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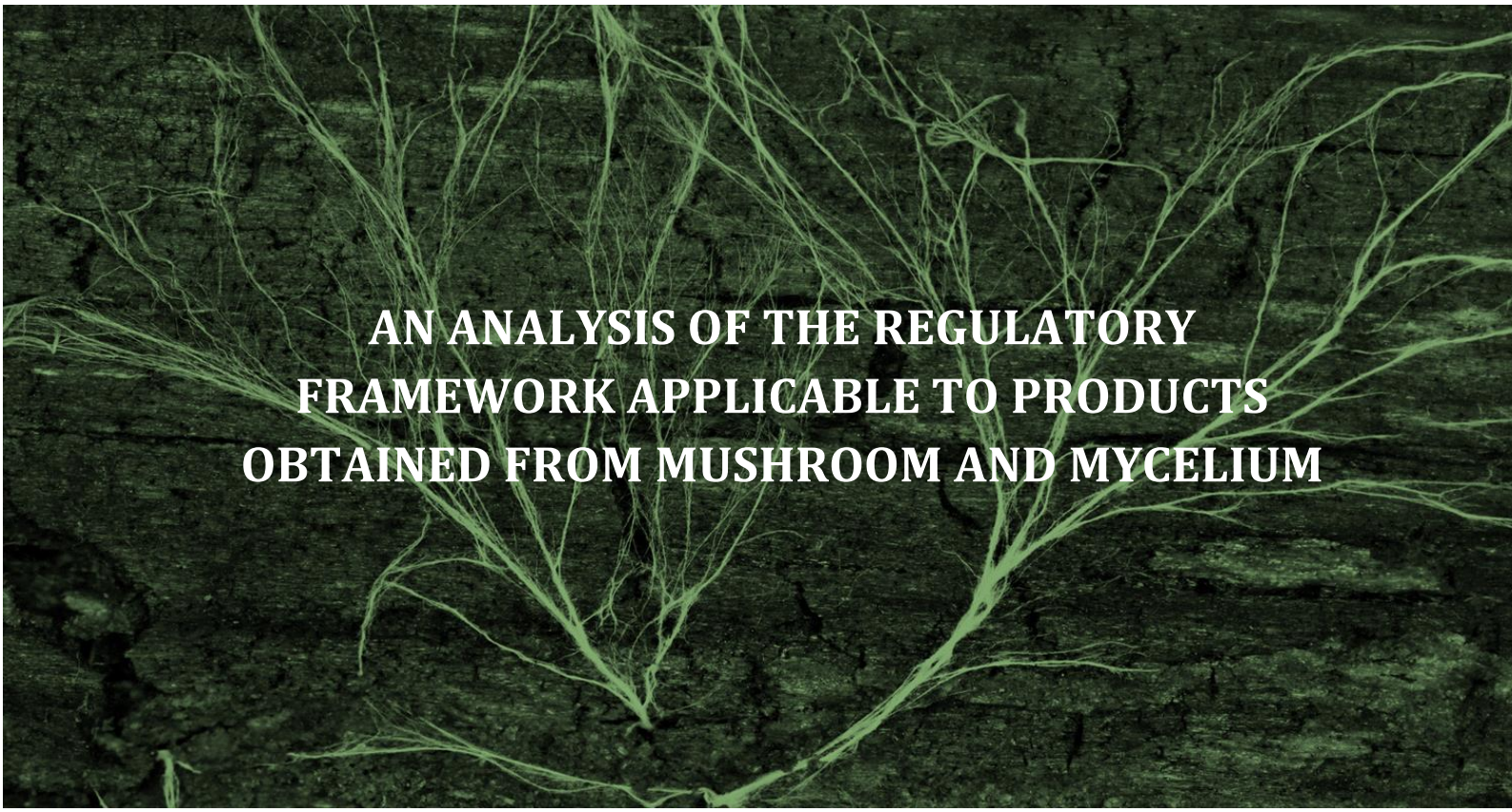
REPORT



AN ANALYSIS OF THE REGULATORY FRAMEWORK APPLICABLE TO PRODUCTS OBTAINED FROM MUSHROOM AND MYCELIUM

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CONTENTS

ABBREVIATIONS

CAP	Common Agricultural Policy
CJEU	Court of Justice of the European Union
EU	European Union
FAR	Food Additive Regulation
GFL	General Food Law
MMP	Mushroom and Mycelium´s product
NFR	Novel Food Regulation
TFEU	Treaty on the Functioning of the European Union
VLS	Voluntary Sustainability Labels
WP	Working Package

KEY TERMS

Agricultural products are products of the soil, of stockfarming and of fisheries and products of first-stage processing directly related to these products falling under one of the categories of Annex I of the Treaty on the Functioning of the European Union.

Authorization procedures are a tool used for pre-market approval of substances and products which are deemed to present potential risks for consumer health and interests and for the environment. They are based on risk analysis and consist of two important steps: an independent risk assessment by scientific authorities and a political decision of risk management taken by political authorities.

Claim is any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics.

Clean labels are labels which reflect the consumers' rejection of highly-processed products and, in their broadest sense, represent the changes in perception which affected consumers, particularly in developed countries, and the increased interest for healthy, natural and sustainable products, both for the people and for the planet.

Fermentation is the chemical breakdown of a substance by bacteria, yeasts, or other microorganisms, typically involving effervescence and the giving off of heat.

Food (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

Food information means information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication.

Feed means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.

Flavourings are products: (i) not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste; (ii) made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof.

Food additive mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such food

Fruiting body is the reproductive structure of the fungal organism, normally growing above the ground, which is, in edible species, consumed by humans.

Fungal mycelium is the filamentous web that constitutes the vegetative body of the fungus, accessing resources and growing through its environment.

Health claims are claims that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed

on, or attached to the packaging or container of food.

Mushrooms are organisms part of the kingdom of fungi. For the scope of this project, we consider organisms part of the phylum *Basidiomycota* which includes the common edible mushrooms.

Medicinal product means any substance or combination of substances presented as having properties for treating or preventing disease in human beings or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Novel food in the European Union means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union and which can be categorized in one of the novel food categories.

Nutrition claim means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: (a) the energy (calorific value) it (i) provides; (ii) provides at a reduced or increased rate; or (iii) does not provide; and/or (b) the nutrients or other substances it (i) contains; (ii) contains in reduced or increased proportions; or (iii) does not contain.

Organic production means the use, including during the conversion period, of production methods that comply with this Regulation at all stages of production, preparation and distribution. Any farm that wishes to produce organically has to undergo a process known as 'conversion', during which production methods need to be used.

Organic product is a product resulting from organic production, other than a product produced during the conversion period. The products of hunting or fishing of wild animals are not considered as organic products.

Petfood is the feed of non-food producing animals.

Processing aid is any substance which is not consumed as a food ingredient itself, which is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that they do not present any health risk and do not have any technological effect on the finished product.

Substrate is the natural environment in which an organism lives, or the surface or medium on which an organism grows or is attached.

EXECUTIVE SUMMARY

This report concerns food law provisions applicable **to mushroom and mycelium products (MMP)** produced or marketed in the EU. The objective of the report is to map the regulatory environment governing mushrooms and mycelium products, highlighting gaps in EU law and pinpointing to areas of further research. Our findings show that the sector is still in the developing phase, and the application of the regulatory framework to MMP includes several legal uncertainties.

The classification of MMP as foods or medicines depends on the intended use. Innovative MMP could be considered medicinal products. This classification excludes food law provisions. Food business operators working with borderline (food/medicine) products should consider their claims and accompanying materials. Mushrooms and mycelia, as well as products derived from them, can be subject to the rules of the common agricultural policy.

The classification of products derived from mushrooms and mycelium as novel foods is challenging. Despite a long history of consumption of some fruiting bodies, products obtained from mycelium of the same species may be subject to Regulation (EU) 2015/2283 on novel foods. This is equally the case of species not commonly consumed. The Novel Food Regulation places significant regulatory requirements on applicants applying for novel food authorisations. This entails the proof of safety via solid and robust scientific evidence, for example numerous toxicity studies or animal models or human data. In the MMP market segment, the authorisation of biomass fermentation with the use of various fungi mycelia is particularly relevant. The pioneering phase of the MMP sector mainly relies on start-ups often with little capitalisation. High regulatory requirements set by the Novel Food Regulation can seriously hamper innovation in the sector. Food business operators already opt for solutions which escape the Novel Food Regulation, thus placing regulatory requirements above other business or societal considerations in their business models. Moreover, the use of food and agricultural by-products as substrates for fermentation could increase the sustainability of the industry but it is limited by food safety provisions.

The use of food additives in the MMP does not raise regulatory concerns. The use of MMP to produce food additives might open more opportunities for the future of this sector.

Companies must also pay attention to a correct labelling of MMP. The first issue to consider is the wording to be used in the name of the food and the list of ingredients of processed products to indicate mushrooms, mycelia as well as products derived from them (e.g. protein powders). Descriptive names are probably the most suitable to not mislead consumers. In the second place, novel foods may require mandatory information that are specified in novel food authorizations.

As for voluntary labelling information, nutrition and health claims can be added, if they do not mislead consumers, and specific conditions are met. Organic certification is provided for in EU law. Food business operators producing, or the marketing of organic products may acquire respective certification by accredited bodies. Finally, MMP are commonly classified as "vegan" or "vegetarian" and bear sustainability claims. In the absence of specific EU or national provisions, private schemes can be used to provide costumers and consumers with indications of which products are vegan or vegetarian. The same is valid for sustainability indications: private labels are the most used solutions.

The regulatory landscape applicable to MMP presents some room for improvement that could be addressed by the legislator. Food business operators are uncertain about the novel food status of their products and using food and agricultural by-products as a suitable substrate for the growth of mushrooms and mycelia. Legal requirements applicable to end products, in particular their labelling, might also bring legal uncertainty.

Our research represents an instrument to navigate the regulatory framework applicable to MMP in the food sector. However, every situation needs to be assessed on a case-by-case basis.

Following the report's publication, we expect to stir academic and policy discussion on the regulation of MMP.

BACKGROUND

INTRODUCTION TO MUSHROOMS AND MYCELIUM PRODUCTS

In 2019, the European Union (**EU**) published the European Green Deal, a package of policies that is designed to make the Union climate neutral by 2050.[1]

The production of animal proteins is one of the most environmentally impacting industries because it requires significant resources. Responding to the growing demand for sustainable alternatives,[2] heavy investments are made into the development of innovative solutions such as cell cultures, insects breeding or plant-based protein brewing.[3] Among them, mushrooms and mycelium products play an important role.

Mushrooms represent a valid alternative to proteins of animal origin.[4] Humans have traditionally consumed fruiting bodies of mushrooms. Recently, food innovators have focused on the potential of mycelium.[5] The mycelium is the filamentous web which constitutes the vegetative body of the mushroom. If cultivated under appropriate conditions, mycelium can serve multiple purposes.

By fermenting suitable substrates, mycelium forms a biomass, which can either be sliced and cooked as such or be used as a starting point to develop meat alternatives, such as vegetarian burgers and sausages. The biomass can also be further processed to obtain protein powders or food additives like dyes, fermenting agents or even bitter blockers. Outside of the food sector, mycelium is also used as a substitute of plastic, leather and wood.[6]

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[1] European Commission, Communication on the European Green Deal COM/2019/640. For a general overview of all policies and actions see the official website of the European Union: https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en#documents

[2] The European Consumer Organisation, 'One Bite at a Time: Consumers and the Transition to Sustainable Food - Analysis of a Survey of European Consumers on Attitudes Towards Sustainable Food' (2020).

[3] As an example of the attention raised by alternative proteins see: Pratibha Vuppuluri, 'The Race For The Alternative Protein Market: Five Investment Areas To Watch' [2020] *Forbes,* available at: <https://www.forbes.com/sites/forbesfinancecouncil/2020/11/02/the-race-for-the-alternative-protein-market-five-investment-areas-to-watch/>; Keith Nunes, 'Investments in Animal Protein Alternatives Surge' [2020] *Food Business News,* available at: <https://www.foodbusinessnews.net/articles/16029-investments-in-animal-protein-alternatives-surge> .

[4] Miruna Popa and Simona Oancea, 'An Overview on Edible Mushrooms with Health Benefits and Applications in the Food Industry' (2020) 15 Brukenthal. Acta Musei 525.

[5] Eben Bayer, 'The Mycelium Revolution Is upon Us' [2019] *Scientific American Blog Network*, available at: <https://blogs.scientificamerican.com/observations/the-mycelium-revolution-is-upon-us/>.

[6] For a review of mycelium application in the food sector and beyond see: Business Insider, *How Mushrooms Are Turned Into Bacon And Styrofoam | World Wide Waste* (2021) available at: <https://www.youtube.com/watch?v=uznXI8wrdag>; Business Insider, *Mushroom Coffins Turn Bodies Into Compost And Make Death Less Toxic | World Wide Waste* (2021) <https://www.youtube.com/watch?v=AurhO4Lf1Is>.

The overall global market of alternative protein is expected to increase up to 22.90 billion euro by 2027.[7] The greatest share of the market is still made by established meat alternatives, in particular soy products. The mushroom market was valued almost 38 billion euro in 2019 and it is expected to grow by 8.3% on average until 2027.[8]

PURPOSE OF THE PROJECT

Applicable law and regulations may have an influence on a successful adoption of food innovations in the society. In fact, regulation can either be viewed as an incentive for innovation,[9] or as an obstacle, particularly in the food sector.[10]

The EU regulatory framework concerning food products derived from mushrooms and mycelium has never been subject to a comprehensive study or review. The lack of legal certainty regarding which provisions apply constitutes a major problem for food business operators and stakeholders willing to access the market and engage in the sector.

Therefore, the main objective of this report is to map the EU regulatory environment applicable to food products obtained from mushrooms and mycelium. In doing so, the report aims at offering guidance to stakeholders (e.g. companies, start-ups, investors and policy makers) and providing an instrument to navigate the EU regulatory landscape. Additionally, the report highlights gaps in the legislation and its interpretation, which may serve as a starting point for future academic research and policies, to make the EU a catalysator in the world's food transformation.

