are conceivable. If the products made from alternative protein sources are novel foods or food or feed derived from genetically modified organisms, it must be determined within the scope of the European Union's authorisation process that they pose no health risk.

The German Federal Institute for Risk Assessment (BfR) is already conducting research into a number of new protein sources, including insects, algae and lupins. It has therefore compiled a selection of questions and answers on the topic of "alternative protein sources".

What are alternative protein sources and what are they used for?

Proteins are essential components of human and animal diets. In addition to certain plantbased foods – for example (soya) beans, peas and lentils – meat, fish and seafood, dairy products, and eggs are traditionally the main sources of protein consumed. As the production of sufficiently large quantities of animal-based foods to secure the protein supply poses significant challenges in terms of production, the use of different protein sources is a topic of discussion. In addition to plant-based alternatives (legumes such as field beans, peas and lupins as well as cereals and macroalgae), there are protein sources that have not yet been extensively researched, authorised or that are new to the market. Examples include insects and products made from them, such as processed animal protein from farmed insects, so-called insect flour, cell culture-based meat substitutes, and industrially utilised microorganisms such as certain bacteria, yeasts, fungi or microalgae.

Alternative protein sources are used in the production of both food and feed. In animal feed, protein and energy are largely supplied through co-products of the vegetable oil industry (known as press cakes, expeller or extraction meal). For ruminants, the so-called basic feedstuffs - feed based on whole plants such as grass, alfalfa and clover in fresh or preserved form (hay, silage) - are an important source of protein. In recent years, soya extraction meal in particular has been used as a protein-supplying component in feed rations. In recent years, soya meal in particular has been used as a protein component in feed consisting mainly of rapeseed and grain legumes (field beans, peas, sweet lupins) has been increasingly used again. Traditionally, there is a wide range of protein alternatives in animal feed. Many protein feeds come from the food processing industry, e.g. dairy farms (whey and skimmed milk powder), breweries (brewer's yeast and spent grains) and distilleries (stillage), as well as from the meat processing (pet food) and fishing (fishmeal) industries.

What alternative protein sources are there?

- Plant-based protein sources

Legumes are an alternative plant-based protein source. In addition to the traditionally used beans, peas and lentils, sweet lupins (especially sweet lupin seeds) have also been used in the food and feed industry for some time.

Lupin seeds have the highest protein content of all domestic grain legumes. In the food sector, the legume is used as an additive in various dishes or as lupin flour for the production of baked goods.

The seeds of the sweet lupin are also used as meal or in crushed form as animal feed, especially in pig and cattle feed, and can replace feed made from grain or soya.

Due to their high protein content, hemp seeds are also used as animal feed.

In addition to the above-mentioned protein sources, the use of small-grain legumes (clover, lucerne, vetches, etc.), whole plant silage (cereals, mustard) or foliage from fast-growing hardwood species are currently being discussed as further alternatives in cattle feed.

- Fungi/mycoproteins from fungi and yeast

Mycoproteins are proteins derived from fungi. High yields of mycoprotein can be obtained from certain fungal cultures. Since the 1980s, fungal cultures have been used on an industrial scale to produce biomass with high protein levels. Mycoprotein with a suitable texture can be considered for use in meat substitute products.

Brewer's yeast originates from beer production. The yeast is killed by heating or adding acid and is used in liquid or dried form as animal feed for pig or cattle being raised for meat production.

- Co-products through fermentation of microorganisms

Protein-rich feed materials of microbial origin are fermentation products that consist primarily of microbial biomass. All microorganisms used for fermentation are inactivated for use as feed materials. The production of feed materials of microbial origin has become increasingly important with the development of biotechnology (i.e. the production of amino acids, vitamins, enzymes etc. through the large-scale cultivation of microorganisms) and the loss of animal protein suppliers as a result of the BSE crisis.

- Macroalgae and microalgae

Algae are photosynthetic organisms that live in water. Algae use sunlight more effectively than terrestrial plants and grow faster. This makes them a suitable alternative source of protein for food and animal feed. Algae are generally divided into macroalgae and microalgae. Macroalgae, such as kelp, are multicellular organisms that grow in the sea. They have been used for many years, particularly in Asia, for food production and are an important source of protein. They are also being used more and more in fish substitute products.

Microalgae are single-celled microorganisms that grow in both fresh water and in the sea. They are increasingly used for food production in dietary supplements and as animal feed. In addition, microalgae are used in the cosmetics industry.

- Insects

According to estimates by the Food and Agriculture Organisation of the United Nations (FAO), around 1,900 insect species are consumed worldwide. Insects convert their food very efficiently into protein that is valuable for humans.

Four insect species are currently authorised in the European Union as **novel foods**. Depending on the type of authorisation, the insects are used as additives in dried, frozen, paste-like or powdered form in certain products such as noodles and pasta or cereal bars.

- Common mealworm/yellow mealworm beetle larvae (Tenebrio molitor)
- European migratory locust (Locusta migratoria)
- House cricket (Acheta domesticus)

- Lesser mealworm/litter beetle larvae (Alphitobius diaperinus)

Insects are also used in the **feed industry**. There are currently eight authorised insect species that are approved for the production of processed animal protein from beneficial insects for use in the production of feed for poultry, pigs or aquaculture animals.