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[7] Research and Markets, 'Alternative Protein Market Report 2021 - Global Forecast to 2027', available at: <https://www.prnewswire.com/news-releases/alternative-protein-market-report-2021---global-forecast-to-2027-growing-urbanization-with-new-consumer-aspirations-301301688.html> .

[8] MarketWatch, 'Mushroom Market - Global Industry Analysis By Development, Size, Share and Demand Forecast', available at: <https://www.marketwatch.com/press-release/mushroom-market---global-industry-analysis-by-development-size-share-and-demand-forecast-2021-07-02> .

[9] Michael E Porter, 'America's Green Strategy' (1991) 264 Scientific American 168.

[10] The case of gene editing technology represent a paramount example in this sense. See for example: Thorben Sprink and others, 'Regulatory Hurdles for Genome Editing: Process- vs. Product-Based Approaches in Different Regulatory Contexts' (2016) 35 Plant Cell Reports 1493. Dennis Eriksson and others, 'Options to Reform the European Union Legislation on GMOs: Post-Authorization and Beyond' (2020) 38 Trends in Biotechnology 465. For the specific case of novel food see: Martin Holle, 'Pre-Market Approval and Its Impact on Food Innovation: The Novel Foods Example' in Harry Bremmers and Kai Purnhagen (eds), *Regulating and Managing Food Safety in the EU* (Springer International Publishing 2018).

RESEARCH AND METHODOLOGY

RESEARCH ORGANIZATION

The project was based on a pre-study (*Vorstudie*) produced by the *Forschungsstelle für Deutsches und Europäisches Lebensmittelrecht* in September 2020, which provided a solid doctrinal basis. At the beginning of the study, research topics were divided in three working packages (**WP**) covering different research questions raised by the pre-study. In particular,

- WP I - "The Authorisation Package" focused on the legal categorization of products obtained from mushrooms and mycelium, paying attention to their novel foods' status and to the impact of methods of production on the categorization of those products.
- WP II - "The Interdisciplinary Package" provided a wider understanding of the sector, by covering (1) the use of food and agricultural by-products and side streams for mushrooms cultivation and (2) the use of food additives in the final products.
- WP III - "The Labelling Package" focused on food information provided to food business operators and consumers, examining all mandatory requirements and additional voluntary aspects of particular importance.

Additional aspects emerged during the project, particularly due to interviews with stakeholders and were addressed accordingly. The final structure of the report is a synthesis of each of these research topics.

RESEARCH METHODOLOGY

First, we carried out a classic doctrinal legal analysis of the wording and syntax of authoritative legal texts, such as legislation, adjudication and the relevant literature. Second, we conducted an empirical legal analysis through interviews with relevant stakeholders.

Doctrinal legal analysis

The doctrinal legal research consisted of an in-depth analysis of relevant EU primary law, including the case law of the Court of Justice of the European Union, EU secondary law (the relevant regulations and directives), as well as the most relevant literature and soft law at the national, European, or international level. Each of these sources were employed to provide a clear understanding of legal requirements applicable to mushrooms and mycelium products in the area of EU food law.

In particular, we considered:

- Applicable law, retrieved from the official legal databases of the EU: Eur-Lex and Curia.
- Peer-reviewed articles obtained from databases Google Scholar and ResearchGate

- Reports from national authorities

Throughout the report, legal provisions are cited in footnotes but paraphrased in the main text to (1) offer to legal advisors or companies' regulatory experts a collection of applicable legislation and (2) make legal provisions accessible to "non-lawyers".

Empirical research

The empirical legal research consisted of 16 semi-structured expert interviews, held via Zoom. The Adalbert-Raps-Stiftung, NX-Food and The Good Food Institute Europe provided us with all necessary contacts. All interviewees were representatives of companies willing to produce mushrooms and mycelium products. The great majority of these companies are start-ups in the developing phase.

Interviews served two purposes. First, they provided first-hand account of regulatory hurdles applicable to food products obtained from mushrooms and mycelium. Second, they were used throughout the report to elaborate on the identified issues with concrete examples.

Despite the focus on the EU regulatory framework, about a third of the interviewed companies and start-ups were not European. This provided us with an external perspective on EU legislation and highlighted hurdles for foreign companies willing to enter in the EU market.

We decided to conduct qualitative interviews as this is methodologically the most appropriate form of expert interviews.[11] It leaves interviewees space to express opinions, ideas and doubts, believing that our final outcome would have been more useful if shaped according to stakeholders´ needs.

Interviews generally lasted up to 1 hour and were divided in three phases: in the first 10 minutes we used to present the project's focus and objectives; in the following 40 minutes, the interview took place, with a semi-structured discussion in which our questions worked as a starting point, but during which stakeholders were free to elaborate on different topics; finally, in the last 10 minutes stakeholders received time to ask their own questions and suggest ways to improve the report.

We signed non-disclosure agreements with companies that requested such an agreement and paused the interview whenever interviewees felt non-comfortable to share confidential information. To respect their will to not disclose confidential information, there are no references to specific companies unless the information is publicly available. Some interviewed companies did not want to be mentioned in this Report, and therefore they are not listed below.

We interviewed representatives from the following companies:

[11] Uwe Flick, ´Qualitative Sozialforschung. Eine Einführung´ 27 (Burghard König ed., Rowohlt Taschenbuch Verlag 2016), 448; Siegfried Lamnek and Claudia Krell, ´Qualitative Sozialforschung´ (Beltz Verlag 6th ed. 2016) 95-98.

Walding Foods	*(Munich, Germany)*
Kinoko Labs	*(Berlin, Germany)*
Inner Elmt	*(Berlin, Germany)*
Mushlabs	*(Berlin, Germany)*
Berlin Organics	*(Berlin, Germany)*
Van Hees	*(Frankfurt, Germany)*
Scicular	*(Cophenagen, Denmark)*
Chromologics	*(Nærum, Denmark)*
The Protein Brewery	*(Breda, Netherlands)*
Enough Foods (Previously 3FBio)	*(Glasgow, Scotland)*
Kinoko Tech	*(Rehovot, Israel)*
MyEats	*(Green Islands, New York, US)*
Mycotechnology	*(Aurora, Colorado, US)*
Bettermeatco.	*(Sacramento, California, US)*
Mycovation	*(Singapore, Singapore)*

LIMITATIONS

Our research faced several limitations. The development of products derived from mushrooms and mycelium is vibrant. The **little** research that is available is **quickly** outdated; hence the literature on the topic is still limited and is subject to constant change.

Companies investing in mushroom and **mycelium** products are usually young small and medium enterprises, with most of them not being active on the market. Almost none of these companies have the capacity**,** at the moment**,** to produce significant volumes **of the food** at the industrial scale. This creates several limitations in identifying actual regulatory obstacles applicable to large scale production and commercialization. For this reason, the report focuses on pre-market approval and on those provisions which to our understanding will shape the sector's future developments (e.g. labelling requirements). Further research is needed to assess the market situation in a two to three years' time, when **most of** the companies will have defined their market position and regulatory hurdles will have become clearer.

Due to the Coronavirus pandemic, we did not have the opportunity to travel and visit stakeholders on their premises. This has come at the cost of getting

additional insights through in-person meetings and tours to production facilities and labs. To cover up for this, stakeholders showed us images and videos of their production which greatly increased our comprehension of the technological conditions under which they operate.

The sample of interviewed people was limited. Not all the interviewees had regulatory expertise, depending on the stage of development of their company and product. The informational gaps between the interviewers and the interviewees, and the often-observed difficulty of the latter in understanding legal context, sometimes caused a slowing down of the discussion. However, these difficulties further highlighted the need for our project and the necessity to make it comprehensible to all stakeholders involved.

CLASSIFICATION OF MUSHROOM AND MYCELIUM PRODUCTS

Key messages

In EU law, the classification of MMP either as foods, feed, medicines, or cosmetics depends on their intended use.

MMP can lawfully be placed on the market as food when they comply with the requirements of EU food law and are not subject to more specific legal frameworks/food law requirements.

Foods and medicines are mutually exclusive concepts.

MMP can be classified as "agricultural products".

This Chapter analyses legal requirements for placing food products derived from mushroom and mycelium ("**mushroom and mycelium products**" or "**MMP**") on the market in the European Union (**EU**). Subsequently, we juxtapose the definition of food with the definitions of medicinal products, cosmetics, and feed/pet foods to illustrate their differences and similarities. Finally, we analyse the conditions to categorize MMP as "agricultural products" under EU law.

DEFINITION OF FOOD IN THE EU

In the EU, food production and commercialization are regulated through an extensive and coherent group of legislative acts collectively known as Food Law.[12] Whenever goods are classified as food, they fall within the scope of EU food law, triggering specific requirements for their placing on the market.

The classification of MMP as "foods" under EU law depends on their intended use.

Regulation (EC) No 178/2002 (**the General Food law** or **GFL**), defines "food" as follows:

'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

[12] Per Article 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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, OJ L 31, 1.2.2002, p. 1–24 (From here on: GFL) 'food law' "means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals".

When products are classified as food, they can lawfully be placed on the market without further notice and their trade cannot be restricted within the Union, providing that:

(1) They comply with the definition of food and do not fall within a separate regulatory framework which would take precedence e.g. regulatory framework applicable to medicines.

(2) They are not subject to more specific food law provisions other than the GFL, for example Regulation (EU) No 2283/2015[13] on novel food or Regulation (EC) No 1829/2003[14] on genetically modified food, which both require pre-market approval to assess risks associated with the products´ consumption.

(3) They are not injurious to health or unfit for human consumption.[15]

(4) Respect all food law requirements such as those on labelling and traceability.[16]

(5) Respect national rules.[17]

Whenever these conditions are met MMP can be placed on the market as foods in the EU.

Almost all companies we interviewed consider the food sector their primary interest. Only one company actively uses MMP for purposes other than food: through collaborations with other start-ups and company's spin off, they use MMP to produce packaging, leather and cosmetics.[18] Three companies expressed some interest in expanding into other (non-food) sectors in the future.

CLASSIFICATION OF MPP UNDER EU LAW

Medicinal products

Food and medicinal products are mutually exclusive concepts.

Some MMP allegedly intended to be used as foods (e.g. protein powders) may trigger the regulatory framework applicable to medicinal products. Requirements applicable to medicinal products are stricter and take

[13] Regulation (EU) No 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 2015, OJ L 327, 11.12.2015, p. 1–22. (From here on: Novel Food Regulation)

[14] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, p. 1–23.

[15] GFL. Article14(1)

[16] ibid. Article 16, 18

[17] ibid. Article 14(9)

[18] Ecovative Design, 'We Grow Materials', available at: <https://ecovativedesign.com> .

precedence over food law provisions.[19] For example, medicinal products must always undergo an authorization procedure and are subjected to severe conditions of use.

Medicinal products (or medicines) are defined as:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medicinal diagnosis.[20]

Foods are substances intended to be ingested, for their nutritional content or because of their taste. Medicinal products are substances, not necessarily ingested, with the specific objectives of (a) treating or preventing a disease and (b) restoring, correcting, or modifying physiological functions by exerting pharmacological, immunological, or metabolic actions, or which are at least presented in a way that suggest that they could actually have these effects. These are cumulative conditions.

Grey areas in the classification of products as foods or medicinal products concern products sold as foods, which claim or possess certain properties within the definition of medicinal products e.g. when they bear specific nutritional and health claims.[21] Among our interviewees, most companies present their products using health and nutrition claims and one company works with food supplements, which can also raise doubts in the classification.

The Court of Justice of the European Union (**CJEU**) adopted a two-tiered approach to the differentiation of medicinal products from other products.[22] First, the presentation of the product (labelling, packaging, forms and claims that could lead the average, well-informed consumer to the assumption that a product actually has medicinal properties) must be considered.[23] Second, the actual properties of the product must be assessed.[24] The two conditions cannot

[19] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67–128
[20] Ibid. Article 1(2)
[21] For an overview of nutrition and health claims see the Chapter: LABELLING OF MUSHROOMS AND MYCELIUM PRODUCTS
[22] *C-140/07 - Hecht-Pharma* [2009] Court of Justice of the European Union ECLI:EU:C:2009:5; *C-319/05 Commission vs Germany* [2007]; *C-211/03 - HLH Warenvertrieb and Orthica* [2005] Court of Justice of the European Union ECLI: EU: C: 2005: 370. Court of Justice of the European Union ECLI:EU:C:2007:623;*C-60/89 - Monteil and Samanni* [1991] Court of Justice of the European Union ECLI:EU:C:1991:138; *C-227/82 - Criminal proceedings against Leendert van Bennekom,* [1983] Court of Justice of the European Union ECLI:EU:C:1983:354; *C-369/88 - Delattre* Court of Justice of the European Union ECLI:EU:C:1991:137.
[23] *C-227/82 - Criminal proceedings against Leendert van Bennekom*; *C-60/89 - Monteil and Samanni*. Paragraph 23
[24] *C-140/07 - Hecht-Pharma*. Paragraph 25

be considered separately,[25] and shall be read together.[26] This implies that some sort of effect on human health must be present by a medicinal product.[27]

It is also possible that some products are classified as medicinal products in one Member State and as foods in another.[28] The different classification potentially violates the provisions on the free movement of goods[29] and has been discussed extensively in EU jurisprudence (*Commission vs Germany*[30], regarding capsules containing garlic powder; *Commission vs Spain*[31], on food supplements containing certain herbal medicine). The presence of active substances with potential effects on the human body among the product ingredients and their substantial effects on humans are critical to determine the final status of those products.

Cosmetics

Cosmetics are defined as follows: "*any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours."*[32]

Cosmetics are not intended to be ingested; hence borderline problems rarely exist. A grey area may exist for those products that are applied on the membranes of the oral cavity. So far, to our knowledge, no MMP have been used this way.

[25] *C-60/89 - Monteil and Samanni*. Paragraph 12
[26] *C-358/13 - Opinion of Advocate General Bot delivered on 12 June 2014* [2014]. Paragraph 37
[27] Fausto Capelli and Barbara Klaus, 'Is Garlic a Food or a Drug? How to Solve the Problem of Free Movement in the European Union of Products That Are Classified in Different Ways in the Member States; with Specific Regards to the Delimitation of Foodstuffs – Including Food Supplements, Novel Foods and Enriched Foodstuffs – and Medicinal Products' (2009) 4 European Food and Feed Law Review 390; Alie de Boer, Florence van Hunsel and Aalt Bast, 'Adverse Food-Drug Interactions' (2015) 73 Regulatory toxicology and pharmacology: RTP 859; Sebastián Romero Melchor and Liesbeth Timmermans, '"It's the Dosage, Stupid": The ECJ Clarifies the Border between Medicines and Botanical Food Supplements' (2009) 4 European Food and Feed Law Review 185.
[28] Capelli and Klaus, 2009.
[29] Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26.10.2012, p. 47–390. (From hereafter: TFEU) Article 28 et sqq.
[30] *C-319/05 - Commission vs Germany*.
[31] *C-88/07 - Commission vs Spain* [2009] Court of Justice of the European Union ECLI:EU:C:1983:354.
[32] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products 2009 59.

Feed and petfoods

"'*Feed' (or 'feedingstuff') means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals".*[33]

To be used as feed, MPP must comply with Regulation (EU) No 767/2009[34] on the placing on the market and use of feed and with all applicable hygienic requirements.[35]

Petfood is feed intended for pet consumption. Pets are defined as non-food producing animals belonging to species fed, bred, or kept, but not normally used for human consumption in the EU. [36] Additional requirements, particularly regarding labelling are applicable to pet foods.[37]

MPP AS AGRICULTURAL PRODUCTS

Foods are regularly considered "goods" in the sense of the provisions of the free movement of goods in the internal market. For most cases, MPP can be classified as food. However, they may also classify as "agricultural products", to which specific EU law provisions apply (the **Common Agricultural Policy** or **CAP**).[38] The CJEU has ruled that CAP rules take precedence over internal market provisions for "goods", guaranteeing a more favourable treatment to foodstuff which are also agricultural products.[39] In particular, specific rules on competition and on the organisation of agricultural markets may be applicable.[40]

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[33] GFL. Article 3(4)
[34] Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC, OJ L 229, 1.9.2009, p. 1–28.
[35] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene, OJ L 35, 8.2.2005, p. 1–22. For more information see "Commission Notice — Guidance document on the implementation of certain provisions of Regulation (EC) No 183/2005 laying down requirements for feed hygiene" (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2019.225.01.0001.01.ENG&toc=OJ:C:2019:225:TOC) and the website of the EU Commission in relation to feed hygiene (https://ec.europa.eu/food/food/animal-feed/feed-hygiene_en).
[36] Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC, OJ L 229, 1.9.2009, p. 1–28 (n 35). Article 3(1)(f)
[37] ibid. Article 19
[38] TFEU. Title III (articles from 38 to 44)
[39] *C-83/78 - Pigs Marketing Board v Redmond* [1978] Court of Justice of the European Union ECLI:EU:C:1978:214.
[40] TFEU. Article 43

While a general definition of "agricultural products" exists in the Treaties,[41] case-law determined that only the list in Annex I of the Treaty on the Functioning of the EU (**TFEU**) defines the scope of agricultural products.[42]

Mushrooms are not explicitly mentioned in Annex I, but they fall under Chapter 7 of the classification "Edible vegetables and certain roots and tubers". Annex I refers to an old tariff classification system for imported goods that was used internationally before 1976, the Brussel Nomenclature. Council Regulation (EEC) No 2658/87[43] clarifies the content of each Chapter of the Brussel Nomenclature in relation to the currently used classification system, stating that Annex I Chapter 7 shall be read as covering edible mushrooms as well.[44] As a consequence, being a part of the mushroom, mycelia may also be classified as agricultural products.

When it comes to products derived from the processing of mushrooms and mycelia, the "agricultural product" status must be determined on a case-by-case basis. Per Article 38(1) TFEU, agricultural products are the products of the soil, of stockfarming and of fisheries and products of *first-stage processing* directly related to these products. However, not only the results of one single processing action on raw materials are subject to agricultural provisions.[45] What must be considered is the economic interdependence between the basic product and the processed product.[46] When the procession of agricultural raw material represents only a marginal cost in the production of the end product, the end product cannot be considered an agricultural product. As an example, mushroom cultivation may fall under the CAP provisions. However, mycelium biomass produced via fermentation, cut in slices and sold B2B is likely to be not considered an agricultural product. At the same time, highly processed end products containing ingredients derived from mushrooms and mycelium e.g. veggie burgers made with protein powders extracted from the mycelium, are not to be classified as agricultural products.

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[41] TFEU. Article 38(1): "*the products of the soil, of stockfarming and of fisheries and products of first-stage processing directly related to these products*"
[42] C-131/87 - *Commission vs Council (glands)* [1989] ECLI:EU:C:1989:581.
[43] Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff, OJ L 256, 7.9.1987, p. 1–675
[44] Ibid. Note 2 to Section I – Chapter 7: "*In headings 0709 to 0712 , the word 'vegetables' includes edible mushrooms, truffles… "*. Heading 07/09 covers other vegetables, fresh or chilled, heading 07/10 vegetables (uncooked or cooked by steaming or boiling in water), frozen, heading 7/11 vegetables provisionally preserve but unsuitable in that state for immediate consumption and heading 7/12 dried vegetables, whole, cut, sliced, broken or in powder, but not further prepared. Also interestingly, this chapter makes distinction between mushrooms and truffles.
[45] As clarified in case law, "First-stage processing" in the definition is not necessarily a temporal condition. As stated in paragraph 13 of the *Hauptzollamt Bielefeld v König* case: "Processed products which have undergone a productive process, the cost of which is such that the price of the basic agricultural raw materials becomes a completely marginal cost, are therefore excluded (from the classification as agricultural products)." For a review of EU agricultural Law see John A Usher, EC Agricultural Law (OUP Oxford 2001).
[46] *C-185/73, Hauptzollamt Bielefeld v König* [1974] Court of Justice of the European Union ECLI:EU:C:1974:61. Paragrah 12 13.

NOVEL FOOD STATUS OF MUSHROOMS AND MYCELIUM´S PRODUCTS

Key messages

Food business operators must verify whether the food which they intend to place on the market within the EU falls within the scope of the Novel Food Regulation.

When filing a novel food application, it is necessary to designate the most appropriate food category under which the novel food in question falls in accordance with Article 3(2) of the Novel Food Regulation.

Proving the history of safe use may exempt a food from the scope of the Novel Food Regulation, if there is a considerable consumption before 15 May 1997, but it facilitates the safety assessment in the authorisation procedure.

The assessment of safety should be based on all available information that supports the safety of the novel food under the proposed conditions of use.

This Chapter provides an in-depth analysis of the EU legal framework applicable to novel foods. We first introduce the concept of food innovation and how it relates to mushrooms and mycelium products. Then, we focus on the scope of the Novel Food Regulation and on the most important aspects of the authorization procedure. Requirements related to evidence of history of safe use are underlined.

MMP AS FOOD INNOVATIONS

The food regulatory space represents a blended environment of different perspectives. There is the perspective of the lawyer/regulatory specialist, following the current law. There is the perspective of the consumer, with his or her own needs, perceptions of foods and purchase habits. There is the perspective of the food business operator, focusing on bringing its products to the market with a profit on a stable basis. And there is the perspective of the regulator, applying state-of-art scientific knowledge to regulatory issues, such as safety, to safeguard fundamental societal values, such as human health or the environment. In ideal conditions, the perspectives align, i.e. the food regulatory space is not disconnected from any of these perspectives.

Different food innovations pursue different objectives. Some are made “just” to bring a better food diversity or sensual enjoyment and pleasure to consumers. Others are developed on the account of solving fundamental societal issues of foods’ climate impact. Food innovations are ideally scalable, as to bring a meaningful contribution to the market, consumers, or the society. By the very character of food, food innovations often explore compounds

available in nature, such as plants, algae or fungi. In food, many familiar compounds may be used for different purposes and uses, (re)discovering their potential through new knowledge, new techniques, processes, and substances.

Developers and producers of mushroom and mycelium products benefit of a remarkable biological diversity in the fungi kingdom. Many strains of fungi have been part of human diet. However, this statement has a great geographical and temporal variability. In some parts of the world, a greater variety of fungi strains are eaten daily compared to other parts of the world. In the past, eating wild mushrooms was more common than today. In different regions of the world, different biotechnological uses of fungi may be found, such as cultivation, fermentation, and others. Climate change impacts the availability of certain fungi in the nature in certain regions. All this impacts how fungi are perceived, used, and regulated in a particular market.

Fungi are decomposers of biomass in the nature – of anything that is hydrocarbon based. This means that fungi can be used for different decomposing purposes but also that for many people, fungi are associated with death and decay. Fungi are not plants. They are not animals either. Some say they represent the digestive tracks of the nature. There are over 1.5 million fungi species, 6 times more than plants. Out of this great number of fungi species, many are poisonous and represent a threat to life. Only a handful have been consumed safely, with the safe consumption to be diligently documented. And only a handful form fruiting bodies. From the long-standing interactions between fungi and humans, current food innovations emerge.

In the development of novel foods based on mushrooms or mycelium, companies search for the best strain that produce the right product characteristic or added value. In the mycelium fermentation processes, strains are selected for the taste or texture they deliver in the biomass, or because of nutritional claims companies may attach to the final product. A focus on functional mushroom strains represents one of the biggest innovative potentials in this market segment. So does the sustainable production of alternative proteins that could contribute to the climate change mitigation.

Scope of the Novel Food Regulation

Regulation (EU) No 2283/2015 on novel foods (the **Novel Food Regulation** or **NFR**), is an EU legislative instrument that responds to different perspectives in the food regulatory space by employing the precautionary principle. In respect to the regulation of novel foods, the precautionary principle plays out in a way that food innovating companies must be granted an authorisation before they may place a product falling within the definition of a novel food on the market.

A food that requires authorisation under Regulation (EU) No 2015/2283 was not used for human consumption to a significant degree within the EU before 15 May 1997 that is in any State that is now a Member State of the EU. Such food does not benefit from the history of safe use exception.

For example, food consisting of, isolated from or produced from animals obtained by traditional breeding practices which have been used for food production within the EU before 15 May 1997 is exempted from the novel food categories.[47] Exempted is also food consisting of, isolated from or produced from plants or a variety of the same species obtained by traditional propagating practices which have been used for food production within the EU before 15 May 1997 and such food has a history of safe use. Similarly, food consisting of, isolated from or produced a plant or a variety of the same species from non-traditional propagating practices which have not been used for food production within the EU before 15 May 1996, where those practices do not give rise to significant changes in the composition or structure of the food (negatively) affecting its nutritional value, metabolism or level of undesirable substances is not considered a novel food.

Also, food enzymes, food additives, food flavourings and extraction solvents used or intended to be used in the production of foodstuffs or food ingredients do not fall within the scope of the Regulation.

NOVEL FOOD CATEGORIES

The procedural elements of the Novel Food Regulation are important to bear in mind. First, there is a general obligation of food business operator to verify whether the food which they intend to place on the EU market falls within the scope of the regulation. This entails verifying whether it can be classified as food that are excluded from the regulation, such as the food enzymes, and whether the food was used to a significant degree before 15 May 1997 in the EU.

Where a food business operator has carried out a verification on a new food, it is recommended that the food business operator should prepare a written and reasoned record of this verification and retains this on file in case the status of the food is questioned. This record should contain the arguments justifying the decision that the food does not fall under the scope of the Novel Food Regulation.

The following factors need to be considered:

- The history of use of the food, i.e. whether the food or its ingredients have been used to a significant degree for food consumption in the EU before 15 May 1997.
- The nature of the food, i.e. whether it falls within one of the categories defined in the Novel Food Regulation.

It is noted that for carrying out this verification the product's composition, characteristics, source material and production process need to be assessed at minimum.[48]

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[47] In this case, it is not important to prove the use for human consumption of such food to a significant degree within the EU; however, it is important to prove any use for food production.

[48] C-383/07, *M-K Europa GmbH & Co. KG v Stadt Regensburg* [2009] Court of Justice of the European Union ECLI:EU:C:2009:8. See as well: Food Supplements Europe,

The fact that all the individual ingredients of a food product have a history of safe use before 15 May 1997 does not exclude the application of the Novel Food Regulation.[49]

If a food business operator has determined that its product is a novel food, the food business operator must apply for authorisation of the novel food to the Commission via an online application form. [50] There are no application fees.

In the online application form, the applicant must first provide information according to the classes under which the novel food falls, such as class 12.9 (protein products, excluding products covered in category 1.8, i.e. dairy analogues, including beverage whiteners).[51]

Second, when filing a novel food application, it is necessary to designate the most appropriate food category under which the food in question falls in accordance with Article 3(2) of the Novel Food Regulation. Categories listed under Article 3(2) are not exclusive categories. The proposed classification is based on the chemistry, production process and source of novel foods, for the purpose of the scientific assessment. Most appropriate food category for novel food candidates of mushrooms, mushroom-derived products and fungal mycelium are:

(i) food consisting of, isolated from or produced from fungi.

This category may include:

- traditional fermentation, using novel fungi to process ingredients derived from plants or other sources, which can result in products with unique flavour and textures
- biomass fermentation using high protein content of fungi to produce large quantities of protein
- fungi used in a food to produce specific compounds that are natural metabolites of those fungi, where the compound is harvested, concentrated, or further purified

"Guidance for food business operators on the verification of the status of a new food under the new Novel Foods" (2019) Available at: https://foodsupplementseurope.org/wp-content/themes/fse-theme/documents/publications-and-guidelines/novelfoods-guidelines-jan2019.pdf .

[49] Food Supplements Europe, "Guidance for food business operators on the verification of the status of a new food under the new Novel Foods" (2019) Available at: https://foodsupplementseurope.org/wp-content/themes/fse-theme/documents/publications-and-guidelines/novelfoods-guidelines-jan2019.pdf.

[50] From 27 March 2021, the EU's new Transparency Regulation will enter into application. As of that date, any new application dossiers relating to authorisation procedures in the area of food chain should be submitted electronically in the updated version of FSCAP, called "E-Submission Food Chain" platform, which will be operational as of Monday 29 March 2021 at 08:00 CET. Link to the new platform: https://webgate.ec.europa.eu/esfc.

[51] This is not meant to reflect the regulatory categories that appear in Administrative Data section, as outlined in Article 3(2) of the Novel Food Regulation.