- Lesser mealworm/litter beetle larvae (Alphitobius diaperinus)
- Common mealworm/yellow mealworm beetle larvae (Tenebrio molitor)
- House cricket (Acheta domesticus)
- Black soldier fly (Hermetia illucens)
- Jamaican field cricket (Gryllus assimilis)
- Tropical house cricket (Gryllodes sigillatus)
- Housefly (Musca domestica)
- Silk moth pupa (Bombyx mori)

For farm animals that are not ruminants, live insects can also be fed, provided they are safe according to the provisions of feed legislation. For pets, these may also be other and/or unprocessed insects.

- Cell culture-based meat substitute components ("cultured meat")

New, cell culture-based meat substitutes - also known as laboratory meat or "cultured meat" - represent an alternative protein source in animal husbandry and food production that has not yet been the subject of much research in Europe and is not yet authorised for food production in the EU.

The meat substitute components are produced in a laboratory from stem cell cultures. First, muscle tissue is removed from an animal (e.g. cattle, pigs or chickens). Stem cells are obtained from this tissue and multiplied in a container (bioreactor) using a culture medium.

The cells go through various stages and form muscle fibres. The cells grow together into a larger mass around a supporting scaffold, usually made of animal collagen.

In Singapore, for example, cell culture-based meat substitutes are already commercially available as cell culture-based chicken meat. In the USA and Israel, the first authorisations for the food sector have been granted, but no products are yet on the market. In summer 2024, the first application for the authorisation of cell culture meat from duck cells was submitted in the European Union.

In which context does the BfR examine alternative protein sources?

The main tasks of the BfR include the assessment of existing health risks and the identification of new ones. As proteins from alternative sources will become increasingly important in the food and feed domain in the future, their potential health risks must be known and further researched.

The BfR is already involved in numerous research projects on alternative protein sources for use in food and feed. These include, for example, the development of detection methods for proteins from alternative protein sources and tests on the allergenic potential of such foods. Furthermore, the BfR investigates the use of alternative protein sources as feed for livestock with regard to animal health and the transfer of undesirable substances into animal-based

foodstuffs. The National Reference Laboratory for Animal Protein and Feed is also based at the BfR. The BfR also conducts research into consumer acceptance and perception.

Overview of BfR projects:

- Development of standardised detection of food and feed ingredients in processed feed/foodstuffs
- Co-development of tests on the allergenic effect of substances
- Research into molecular mechanisms of allergy development
- Third-party funded project "<u>AllergenPro</u>" Development of detection methods for allergenic components in foods containing insects
- Research into the conversion of otherwise unusable biomass into proteins that can be utilised as food and feed using alternative protein sources (e.g. "<u>BioInsectomy</u>", "ContamInsect"
- Projects on consumer perception/acceptance
- Research into the use of alternative protein sources as feed for livestock; identification of possible undesirable substances and their transfer into animal-based foodstuffs
- Research on the food safety of aquatic organisms from aquaculture

Can allergic reactions occur in connection with foods from alternative protein sources?

Certain alternative protein sources may contain ingredients to which some people are allergic.

For example, insects can contain allergens to which people with an existing allergy to crustaceans, molluscs and/or dust mites can react. This is known as a cross-reaction and in this case is due to the fact that allergenic proteins in crustaceans, molluscs or dust mites are very similar in structure to certain insect proteins. However, allergic reactions can also develop to previously unknown proteins.

The German Federal Institute for Risk Assessment (BfR) is not yet aware of any serious allergic reactions to insects in Germany. It should be noted, however, that the consumption of insect foods in Germany is still rare.

New allergies can also occur and a possible "carry-over" effect can develop. This means that potentially allergenic proteins enter animal products through animal feed and trigger allergies in people who consume them.

Further information on possible allergic reactions to <u>insects</u> and <u>lupins</u> can be found on the BfR website.

In the feed sector, the undesirable substances contained in alternative protein sources are being investigated both for their effects on the health of livestock and their transfer into animal-based foods.

Can foods made from alternative protein sources harbour microbiological risks?

In principle, new protein sources can also introduce pathogens into the food chain. As with other foods, hygiene deficiencies or errors in temperature management can increase the risk of foodborne illnesses.

In addition, there is still only limited experience with some of the technologies for producing and processing the new protein sources. This poses new challenges, e.g. the use of new raw materials, production hygiene, or inactivation processes. However, the BfR is not yet aware of any new pathogens that are specifically associated with alternative protein sources.

Can contaminants be present in foods from alternative protein sources?

As in other foods of plant or animal origin, contaminants can also occur in alternative protein sources.

There is discussion concerning various elements as well as myco- and plant toxins or their metabolites as potentially relevant groups of substances in protein sources such as legumes (field beans and peas), almonds or sunflower seeds and algae. There could be a relevant contribution to exposure, especially for people with high consumption levels.

Can foods from alternative protein sources have altered nutrient profiles?