For example, chitin-glucan from *Aspergillus niger* was authorised to be placed on the EU market as a novel food ingredient to be used in food supplements.[52]

The Commission also authorised the placing on the market of lycopene obtained by extraction and crystallisation from a fungal fermentation of *Blakeslea trispora*.[53]

(ii) food consisting of, isolated from or produced from cell culture or tissue culture derived from fungi.

This category was explicitly included after announcements of 'cultured' meat produced in the lab.

In both cases fungi would cover the cases of mushrooms, fungal mycelium or of food that consists or is produced from fungi cell culture or tissue culture.

Two further classifications may be considered:

(iii) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997.

For example, it may be that genetically modified fungi strains could be used in fermentation processes but not digested. A fungus that is used to produce a novel food does not fall under the Novel Food Regulation if it is not part of the novel food and thus not ingested. The safety of the fungus in the context of the manufacturing process of the novel food will be considered during the risk assessment of the novel food. If the fungi are ingested, however, their novel food status needs to be verified.[54]

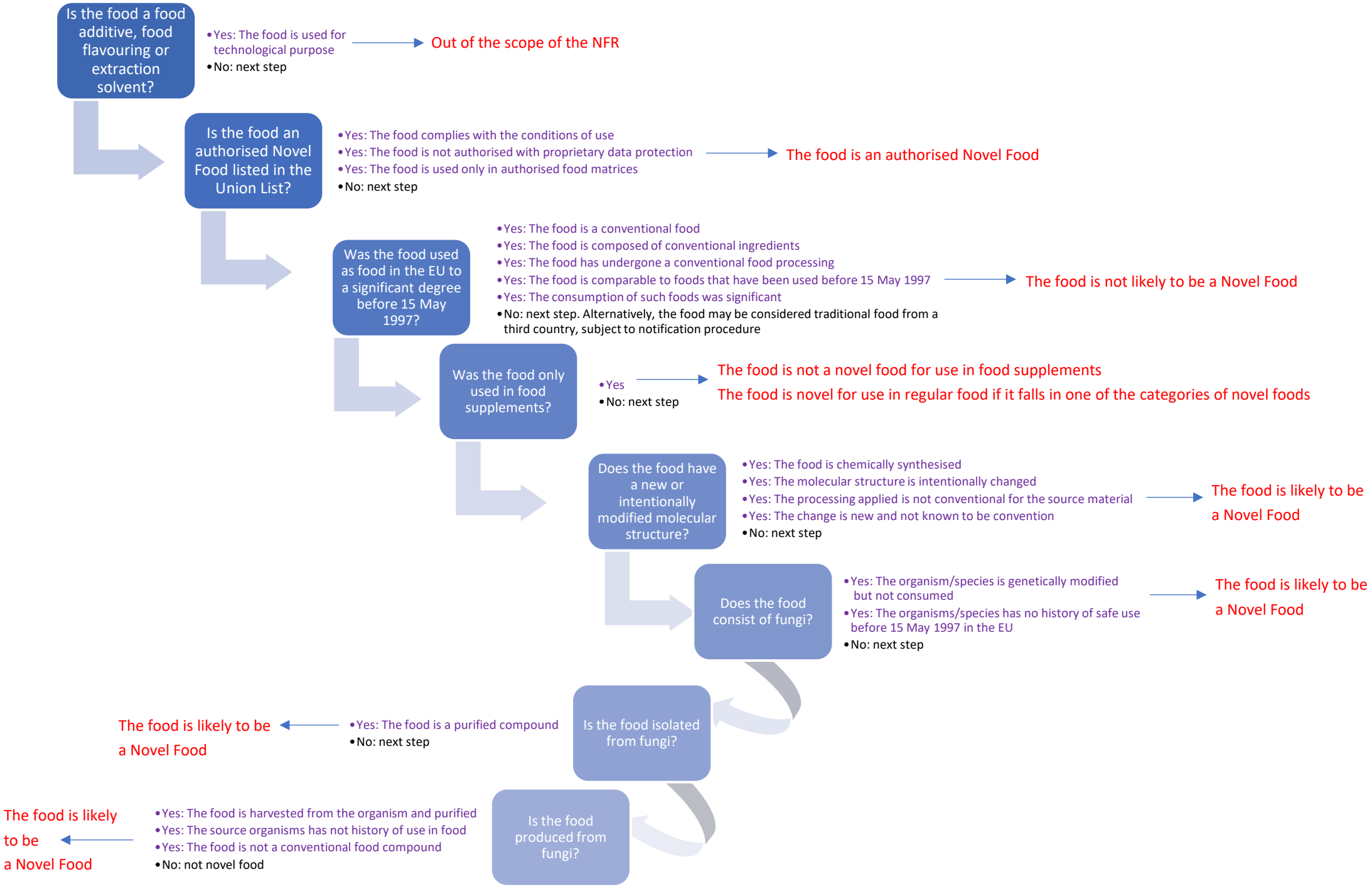
In a recent case, the EFSA evaluated a novel food whose primary constituent is a structurally identical 3-fucosyllactose, a naturally occurring trisaccharide occurring in human milk, produced through fermentation by a genetically modified microorganism (E. coli) and subsequent purification.[55]

(iv) 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.

In this case, the classification of a novel food depends on the specific manufacturing/use practice.

A representative decision[56] tree was suggested here:

[52] 2011/76/EU: Commission Decision of 2 February 2011 authorising the placing on the market of a chitin-glucan from Aspergillus niger as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.
[53] 2006/721/EC: Commission Decision of 23 October 2006 authorising the placing on the market of lycopene from Blakeslea trispora as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council
[54] Food Supplements Europe, "Guidance for food business operators on the verification of the status of a new food under the new Novel Foods" (2019) Available at: https://foodsupplementseurope.org/wp-content/themes/fse-theme/documents/publications-and-guidelines/novelfoods-guidelines-jan2019.pdf
[55] Dominique Turck and others, 'Safety of Lacto-N-neotetraose (LNnT) Produced by Derivative Strains of E. Coli BL21 as a Novel Food Pursuant to Regulation (EU) 2015/2283' (2020) 18 EFSA Journal e06305.
[56] Adapted from: Guidance for food business operators on the verification of the status of a new food under the new Novel Food Regulation (EU) 2015/2283 (NFR)


Is the food a food additive, food flavouring or extraction solvent?
•Yes: The food is used for technological purpose
•No: next step
Out of the scope of the NFR
Is the food an authorised Novel Food listed in the Union List?
•Yes: The food complies with the conditions of use
•Yes: The food is not authorised with proprietary data protection
•Yes: The food is used only in authorised food matrices
•No: next step
The food is an authorised Novel Food
Was the food used as food in the EU to a significant degree before 15 May 1997?
•Yes: The food is a conventional food
•Yes: The food is composed of conventional ingredients
•Yes: The food has undergone a conventional food processing
•Yes: The food is comparable to foods that have been used before 15 May 1997
•Yes: The consumption of such foods was significant
•No: next step. Alternatively, the food may be considered traditional food from a third country, subject to notification procedure
The food is not likely to be a Novel Food
Was the food only used in food supplements?
•Yes
•No: next step
The food is not a novel food for use in food supplements
The food is novel for use in regular food if it falls in one of the categories of novel foods
Does the food have a new or intentionally modified molecular structure?
•Yes: The food is chemically synthesised
•Yes: The molecular structure is intentionally changed
•Yes: The processing applied is not conventional for the source material
•Yes: The change is new and not known to be convention
•No: next step
The food is likely to be a Novel Food
Does the food consist of fungi?
•Yes: The organism/species is genetically modified but not consumed
•Yes: The organisms/species has no history of safe use before 15 May 1997 in the EU
•No: next step
The food is likely to be a Novel Food
Is the food isolated from fungi?
•Yes: The food is a purified compound
•No: next step
The food is likely to be a Novel Food
Is the food produced from fungi?
•Yes: The food is harvested from the organism and purified
•Yes: The source organisms has not history of use in food
•Yes: The food is not a conventional food compound
•No: not novel food
The food is likely to be a Novel Food

(1) If a food consists of, is isolated from or produced from fungi, the identity according to internationally recognised database or methodology should be verified. Furthermore, the taxonomic name (full Latin name – family, genus, species, strain) and other names, synonyms, *et cetera*, where applicable and where they may be used interchangeably with preferred scientific name) should be submitted. For yeasts, the species and strain identity according to internationally accepted methods should be verified. Next, the origin of the fungi should be indicated, as well as the deposition in an officially recognised culture collection with access number, if available.

(2) If the novel food consists of, is isolated from or produced from cell culture or tissue culture derived from fungi, the applicant should state the following information, where available:

- Biological source (taxonomic information on family, genus, species, subspecies, variety) according to the international codes of nomenclature
- Verification of the identity of a fungus according to internationally recognised databases and methodology
- Organ and tissue or part of the organism sources
- Laboratory or culture collection sourced
- Information on the identity of cells
- Cell or tissue substrate used as a novel food
- Type of cultures

History of Safe Use

Proving the history of safe use may exempt a food from the scope of the Novel Food Regulation, if there is a considerable consumption before 15 May 1997, but it also facilitates the safety assessment in the authorisation procedure. As for the latter, for example, the assessment of the safety of a novel food benefit of the information about the normal quantities consumed, whether the new purpose of the novel food would correspond to such quantities or would lead to significantly higher intakes or whether the amounts that are intended to be used would deviate extensively to those normally consumed with common food.

History of safe use within the EU is not defined in Article 3(2) of the Novel Food Regulation, however, the said article defines history of safe food use in a third country as when the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country prior to the notification according to the Novel Food Regulation. A use of a food in third countries only as well as data on non-food use is not acceptable to demonstrate a history of food use within the EU, however they could be relevant for assessing the safety of the novel food.

Extent of consumption in the EU

In the novel food application, as to the question concerning the extent of the consumption of the food in question, details should be provided about the extent that relates to the consumption throughout the EU or in one Member State.

Details should be provided if the food was consumed only regionally or on small local scale in the EU before 15 May 1997 or if the food was available as an ingredient for specific target population, for example for a special medical purpose. It should be decided in each individual case whether local use should be considered a consumption with significant degree.

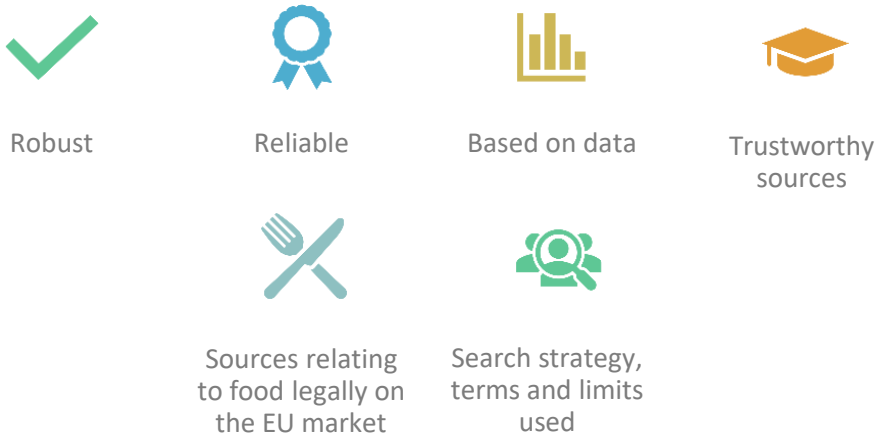
Other relevant factors to be considered is whether food business operators were present on the market continuously or not, or whether the use of the food is linked to local or regional traditions.

Type of information	*Type of evidence*	*Possible weighting*
Comprehensive sales information	Invoices Details on the sale of the food Evidence of large quantities of sale in the EU	Very good evidence, if purpose (food use) is indicated
Sales information	Invoices Details on the sale of the food	Good evidence, if purpose (food use) is indicated
	Catalogues (recognised) Sales brochures	Supporting evidence, if purpose (food use) is indicated
Government import/export information	Official documents	Supporting evidence, if purpose (food use) is indicated
Expert knowledge	Personal testimonies	Supporting evidence
Supporting information	Magazine articles Recipe books	Supporting evidence
Other information	Other	Supporting evidence

Figure 1: Adapted from: « Human Consumption to a Significant Degree» Information and Guidance Document

Some of the evidence, such as extensive sales data, provides very unequivocal information about the foods' status as novel foods. However, it is more often the case that the evidence that now needs to be presented is more than 26 years old, and therefore the whole picture needs to be examined carefully. Evidence must be robust, reliable, and based on data taken from trustworthy sources and sources that relate to food which have been legally on the EU market. Only foods that have been legally placed on the market in any of the EU Member States can be considered. This means that individual pieces of information, such as import or distribution lists, cannot provide a sufficient basis for establishing the status of the food as non-novel. Other relevant sources of information could include invoices, recipes, cookbooks, catalogues, *et cetera*. Comprehensive literature review on history of use and human studies on relevant safety outcomes should be included as well. Information on the search strategy used to retrieve the studies should be indicated, together with sources used to retrieve pertinent data, and terms and limits used (e.g. publication dates, publication types, language, population, default tags). Full study-reports should be provided, if available. Where applicable, the published literature should be reviewed by considering EFSA's systematic review principles.

Evidence of history of safe use:



Any other supporting information that would assist in determining the novel food status should be clearly indicated. Also, it should be shown whether a source from which the food is produced is not normally consumed as part of the diet. Consumption quantity varies also depending on the type of the food, for example, herbs versus cereals. It can also vary if one considers a normal diet of the average population versus specific population groups only. In that population group, information should be provided as to the role of the novel food in the diet, the handling and preparation of the food and on precautions of use. A reference should be made to typical levels of consumption for specific product categories. Information about consumption quantity should be accompanied with the information on the availability on the market (distribution via specialised or a limited number of shops or big retail or common supermarkets) and the nature of the selling points (door-to-door sale,

for example). Food used at specific occasions like ceremonies, festivities, *et cetera*, may be considered significant use. It is also of interest to the EFSA, whether the food has been available on a regular basis or only occasionally or at one time, as a fair trade, for example. However, evidence of commercial availability takes precedence over any private domain use. In other words, evidence that mushrooms have only been used as food by some people or that mushrooms have been picked in a forest is only of a limited value. If a food was imported for personal consumption only is not a relevant information. Also, food that is on the market only in emergency situations is not considered significant use, if it is not also placed on the market regularly and in a commercially sustainable way.

In the consultation procedure (see below), Member States may help to determine whether apparently small quantities would require authorisation under the Novel Food Regulation. For example, it may be that certain mushrooms are available on local farmers' markets, with limited commercial value, and they may be therefore included in official documentation for edible mushrooms. This could be considered a sufficient proof of significant consumption of those mushrooms. References to the foods in relevant national and EU legislation could also provide good evidence.

Uses of the food such as food additives, flavourings, or extraction solvents, cannot be considered as the relevant food use. A use exclusively in food supplements would also not be considered human consumption to a significant degree.

The use to a significant degree also does not automatically apply if the product in question has been subject to additional processing, such as if this processing alters the composition of the food and is produced from a new source material or by a new production process. In that regard, specific selective extracts of a fungus could be considered a novel food if they have not been used for human consumption as such, even where the source material has been widely consumed. Consideration should be also given to the type of extracts, such as aqueous extract versus other solvent based extract. By extension, this also applies to other parts of a fungus which cannot demonstrate the history of safe use, such as fruiting body versus mycelium of a mushroom. Different parts of a fungus require different assessment of the history of safe use and consequently of safety.[57]

[57] Dominique Turck and others, 'Guidance on the Preparation and Presentation of an Application for Authorisation of a Novel Food in the Context of Regulation (EU) No 2015/2283' (2016) 14 EFSA Journal e04594.

The information above can be simplified in the following decision-making table:

Mycelium of (for example)	Yes	No	No available information
was consumed by a large number of people as a food or food ingredient throughout in the EU prior to 15 May 1997			
was consumed only regionally/on a small local scale.			
was used in the private domain only			
was available as an ingredient designed for a specific target population			

Information	Evidence	Summary
It was consumed as a normal part of the diet.		
It was placed on the EU market and was available for purchase by consumers (e.g. not only in pharmacies, health shops or specific restaurants)		
It has been consumed for a long period of time		
It has been consumed in quantities typical for similar products of the specific food category		
It was harvested from the wild		
It was available as an ingredient for a specific target population group		
Its use was restricted to individuals with an underlying medical condition.		

Figure 2: Decision Making Box to Determine History of Safe Use

Where food business operators are unsure whether the information in their possession is sufficient to prove that the food concerned has been used for human consumption to a significant degree within the Union before 15 May 1997, they may consult other food business operators or food business operator federations in order to gather sufficient information.

The following decision tree can be followed to assist applicants with the determination of the novel food status:

Figure 3: Adapted from: « Human Consumption to a Significant Degree »Information and Guidance Document

Consultation on novel food status

A food business operator must consult the Member State where it first intends to place a food on the market if the food business operator is unsure whether the food falls within the scope of the Novel Food Regulation. A Member State should reach a conclusion within 4 months (plus 4 months in case of extension)

In this respect, it is important to consider Commission Implementing Regulation (EU) No 2018/456[58] on the procedural steps of the consultation process for determination of novel food status, that implements Article 4 of the Novel Food Regulation on the determination of novel food status. The consultation process is initiated by the food business operator with a request to a Member State, even where there are simultaneous market launches contemplated. The consultation request shall contain a cover letter, a technical dossier, supporting documentation and an explanatory note clarifying the purpose and relevance of the submitted documentation. The purpose of the technical dossier is to conclude the novel food status. Additional information may be requested for this purpose. Some of the information submitted by the applicant are to be treated as confidential, except of the summary of the studies and where appropriate, the analysis method. According to Annex II that provides for template technical dossier, the applicant should provide description of the food in question, as well as proposed category of the novel food in accordance with Article 3(2)(a) of the Novel Food Regulation. The applicant should include further characterisation of the food and/or source of the food, where relevant. If this includes organisms, including fungi, the applicant should specify, where applicable, which part of the organism (here fungi) the use for human consumption before 15 May 1997 within the Union refers to. The applicant should also include information about purity and concentration.

The following consultation processes of novel food status relating to mushroom or mycelium products have been conducted. They noted that the foods concerned are considered novel foods since they do not present history of safe and significant consumption in the European Union before 15 May 1997, and it is not possible to establish an equivalence relationship between the reproductive and vegetative part of the fungus in terms of nutritional composition, metabolites and potentially active substances, falling within the scope of the Novel Food Regulation:

[58] Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, OJ L 77, 20.3.2018, p. 6–13

1. ***Agaricus blazei*** dehydrated mycelium powder.[59]
2. The dehydrated mycelium powder of the fungus ***Coprinus comatus***.[60]
3. ***Ganoderma lucidum*** dehydrated mycelium powder.[61]
4. ***Grifola frondosa*** dehydrated mycelium powder.[62]
5. ***Hericium erinaceus*** dehydrated mycelium powder.[63]
6. ***Lentinula edodes*** dehydrated mycelium powder.[64]
7. ***Pleorotus eryngii*** dehydrated mycelium powder.[65]
8. ***Pleorotus ostreatus*** dehydrated mycelium powder.[66]
9. ***Polyporus umbellatus*** dehydrated mycelium powder.[67]

Furthermore, the following consultations have been conducted:

10. The use of ***Aspergillus oryzae*** in food production is not novel as a history of consumption in the EU exists before 1997.[68] The dried fungal biomass is intended as an alternative source of certain minerals in foods and food supplements. The nine mineral salts listed in this request are not novel because their addition to foods and

[59] Application for consultation to determine the status of a novel food, *Agaricus blazei* dehydrated mycelium powder, available at: <https://ec.europa.eu/food/system/files/2019-10/novel-food_consult-status_agaricus-blazei_aesan.pdf>.
[60] Application for consultation to determine the status of a novel food, *Coprinus comatus* dehydrated mycelium powder, available at: <https://ec.europa.eu/food/system/files/2019-10/novel-food_consult-status_coprinus-comatus_aesan.pdf>.
[61] Application for consultation to determine the status of a novel food, *Ganoderma lucidum* dehydrated mycelium powder, available at: <https://ec.europa.eu/food/system/files/2019-10/novel-food_consult-status_ganoderma-lucidum_aesan.pdf.
[62] Application for consultation to determine the status of a novel food, *Grifola frondosa* dehydrated mycelium powder, available at: <https://ec.europa.eu/food/system/files/2019-10/novel-food_consult-status_grifola-frondosa_aesan.pdf>.
[63] Application for consultation to determine the status of a novel food, *Hericium erinaceus* dehydrated mycelium powder, available at: <https://ec.europa.eu/food/system/files/2019-10/novel-food_consult-status_hericium-erinaceus_aesan.pdf>.
[64] Application for consultation to determine the status of a novel food, *Lentinula edodes* dehydrated mycelium powder, available at: <https://ec.europa.eu/food/system/files/2019-10/novel-food_consult-status_lentinula-edodes_aesan.pdf>.
[65] Application for consultation to determine the status of a novel food, *Pleorotus eryngii* dehydrated mycelium powder, available at: <https://ec.europa.eu/food/system/files/2019-10/novel-food_consult-status_pleorotus-eryngii_aesan.pdf>.
[66] Application for consultation to determine the status of a novel food, *Pleorotus ostreatus* dehydrated mycelium powder, available at: <https://ec.europa.eu/food/system/files/2019-10/novel-food_consult-status_pleorotus-ostreatus_aesan.pdf>.
[67] Application for consultation to determine the status of a novel food, *Polyporus umbellatus* dehydrated mycelium powder, available at: <https://ec.europa.eu/food/system/files/2019-10/novel-food_consult-status_polyporus-umbellatus_aesan.pdf>.
[68] Notified to the Danish list of food cultures.

food supplements is permitted in accordance with Regulation (EC) No 1925/2006 and Directive 2002/46/EC respectively (as amended).[69]

11. While button mushrooms have a significant history of consumption prior to the 15 May 1997, a significant history of consumption of ***Agaricus bisporus*** purposefully grown on enriched selenium or vitamin B12 substrates cannot be demonstrated.[70]

Further application details

The application for the authorisation of a novel food must contain:

- A cover letter drafted in accordance with a template
- A technical dossier containing administrative data and scientific data
- A summary of the dossier

The dossier submitted should enable a comprehensive risk assessment of the novel food.

The novel food must be tested as they are intended to be marketed.

To this purpose, the applicant must provide documentation on the procedure and strategy following when gathering all relevant data.

Specifically, the applicant should submit a description of the safety evaluation strategy and the corresponding testing strategy and should justify the inclusion or exclusion of specific studies or information.

On request, the raw data for the individual studies, published and unpublished, undertaken by the applicant, or on their behalf, must be provided.

On receipt of an application, the Commission verifies without delay whether the application falls within the scope of the Novel Food Regulation and whether it fulfils all the prescribed requirements. The Commission informs the applicant, the Member States and the EFSA about the validity of the application.

The EFSA assesses an application on a novel food, usually following a request from the European Commission. The EFSA then delivers an opinion, such as a recent one, in which the EFSA considered thermally dried yellow mealworm, either as whole dried insect or in the form of powder.[71]

An application may be also submitted to modify the conditions of use, the specifications, additional specific labelling requirements and post-marketing requirements of an authorised novel food.

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[69] Food Safety Authority of Ireland, Opinion on the novel food status of "Mineral enriched fungal biomass (*Aspergillus oryzae*)" , available at: < https://ec.europa.eu/food/system/files/2019-01/novel-food_consult-status_aspergillus-oryzae.pdf >-

[70] Application for consultation to determine the status of a novel food, Selenium and Vitamin B12 mushrooms, available at: <https://ec.europa.eu/food/system/files/2019-12/novel-food_consult-status_agaricus-bisporus.pdf.

[71] EFSA, 'Safety of dried yellow mealworm (Tenebrio molitor larva) as a novel food pursuant to Regulation (EU) 2015/2283', available at: https://www.efsa.europa.eu/en/efsajournal/pub/6343.

Novel food's specification are key parameters that characterise and substantiate the identity of the novel food. The applicant must provide a rationale for the selected parameters. The parameters should be presented in a table format and include:

- Minimal purity
- Limits for impurities and degradation products, in particular if toxicological or nutritional relevance
- Maximum levels of contaminants, where there are no legal requirements
- Methods used for analysis

An applicant may ask for a confidentiality request covering certain information that the applicant submitted in the dossier.[72] The non-confidential version of the application dossier can be subject to public consultation. The EFSA then publishes third party comments and the outcome of public consultation is annex to the EFSA opinion. The aim of the public consultation is to collect new or additional evidence/data or information to assess an application.

A successful application for novel food gives rise to a generic authorisation upon which not only the original applicant but also other food business operators which fulfil the food's specifications, conditions of use and other requirements may produce the same generic product. Despite this advantage, the Novel Food Regulation gives applicants a competitive advantage in so far as it protects newly developed scientific evidence or scientific data supporting

[72] The following information may be considered confidential by the EFSA:

- The manufacturing or production process, including the method and innovate aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety
- Commercial links between a producer or importer and the applicant where applicable
- Commercial information revealing sourcing, market shares or business strategy of the applicant
- Quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety
- Where applicable, information provided in detailed description of starting substances and starting preparations and on how they are used to manufacture the novel food, and detailed information on the nature and composition of the specific foods or food categories in which the applicant indents to use that novel food, except for information which is relevant to the assessment of safety
- Where applicable, detailed analytical information on the variability and stability of individual production batches, except for information which is relevant to the assessment of safety
- Any other person data except for the name and address of the application, the names of authors of published or publicly available studies supporting such requests and the names of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any ad hoc group meeting on the subject matter
- Personal data of individuals involved in testing on vertebrate studies or in obtaining toxicological information.

their applications. Such data shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant. The data protection shall be granted by the Commission where the following conditions are met:

(a) the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made;

(b) the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and

(c) the novel food could not have been assessed by the Authority and authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant.

However, the initial applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used.

During the period of data protection, the novel food is authorised for placing on the market within the Union only by the initial applicant, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected or with the agreement of the initial applicant.

INFORMATIVE BOX #1

A typical process on the application may look as follows:

1. On 24 January 2020 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of mushroom powder (Agaricus bisporus) as a novel food.

2. On 24 January 2020, a valid application on the safety of vitamin D2 mushroom powder (Agaricus bisporus) as a novel food, which was submitted by MBio, Monaghan Mushrooms, was made available to EFSA by the European Commission through the Commission e-submission portal and the scientific evaluation procedure was initiated.

3. On 8 May 2020, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.

4. On 5 November 2020, additional information was provided by the applicant through the Commission e-submission portal.

5. On 26 November 2020, 23 December 2020 and 15 January 2021, EFSA requested the applicant to provide further clarifications to the additional information provided.

6. On 3 December 2020, 7 January 2021 and 26 January 2021 additional clarifications were provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.

7. During its meeting on 24 February 2021, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of vitamin D2 mushroom powder (Agaricus bisporus) as a NF pursuant to the Novel Food Regulation.

As an overall guidance for initial information, characterisation of the novel food, source of novel food, qualitative and quantitative data on the composition

and information on impurities/contaminants of the novel food should be provided. The purpose and intended use of the novel food should be described. The applicant should further specify how the food is intended to be used (e.g. ingredient, whole food). The applicant should state the form and/or concentration of the product (fluid, extract, etc.) and if ingredient is present in a food supplement, the applicant should also state possible indication of the quantity/amount.

This should be demonstrated by certified analyses, with full description and references, on preferably at least 5 representative, independently produced (non-consecutive) batches of the novel food for each proposed production process. Analyses should be preferably performed by accredited facilities.[73]

The novel food should have a certain target population (adults, children, the general population, et cetera). The target population should be cross-references with relevant safety data. Also, certain population subgroups might be urged to avoid consumption of the novel food, such as those with certain physiological conditions. The applicant should also propose the maximum amount of consumption of the novel food, together with the proposed average and maximum daily intakes for different age/gender/target population groups as appropriate (per kg body weight or in absolute amounts). Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population, the safety data provided must also cover those groups. Chronic intake estimates should be provided too. The methodological aspects of the intake assessment should consider the EFSA guidance on default values and rounding[74] and should document sources of data used scientific principles and methods applied, in particular regarding the model.