Legumes contain antinutritive substances (e.g. phytic acid, lectins, tannins or saponins). They should therefore only be eaten cooked.

Dried <u>algae</u>, for example, can have a very high iodine content. If too much of this vital nutrient is ingested, it can lead to potentially health-relevant effects on the thyroid gland.

Can foods from alternative protein sources contain unknown toxins?

Some new protein sources may contain toxins that are not yet sufficiently researched or known. This applies in particular to exotic plants or newly discovered microorganisms.

If it is a "novel food" in accordance with the Novel Food Regulation (EU) 2015/2283, it may only be marketed in the EU after authorisation. Part of this procedure is a health risk assessment by the European Food Safety Authority (EFSA). Authorisation by the EU Commission is only possible if there are no safety concerns for human health.

If the food is a genetically modified food according to Regulation (EC) No 1829/2003, a safety assessment in accordance with a European procedure is also required before it is placed on the market.

What is known about the health risks associated with alternative protein sources as animal feed?

Feed used as an alternative source of protein may also contain undesirable substances or contaminants that can both have a negative impact on animal health, and also pass into animal foodstuffs (so-called "transfer"). These can be, for example, various (toxic) elements, persistent organic contaminants, and myco- and plant toxins or their metabolites.

What is the current state of consumer behaviour surrounding/acceptance of alternative protein sources as food?

The BfR considers that studies on consumer behaviour regarding alternative protein sources and a targeted communication with consumers should be taken into account at an early stage in the process of diversifying food and feed production.

While plant-based protein sources and proteins derived from fungi are highly accepted by consumers in Europe, there are some reservations about the idea of eating insects. The individual disgust barrier and concerns about hygiene and tolerability are major hurdles to the acceptance of insects as food. It is often not realised that insects are mainly contained in processed form as insect meal in certain products. In addition, insects are only kept on defined substrates that fulfil the legal requirements for animal feed, meaning they may not be fed with household or organic waste or other prohibited substances.

How are foods containing proteins from novel sources regulated by law?

- Novel foods

Many foods that consist of or contain alternative proteins belong to the food group known as "novel foods". The European Novel Food Regulation applies to these novel foods. These are foods that were not consumed to any significant extent in the EU before 15 May 1997 and that can be assigned to at least one of the food categories listed in the Novel Food Regulation (EU) 2015/2283. They may only be marketed in the EU after authorisation. Part of this procedure is a health risk assessment by the European Food Safety Authority (EFSA). Authorisation by the EU Commission is only possible if there are no safety concerns for human health.

Novelty may also refer to a novel production process. The authorisation is only valid for very specific uses and preparations of a foodstuff applied for by the applicant. Authorisation can be granted generically or with data protection for a period of five years for a specific applicant.

Alternatively, depending on the individual case, foods with or from alternative proteins may require authorisation in accordance with Regulation (EC) No. 1829/2003 on genetically modified food and feed if they or their components contain a genetically modified organism (GMO) or were produced from GMOs. Such an authorisation also requires a risk assessment by the EFSA.

List of authorised novel foods: https://food.ec.europa.eu/food-safety/novel-food/authorisations/union-list-novel-foods_en

List of current applications:

https://food.ec.europa.eu/safety/novel-food/authorisations/summary-applications-andnotifications_en

- Labelling obligation

The Novel Food Regulation stipulates specific labelling requirements for novel foods. This also includes the indication of allergens in case of possible known cross-reactions. Genetically modified food and feed must always be labelled.

Insects may be contained in baked goods, biscuits or pasta, for example, in ground or powdered form. For consumers, the use of insects is evident from the list of ingredients. The German and Latin name of the insect will therefore appear in the list of ingredients for foods containing insects that have been authorised to date, as well as the form of the food used, such as dried or powdered. In addition, a note is required that refers to the risk of allergic reactions in people with allergies to crustaceans and molluscs and products made from them, as well as to dust mites.

Other alternative protein sources that are used as ingredients and are listed as allergens in Annex II of EU Regulation No. 1169/2011 must be listed as an ingredient (e.g. in bold).

List of allergens requiring labelling in the EU (14 groups): <u>https://www.produktqualitaet.com/en/food/allergens/mandatory-labelling.html</u>

Further information on the BfR website:

A-Z Index: Proteins https://www.bfr.bund.de/en/a-z_index/proteins-130283.html#fragment-2

A-Z Index: Insects (in German) https://www.bfr.bund.de/de/a-z_index/insekten-199312.html#fragment-2_

A-Z Index: Lupin protein https://www.bfr.bund.de/en/a-z_index/lupin_protein-129864.html

Protocol of the Commission for Contaminants in the Food Chain (in German): <u>https://www.bfr.bund.de/cm/343/28-sitzung-der-bfr-kommission-fuer-kontaminanten-in-der-lebensmittelkette.pdf</u>

Novel foods:

https://www.bfr.bund.de/en/novel_food-1809.html

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About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. The BfR advises the Federal Government and the States ('Laender') on questions of food, chemicals and product safety. The BfR conducts independent research on topics that are closely linked to its assessment tasks.

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