An information on whether the novel food is intended to replace another food should be appended. The applicant should also explain why the novel food is intended to replace another food and whether it is reasonable to expect that the novel food would succeed in doing so. This is particularly relevant for mycelium fermented proteins that are considered a type of meat substitutes and where the comparison of the protein content could be of relevance.

For mushroom and mycelium, it could be also particularly relevant to indicate the combined intake from the novel food and other sources, particularly by stating:

- Mean and high daily intakes from natural sources (background diet)
- Daily intake from food fortification and supplements
- Daily intake from other uses, including non-dietary sources (e.g. consumer products and pharmaceuticals)

[73] Dominique Turck and others, 'Guidance on the Preparation and Presentation of an Application for Authorisation of a Novel Food in the Context of Regulation (EU) No 2015/2283' (2016) 14 EFSA Journal.
[74] 'Guidance on Selected Default Values to Be Used by the EFSA Scientific Committee, Scientific Panels and Units in the Absence of Actual Measured Data' (2012) 10 EFSA Journal 2579.

Conservative scenarios should be used.

Moreover, following information must be also provided:

- Absorption, distribution, metabolism and excretion
    - Kinetic data of toxicologically relevant constituents, tested according to the requirements and tiered approach described in the EFSA Guidance for submission for food additive evaluations[75]
    - It should also establish whether nutrients, vitamins and minerals, are absorbed and distributed throughout the body
    - Data on human and animals, considering nutritional and toxicological impact of the novel food should be used
- Bioavailability (non-mandatory)
- Nutritional information
    - Bioavailability of nutrients, taking into account influences of the production process, storage and further processing prior to consumption
    - Effects of processing/handling/preparation for the intended use
    - Content and effect of antinutritional factors in the novel food and other known interactions with nutrients in the novel food. Estimation of the intake of potentially and nutritional substances from the novel food and comparison with health-based guidance, if available
    - *If a novel food is indented to replace another food, demonstration that the novel food that does not differ in a nutritionally disadvantageous way under the proposed conditions of use*

SAFETY

The assessment of safety should be based on all available information that supports the safety of the novel food under the proposed conditions of use. The information includes primarily the results of toxicity studies and any identified adverse effects using human data. The assessment must also consider sources of uncertainties. Specifically, the following information must be submitted. Information listed below in italics shall be submitted only if needed.

- Toxicological information
    - Rationale for the toxicity testing strategy applied. Testing strategy depends on the type of test material (single, simple mixture versus complex mixture versus whole foods that should be tested like complex mixtures[76])

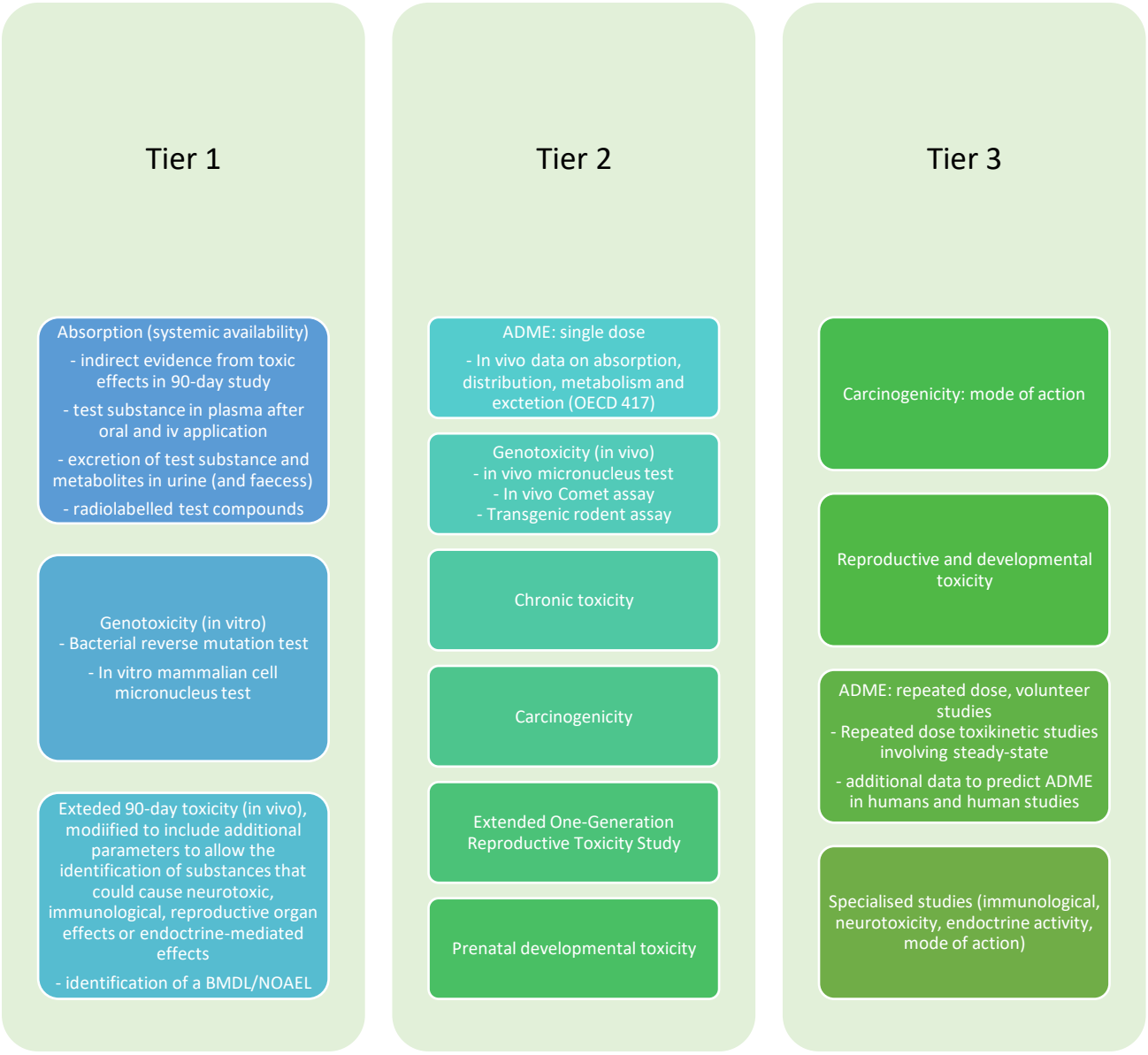
[75] 'Guidance for Submission for Food Additive Evaluations' (2012) 10 EFSA Journal.
[76] According to the Scientific Panel on Food Additives and Nutrient Sources added to Food's Guidance, complex mixtures are "conventional metabolism and toxicokinetic studies may not be feasible for all components in the mixture, but should be provided for toxicologically relevant constituents. Toxicologically relevant constituents are generally considered to be the major components and those other components with known or demonstrable biological or toxicological activity, and should be determined on a case-by-case basis with a scientific justification and the rationale for their selection provided".

- Overview table of study reports
- Summary table of statistically significant observations in toxicity studies, summarising the statistically significant differences between controls and the novel food
- *Considerations of the relevance of toxicologically relevant components (e.g. impurities, by-products, residues, chemical or microbiological contaminants) in relation to their estimated intakes, possible background exposure and their health-based guidance (e.g. tolerable daily intakes), where applicable*

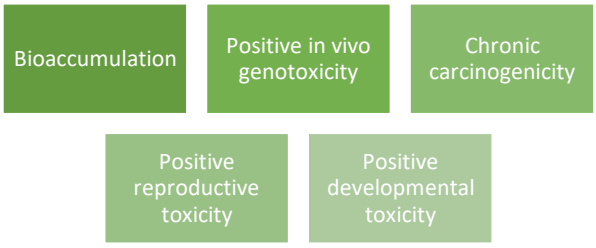
- Genotoxicity
  - Study report of genotoxicity studies
    - A basic battery of *in vitro* tests
    - *Follow-up approaches in case of positive results of the basic battery*
- Subchronic toxicity
  - Study report of subchronic toxicity studies, carried out for at least 90 days, modified to include assessment of some additional parameters (endocrine related endpoints) described in the more recent guideline on repeated-dose 28-day oral toxicity studies in rodents[77]
    - Determination of the benchmark dose (lower confidence limit) or the no-observed-adverse-effect-level
    - When kinetics testing indicates a lack of systemic availability, studies should at least investigate both pathological and physiological effects in the gastrointestinal tract
    - The effects of unabsorbed materials on gastrointestinal function and tolerance
    - Additional markers of potentially adverse nutritional and/or metabolic effects on a case-by-case basis
- Chronic toxicity and carcinogenicity
  - *Study report of chronic toxicity and carcinogenicity studies*
    - *Tiered approach.*
- Reproductive and development toxicity
  - *Study report of reproductive and development toxicity studies*
    - *Tiered approach. Tier 3 is triggered when specific end points of Tier 2 need additional clarification.*
- Human data
  - Overview table
  - Available human intervention, epidemiological and observational studies relevant to the safety assessment should be organised according to a hierarchy of study designs and research questions, reflecting the relative strength of evidence which may be obtained from different types of studies

[77] EFSA, 'Draft for Public Consultation Scientific Opinion Guidance On Repeated-Dose 90-Day Oral Toxicity Study On Whole food/feed in rodents', available at: https://www.efsa.europa.eu/sites/default/files/consultation/110707.pdf.

        - Physical examination, blood chemistry, haematology, urine analysis, blood pressure, organ function tests, monitoring of adverse reactions
    - *In case there are indications that the novel food could trigger specific biological processes (e.g. immunotoxicity, hypersensitivity, food intolerance, neurotoxicity, endocrine activity), which have not been fully considered in the core areas for evaluation, the applicant shall submit additional studies addressing these pharmacodynamic effects*
- Allergenicity
    - Allergenic potential of the novel food, considering its composition, particularly its protein, its source (including taxonomic relationships), the production process and available experimental and human data, including information on cross-reactivity
    - A comprehensive literature review in order to retrieve available information on sensitisation
    - Case reports of allergic reactions
    - Allergenicity studies (*in vitro*, in animals, in humans) of the novel food and/or its source
    - Other appropriate methods to further investigate the potential allergenicity of foods:
        - Protein content in the novel food (including limit of detection and quantification) and accurate description of the methods used
        - Molecular weight of the potentially allergenic protein, heat stability, sensitivity to pH, digestibility by gastrointestinal proteases
        - Degree of sequence homology with known allergens
        - Immunological tests
        - Detection of specific IgE antibodies
        - Skin prick testing
        - Double bling placebo-controlled food challenge studies



Triggers for Tier 3



The supporting evidence on history of safe use can be also used in safety assessment. For example, if it is relevant for the safety assessment, a comprehensive literature review of studies with specific and safety-related components of the novel food and for studies with similar foods from the same or other closely related sources. This is important because all available information on previous human consumption of a fungus and its source as well as other information, such as kinetic data, anticipated use, non-food use is

considered in order to decide which toxicity studies are necessary to be conducted to prove the novel food's safety.

As such, subchronic toxicity studies would be required for glucosamine from genetically modified *A. niger* but not for milk fermented with *Bacteroides xylanisolvens* with well characterised source with a significant history of food use, comprehensive compositional data, no concerns from production process, and knowledge on the main components.[78]

Toxicological studies shall be conducted in facilities which comply with the requirements of Directive 2004/10/EC[79] or, if they are carried out outside the territory of the Union, they shall follow the OECD Principles of Good Laboratory Practice. The applicant shall provide evidence of compliance with those requirements and shall justify any deviation from the standard protocols.

For genotoxicity studies, the approach proposed by the "Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment" should be followed.[80]

For genotoxicity, subchronic toxicity, chronic toxicity and carcinogenicity studies and for reproductive and developmental toxicity studies, a certificate of analysis of the test material used in these studies must be provided. If any of these studies used a test material different from the novel food, an explanation must be provided that would explain why the test material used is appropriate for the safety assessment of the novel food. This is because toxicological studies should be in principle carried out with the novel food as intended to be marketed, i.e. the test material should be manufactured according to production process described and meet the compositional characteristics and the specifications provided.

For each biological or toxicological study, the applicant must clarify whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the novel food under consideration.[81]

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[78] See https://www.efsa.europa.eu/sites/default/files/170615-p01.pdf.

[79] Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, OJ L 50, 20.2.2004, p. 44–59

[80] Available at: https://www.efsa.europa.eu/en/efsajournal/pub/2379

[81] Specifications include:
-the limits and information on the exact method for each of the selected parameters (i.e., as a minimum, the contents and/or limits for the parameters on the identity of the product, the minimal purity, limits acceptable for impurities and degradation products, in particular those of toxicological or nutritional relevance. In the absence of legal requirements in the EU, it also includes maximum levels of contaminants)
-the limits and information on nutritional or biologically active components or, when these are not known, on selected chemical markers
-the limits and information on concentrations of the major group of constituents (e.g. amino acids, proteins, etc.)

(Quantitative) structure activity relationship is also relevant ((Q)SAR).[82] It is suggested that findings from QSAR analyses can be further used as input parameters for physiologically based toxicokinetic modelling (PBTK). [83] Toxicological data on structurally related substances (read-across) should be considered in case of insufficient other data. The EFSA Compendium of Botanicals contain a database of botanicals reported to contain naturally occurring substances of possible concern. It is used to identify adverse health effect with specific species and may be used for read-across data. The compendium currently does not include algae, cyanobacteria and fungi; they will be considered for possible inclusion in the future.[84]

For subchronic toxicity studies in wholefood, EFSA's guidance should be consulted.[85] The testing requirements should be determined using a case-by-case approach. Dose selection and the avoidance of nutritional imbalances should be specifically considered.

For chronic toxicity and carcinogenity, studies need to be provided only if there are critical findings in the subchronic study as well as results of in vitro or in vivo toxicity tests, including genotoxicity tests. Further guidance on the triggers for these studies and their implementation are outlined in the guidance on food additives [86] and respective OECD Guidelines [87] . This corresponds to the tiered toxicity testing approach as proposed for food additives.

For reproductive and development toxicity, studies are necessary in the light of kinetic and toxicity data, including read-across data. Any indications of effects on reproductive organs or parameters, for example in the modified 90-day oral toxicity, will trigger testing for reproductive and developmental toxicity. Reproductive and developmental toxicity testing may not be required, if argued on a case-by-case basis.

Allergenicity testing is particularly import for proteins produced via mycelium fermentation. The default assumption for novel foods containing proteins is that they have allergenic potential. This is due to a risk of de novo sensitisation or cross reactivity.[88] However, the applicant wishing to prove that the novel

[82] Webinar on Scientific Aspects to consider when preparing a Novel Food Application, held by Prof. Marina Heinonen Dr. Inge Mangelsdor. Available at: https://www.efsa.europa.eu/sites/default/files/170615-p01.pdf.
[83] Alie de Boer and Aalt Bast. "Demanding Safe Food – Safety Testing under the Novel Food Regulation (2015/2283)". Trends in Food Science & Technology 72 (2018), pp. 125-133.
[84] EFSA, "Compendium of botanicals" (2021). Available at: https://www.efsa.europa.eu/en/data-report/compendium-botanicals
[85] 'Guidance on Conducting Repeated-Dose 90-Day Oral Toxicity Study in Rodents on Whole Food/Feed' (2011) 9 EFSA Journal 2438.
[86] 'Guidance for Submission for Food Additive Evaluations' (2012) 10 EFSA Journal 2760.
[87] OECD, Guidance Document 116 on the Conduct and Design of Chronic Toxicity and Carcinogenicity Studies, Supporting Test Guidelines 451, 452 and 453, (2014), OECD Series on Testing and Assessment, No. 116
[88] Alie de Boer and Aalt Bast. "Demanding Safe Food – Safety Testing under the Novel Food Regulation (2015/2283)". Trends in Food Science & Technology 72 (2018), pp. 125-133.

food is unlikely to trigger an allergic reaction should follow EFSA guidance on the preparation and presentation of applications pursuant to Article 21 Paragraph 2 of Regulation (EU) No 1169/2011, as amended.[89] Alie de Boer suggest to detect a potential allergen in four phases:

1. "*Collect information about the history of exposure to the protein, while taking into account environmental and geographical factors*
2. *Observe the taxonomy of the novel food proteins and the relationship between these proteins and known allergens to indicate potential allergens*
3. *Identify the novel food proteins and compare them with proteins in specific databases*
4. *Consider the way that consumers will use the product because of potential matrix changes due to processing and preparation of the novel food and its influence on the putative allergenic potential*"[90]

Mushroom and mycelium products may exhibit characteristics that should be specifically considered in safety assessments, including anti-nutrients, toxic potential (mycotoxins, heavy metals), allergenic potential, or microbial safety (spores and surface colonization), or controlled breeding conditions (substrate, breeding, personnel). Since the EFSA recognises that a variety of fungal species are used in food and feed production, either directly (to produce fermented foods) or as additives, food enzymes and other components of food, specific administrative guidance has been provided for microorganisms, yeasts species. [91] Some biological agents may be granted a Qualified Presumption of Safety (QPS) status that is established by the EFSA Panel on Biological Hazards. Such biological agents are included on a list of microorganisms with QPS status.[92] However, significant limitations may apply to QPS status. The list currently features the following yeast species (members of the fungus kingdom):

Yeasts (species)	Qualifications
Candida cylindracea	QPS only applies if the species is used for enzyme production

[89] EFSA, "Guidance on the preparation and presentation of applications pursuant to Article 21 Paragraph 2 of Regulation (EU) No 1169/2011" (2013). Available at: https://www.efsa.europa.eu/en/efsajournal/pub/3417

[90] Alie de Boer and Aalt Bast. "Demanding Safe Food – Safety Testing under the Novel Food Regulation (2015/2283). Trends in Food Science & Technology 72 (2018), pp. 125-133.

[91] EFSA FEEDAP Panel (EFSA Panel on Food Additives and Nutrient Sources added to food), 'Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance.' (2012) EFSA Journal 10(6).

[92] Kostas Koutsoumanis and others, 'Update of the List of QPS-Recommended Biological Agents Intentionally Added to Food or Feed as Notified to EFSA 14: Suitability of Taxonomic Units Notified to EFSA until March 2021' (2021) 19 EFSA Journal.

Cyberlindnera Jadinii		
Debaryomyces hansenii		
Hanseniaspora uvarum		
Kluyveromyces lactis	**Kluyveromyces marxianus**	
Komagataella pastoris	**Komagataella phaffl**	QPS only applies if the species is used for enzyme production
Lindnera jadinii		QPS only applies if the species is used for enzyme production
Ogataea angusta		QPS only applies if the species is used for enzyme production
Saccharomyces bayanus	**Saccharamyces cerevisiae** **Saccharamyces pastoranius**	For *Saccharamyces cerevislae*, the general qualification applies for yeast strains able to grow above 37°C
Schizosasscharomyces pombe		
Wickerhamomyces anomalus		QPS only applies if the species is used for enzyme production
Xanthophyllomyces dendrorhous		
Yarrowia lipolytica		QPS applies for production purposes only
Zygosaccharomyces rouxil		

Figure 4: EFSA, Updated list of QPS status recommended biological agents in support of EFSA risk assessments

Any listed strain with the QPS status is freed from the exhaustive safety assessment requirements. However, the absence of antimycotic resistance should be proved if the yeasts are to be used as viable organisms in the food and feed chains. The QPS is also not a criterion to decide on the novel food status. Fungi that do not have QPS status are not necessarily considered novel.

In this regard it is important to note that filamentous fungi, bacteriophages, *Streptomycetes*, *Oomycetes*, *Enterococcus faecium*, *Escherichia coli* and recently also *Clostridium butyricum* are excluded from the QPS assessments based on an ambiguous taxonomic position or the possession of potentially harmful traits.[93]

The distinction between a filamentous fungus and a yeast, and thus whether an organism would be eligible for QPS evaluation and status (yeast), or not (filamentous fungi) is sometimes not clear-cut.[94]

Yeasts are defined as follows: "*In summary, yeasts, whether ascomycetes or basidiomycetes, are generally characterised by budding or fission as the primary means of asexual reproduction and have sexual states that are not enclosed in fruiting bodies*."[95] Yeasts are therefore not expected to belong to any other fungal phylum than ascomycetes and basidiomycetes. Of the three lineages within the Ascomycota, only two contain yeasts, whereas the third (*Pezizomycotina*) does not. The basic body plan of the *Pezizomycotina* is filamentous and anastomosed, and a reference is not made to any fungi within *Pezizomycotina* as 'yeasts', or 'yeast-like' either. [96] Typically, members of *Pezizomycotina* contain a high abundance of enzymes for secondary metabolism, which is generally in contrast to yeasts but similar to filamentous fungi.[97]

The decision whether a species should be considered to be a yeast or a filamentous fungus for QPS purposes is taken on a case-by-case basis, but applying the following general principles: A fungus may be subject to evaluation if it i) belongs to the phyla Ascomycota (excluding the *Pezizomycotina*) or Basidiomycota and ii) is treated as a yeast by taxonomic literature. [98] As supporting information, the taxonomy applied by internationally recognised microbial culture collections is considered.[99]

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[93] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis K et al. 'Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 12: suitability of taxonomic units notified to EFSA until March 2020." (2020) EFSA Journal 18(7).
[94] Ibid.
[95] Kurtzman et al. (2011). The Yeasts: a taxonomic study definition, classification and nomenclature of the yeasts.
[96] Kurtzman et al. (2011), Naranjo-Ortiz and Gabaldón, 2019.
[97] Koutsoumanis K et al. 'Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 13: suitability of taxonomic units notified to EFSA until September 2020." (2021) EFSA Journal 19(1).
[98] Ibid.
[99] Fungal Biodiversity Centre (CBS) - Fungi strains; https://wi.knaw.nl/page/fungal_table with the yeast page https://theyeasts.org/.

If a fungus (microorganism) is not assigned a QPS status, the following decision tree was proposed on the safety assessment of such a fungus.

Literature suggests also other methods for safety screening, such as the Threshold of Toxicological Concern which is calculated based on exposure data, chemical structure, metabolism and findings on toxicity. Exposure below the TTC level is considered to not present any safety concern and exceeding this level signals a need to further investigate safety issues of the specific compound. If this approach would be more suitable for MMP is a question open to debate.[100]

However, these are other methods that need to be explicitly recognised in the EFSA guidance documents to gain relevance.

[100] Alie de Boer and Aalt Bast. "Demanding Safe Food – Safety Testing under the Novel Food Regulation (2015/2283). Trends in Food Science & Technology 72 (2018), pp. 125-133.

Strain characterisation and genome sequencing	Has the strain been characterised to genus and species level? **AND**	If NO – do it If YES – next step
	Has the strain been completely genome-sequenced?	
Screening for undesirable attributes and metabolites	Is the strain free from genetic elements encoding known virulance factors and/or toxins associated with pathogenicity? **AND**	If NO – additional safety studies required If YES – next step If useful in human medicine, not appropriate for consumption
	Is the strain free from of functional and transferable antibiotic resistence gene DNA?	
	Does the strain produce antimicrobial substance useful in human medicine?	
Gene modification	Has the strain been genetically modified?	If YES, additional safety studies required + authorisation IF NO – next step
Strain origin	Was the strain isolated from a source that has a history of safe consumption for which the species is a substantial and characterizing component (not simply an incidental isolate)? **AND**	If NO – additional safety studies required If YES – go on
	Has the species undergone comprehensive peer reviewed safety evaluation (e.g. QPS) or has it been affirmed safe by authoritiative group/qualified scientific experts? **AND**	
	Do findings published since completion of the peer review continue to support safety?	
Exposure levels	Will the intended use of the strain expand exposure of the species beyond the group that typically consume the species in foods in which it is typically found? **AND**	If NO – strain is considered safe If YES – additional safety studies are required
	Will the intended use of the stain expand overall intake of the species (e.g. increasing the number of foods beyond foods in which the speciesis typically found or using the strain as probiotic rather starter culture)?	
Additional safety studies	Does the strain induce undesirable physiological effects in appropriately designed safety studies (e.g. animal models or clinical trials)?	If NO – strain is considered safe If YES – strain is not appropriate for human consumption

Figure 4: Adapted from: Pariza et al. Determining the safety of microbial cultures for consumption by humans and animals

The applicant shall propose an overall conclusion on the safety of the proposed uses of the novel food.

Also, any food business operator which has placed a novel food on the market shall immediately inform the Commission of any information of which it has become aware concerning:

(a) any new scientific or technical information which might influence the evaluation of the safety of use of the novel food;

(b) any prohibition or restriction imposed by a third country in which the novel food is placed on the market.

INFORMATIVE BOX #2 - Approval of *Lentinula edodes*

An example of a novel food which was granted authorisation and contains fungi is an aqueous extract obtained from the Shiitake mushroom *Lentinula edodes* cultivated in submerged fermentation.

Compositional data on the novel food retrieved from 5 batches informs on water, pH, concentration of lentinan (the principle constituent of the novel food), free glucose, N-containing constituents (using the Kjeldahl method) and proteins (using the Bradford method). The applicant further provided data on the content of fat, amino acids and related biogenic amines, ash and ions. Data on the contents of water-soluble vitamins were also provided for 3 batches. For one batch, data on heavy metals and formaldehyde was provided. Analytical methods were also used to demonstrate that contents of 297 pesticides were below the limits of detection. As for representatives of potential mycotoxins, analytical data on aflatoxins and ochratoxin was provided.

As for secondary metabolites, the EFSA Panel agreed that under the specified fermentation conditions, the formation of secondary metabolites was unlikely. This was also supported by the history of consumption of the fruiting body: *Lentinula edodes* is indigenous to China, Japan and other Asian countries where it grows on fallen deciduous trees. It is a common food in Asia. Fresh mushrooms are widely cultivated. The world production amounted to several millions of tons. The fruiting body has an established history of consumption.

The novel food was intended to be used in a wide range of products, such as dietary supplements, yoghurts, soft drinks, cooked and processed food and baked goods.

The applicant did not provide studies on genotoxicity.

As for toxicity studies, the applicant used a literature search and provided information on studies on animals involving the acute toxicity of lentinan, a 6-month study where lentinan was given intravenously (this study was not considered relevant) and other animal studies providing no or very limited evidence to support the safety of the novel food ingredient.

The applicant, however, conducted an efficacy and safety study of the novel food which did not provide evidence for safety concerns, although it also did not provide evidence on a possible safety margin. A second human study also provided supporting but limited evidence for the safety of the novel food.

A Member State expressed concerns as to a potential contraindication for people suffering from auto-immune diseases. However, pointing to other studies, the Panel concluded that the risk of adverse immunological effects due to the novel food ingredient, if any, was expected not to be higher than that resulting from the normal consumption of the fruiting body of the Shiitake mushroom.

Owing to the fermentation of the novel food ingredient from the mycelium and the final application of a heat-induced sterilisation step, adverse effects reported after the consumption of the fruiting body of the Shiitake mushroom are not considered relevant.

There were several case reports on photosensitivity, intolerance and allergic reactions related to the consumption of Shiitake mushrooms or products derived thereof. Lentinan has been also implicated as a causative substance of Shiitake dermatitis.

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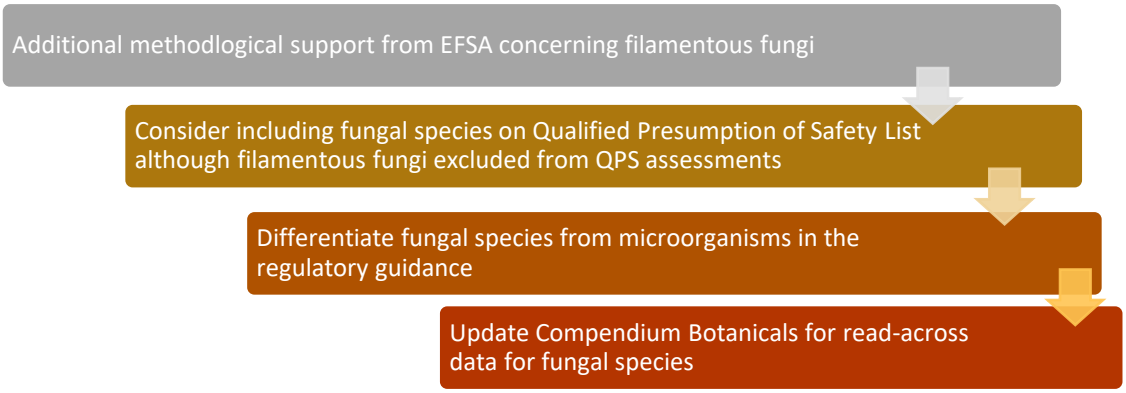
The applicant did not provide any studies to evaluate the allergenicity of the novel food. The Panel concluded that despite the low intake of lentinan at the proposed use levels, it cannot be excluded that the novel food poses an allergenic risk to sensitive subjects. However, the risk is expected not to be higher than that resulting from the normal consumption of the fruiting body of the Shiitake mushroom.

Source: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1685

The novel food authorization procedure is a long process, which requires efforts from all parties involved. Suggestions can be made to policy makers which could represent a way forward for the regulation of novel foods derived from mushrooms and mycelium:



Key messages

The production process should be described in detail in the novel food application to provide enough information that will serve for the basis for the evaluation of the bioavailability, nutritional value and safety.

New production techniques may trigger the novel food status even where the organism, or its part, used in the novel food has a demonstrable history of safe use itself.

The employment of new technologies in the production process can also alter the safe use assessment.

This Chapter introduces the concept of fermentation, and we focus on how fermentation processes might change the novel food status of MMP products. We briefly introduce the use of agricultural by-products as a substrate for mushrooms and mycelium products.

FERMENTATION PROCESSES AND CHANGES IN THE NOVEL FOOD STATUS OF MMP

From the market perspective, one of the most promising segments is the production of protein biomass or whole-cut "meats" as meat substitutes using mycelium in fermentation processes. Companies which are planning to introduce a novel food using mycelium as a fermentation agent use different types of fermentation processes. Among these, one may find solid-state fermentation or submerged fermentation, or fermentation in continuous fermentation tanks or in batches. Some companies experiment with recombinant or precise fermentation.[101] There are different reasons why companies opt for different types of fermentation for different fungi strains, such as the growth time, growth space, control of physicochemical parameters, seasonality and others. Many fermentation processes use standard techniques, for example those of the dairy industry, and therefore do not raise any novelty or safety issues. Many microorganisms are used for that purpose. Most conventional fermentation processes using microorganisms with a history of use for such purpose would not be covered by the Novel Food Regulation – they would not raise novelty issues. However, mycelium represents a novel fermentation agent. It may also appear, although rarely, in co-cultures with other traditionally used fermentation agents, such as yeast or lactic acid. For that reason, fermentation is often described as the third pillar in the

[101] Sally Ho, 'Spanish Startup Libre Foods Wants To Be "World's Leading Provider" Of Whole-Cut Mycelium Steaks', available at: <https://www.greenqueen.com.hk/spanish-startup-libre-foods-wants-to-be-worlds-leading-provider-of-whole-cut-mycelium-steaks/>.

alternative protein landscape.[102] Whether in the production of whole cut alternative "meats" using filamentous fungi strains or in the production of biomass with other fungi strains, fermentation plays a crucial role. Fermentation with a fungi mycelium may lead to the formation of filamentous and pellet mycelial biomass without the formation of fruiting bodies.

New production techniques may trigger the novel food status even where the organism, or its part, used in the novel food has a demonstrable history of safe use itself.

In the following examples of novel food applications, fermentation processes were employed:

1. In a recent case, the Belgian national authority evaluated the novelty of a plant protein concentrate that is fermented with the mycelium of shiitake (*Lentinus edodes*). The authority concluded that mycelium, in this context, is to be regard as an ingredient of the product – it is a food consisting of, isolated from or produced from microorganisms, fungi or algae. As explained above, although the shiitake mushroom has a demonstrable history of consumption, this cannot be said for the mycelium. In this case, the novel food status of the other ingredients and of the process applied has not been evaluated.[103]

   The Panel concluded that the employed technology based on submerged cultivation of mycelium in sterilising liquid medium enable the reproducible and standardised production of the novel food. The culture conditions are unlikely to lead to the production of secondary metabolites. From the safety perspective, it is also interesting to remark that the Panel noted the presence of soy peptides in the medium culture.[104]

Authorised Novel Food	**Specification**
Mycelial extract from Shiitake mushroom (Lentinula edodes)	Description/Definition The novel food ingredient is a sterile aqueous extract obtained from the mycelium of Lentinula edodes cultivated in a submerged fermentation. It is a light, brown turbid liquid. Lentinan is a β-(1-3) β-(1-6)-D-glucan which has a molecular weight of approximately 5 x 10^5 Daltons, a degree of branching of 2/5 and a triple helical tertiary structure Purity/Composition of the mycelial extract from Lentinula edodes Moisture: 98 %

[102] ibid.

[103] Application for consultation to determine the status of a novel food, Plant protein concentrate that is fermented with the mycelium of shiitake, available at: <https://ec.europa.eu/food/system/files/2019-02/novel-food_consult-status_lentinus-edades.pdf> . The production technology was based on submerged cultivation in sterilised liquid medium. Lentinula edodes mycelium was cultivated in a liquid aerobic fermentation process. The mycelium of the cultivated Lentinula edodes is submerged in defined medium, comprising glucose, malt extract, soy peptone and yeast extract. Controlled fermentation conditions (temperature, aeration rate, pH) are applied. The biomass is removed by filtration and the resulting fermentation liquid is the raw material for the lentian-based products. Final concentrations of lentinan are adjusted by dilution with water. The liquid is sterilised by head and sodium benzoate is added as a preservative. Based on this opinion, company MycoTechnology, Inc. submitted a dossier in the novel food authorisation process for pea and rice protein fermented by Shiitake mycelia.

[104] See https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1685.

	Dry matter: 2 % Free glucose < 20 mg/ml Total protein (Bradford method): < 0.1 mg/ml N-containing constituents (Kjeldahl method): < 10 mg/ml Lentinan: 0.8 – 1.2 mg/ml

2. In another case concerning fermented apricot kernel cream, evaluated by the Austrian national authority, it was noted that its ingredients are not novel (such as apricot kernels) and are used for similar purposes in products available on the EU market (such as almond drink, almond yoghurt). The production process of fermented apricot kernel cream just includes common and widely used production practices (process technologies) and can be compared to existing products such as nut drinks and nut yoghurts. Cultures used for the fermentations are also used frequently in other products on the market, while the driver of fermentation is added sugar. The common and traditional use of apricot kernels is well demonstrated and documented in various legislation (flavouring regulation, import control on pesticide residues and contaminants), as well as in the Codex Alimentarius Austriacus and the German Food Code (*Lebensmittel- und Bedarfsgegenstände- und Futtermittelgesetzbuch*).[105]

3. On the other hand, in a third case concerning fermentation, a history of consumption to a significant degree within the EU prior to 15 May 1997 has not been demonstrated for fermented wheat germ extract.[106]

4. Also, in case of fermented soybean extract, a novel food authorisation was obtained.[107] The extract contains nattokinase, which is a serine protease composed of 275 amino acid residues. Nattokinase was originally isolated from natto, a traditional Japanese foodstuff which is produced by the fermentation of soybeans (Glycine max L.) with *Bacillus subtilis var. natto*. Soybean powder is fermented at 37°C using a strain of *B. subtilis var. natto*, with the addition of corn starch, soybean oil, calcium carbonate and water. Thereafter, nattokinase is isolated by performing several filtration steps. Vitamin K2 is removed during the manufacturing process. The EFSA Panel considered that the production process is sufficiently described and did not raise concerns about the safety of the NF.

Authorised Novel Food	**Specification**
Fermented soybean extract	**Description/Definition** Fermented soybean extract is an odourless milk-white coloured powder. It is comprised of 30 % fermented soybean extract powder and 70 % resistant dextrin (as carrier) from corn-starch, which is added during the processing.

[105] Application for consultation to determine the status of a novel food, Apricot Kernel Drink and Fermented Apricot Kernel Cream, available at: <https://ec.europa.eu/food/system/files/2021-03/novel-food_consult-status_apricot-kernel.pdf>.
[106] Application for consultation to determine the status of a novel food, Fermented wheat germ extract, available at: <https://ec.europa.eu/food/system/files/2020-04/novel-food_consult-status_fermented-wheat.pdf>.
[107] EFSA, 'Safety of fermented soybean extract NSK-SD® as a novel food pursuant to Regulation (EC) No 258/97 EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)'(2016), available at: https://doi.org/10.2903/j.efsa.2016.4541 .

	Fermented soybean extract contains nattokinase isolated from natto, a foodstuff produced by the fermentation of non-genetically modified soybeans (Glycine max. (L.)) with a selected strain of *Bacillus subtilis var. natto*. Nattokinase activity (assay method as described by Takaoka, et al., 2010): 20 000 – 28 000 Fibrin degradation unit/g Identity: Confirmable Condition: No offensive smell or taste Loss on drying: ≤ 10 % Vitamin K2: ≤ 0.1 mg/kg **Heavy metals** Lead: ≤ 5.0 mg/kg Arsenic: ≤ 3.0 mg/kg **Microbiological criteria** Total viable aerobic count: ≤ 10^3 CFU (^{3})/g Yeast and mould: ≤ 10^2 CFU/g Coliforms: ≤ 30 CFU/g Spore-forming bacteria: ≤ 10 CFU/g *Escherichia Coli*: Absence/25 g *Salmonella*: Absence/25 g Listeria: Absence/25 g

5. Fermented black bean extract or Touchi extract, which is a protein-rich powder obtained by water extraction of small soybeans (Glycine max.) fermented with *Aspergillus oryzae*. This extract is typically produced from small soybean grown in the Sichuan province of China. *A. oryzae* is a well-established fungus employed in the production of soy sauce, sake and miso. The processing uses conventional processing techniques. In this case, it was the specific food being significantly different from existing foods, which was not used in the EU before 15 May 1997, that triggered the novel food status, not the source material and the fermentation.[108]

> The employment of new technologies in the production process can also alter the safe use assessment. For that matter, the production process should be described in detail in the novel food application to provide enough information that will serve for the basis for the evaluation of the bioavailability, nutritional value, and safety. The information incudes measures of production control and quality and safety assurance (e.g. HACCP, GMP, ISO) and standardisation criteria (chemical markers for the novel food). Key steps and parameters of the production process, including information on potential impurities, by-products, contaminants, operational limits should be described in detail. Flow chart of production process can be included as well, including quality and safety control checks. The applicant should inform in this respect whether a production process is novel and characterise the novel aspects of the process. Information should also be provided on the handling of the sources, for example, the propagation growth and harvesting conditions for fungi (e.g. wild or cultivated, time of harvest, cultivation practices which also include information on the use of pesticides, antimicrobials and antiparasitic agents). Post-harvesting handling, e.g. transport, drying techniques and storage

[108] 2011/497/EU: Commission Implementing Decision of 9 August 2011 authorising the placing on the market of fermented black bean extract as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

conditions (duration, light, moisture and temperature) of unprocessed foods and the raw material should be specified and information on other starting substances or materials. Culture conditions and growth medium should be specified. Also, it should be explained in detail how the raw material is conversed to an ingredient, or a preparation intended for a food product. Examples of processes may include heat treatment, extraction, distillation, squeezing, fractionation, purification, concentration, *fermentation*, chemical synthesis, enzyme-catalysis, or isolation from a natural source or others. Information on substances used in the manufacturing process, e.g. identity of the extraction solvents, ratio of extraction solvent to the material, reagents, residues, etc. should be provided.

It is also important to mention that fermentation plays an important role in the production of food enzymes which are dealt with in detail in at pages 66-68 of this report, however, they are excluded from the scope of the Novel Food Regulation. Although, the application for novel foods differs from the application for food enzymes, the EFSA's guidance concerning the data necessary of food enzymes safety assessments could, by analogy, also help in the preparation of the novel food dossier.

In the application for food enzymes in accordance with Regulation (EC) No 1331/2008, information on the fermentation stage of the production of the food enzymes should specify the type of the fermentation system used (e.g. continuous, (fed-) batch or solid state). A list of the raw materials contributing to the medium and reagents used for process control is required. For the raw materials which provide nitrogen and carbon sources in order to meet mineral and vitamin requirements or to control pH, only qualitative data is needed. Quantitative data may be required for medium ingredients of potential concern.[109]

Also, the need for data on chemical purity is determined by the nature of the fermentation process. Quantitative data should be provided on the concentration of medium ingredients added for purposes other than nutrition or pH control which may be carried over into the food enzyme.[110]

Also, any proteinaceous material with known allergic properties included in the fermentation medium must be considered in the assessment of potential allergenicity.

Also, for the testing strategy, samples from independent batches should be taken from industrial-scale process. Samples from pilot-scale process are acceptable if it can be justified that those from industrial process are not available. In this case, it should be documented that the pilot-scale process (fermentation) is representative of the industrial-scale process. [111]

[109] EFSA. Guidance of the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes for Safety Evaluation, available at: https://www.efsa.europa.eu/en/efsajournal/pub/6851.
[110] Ibid.
[111] Ibid.

The employed technology may further affect a novel food labelling, provided that the authorisation is successful. For example, UV treated mushrooms *Agaricus bisporus*, the designation on the label of the novel food as such or of the foodstuffs containing it shall be accompanied by indication that a controlled light treatment was used to increase vitamin D levels or UV treatment was used to increase vitamin D2 levels.

INFORMATIVE BOX #3 – Substantial equivalence of *Lentinula edodes* fruiting body and mycelium?

In the recent application for the novel food authorisation, the applicant submitted that the fermentation organism used to produce the novel food, *Lentinula edodes* is commonly consumed as food and *Lentinula edodes* fruiting body is substantially equivalent to the *Lentinula edodes* mycelia used in the fermentation of the pea and rice protein. Following fermentation, there is no live *Lentinula edodes* mycelia or fungal enzymes in the final novel food preparation as a result of multiple heat treatment steps and thermal deactivation.

The weight-of-evidence from reliable published toxicological and human clinical studies using the same or closely-related (e.g. *Lentinula edodes* mycelial extracts, reconstituted powdered *Lentinula edodes*) test materials as those components included in the novel food, support a conclusion that no adverse health effects are expected at dietary intake levels of the heat-killed *Lentinula edodes* mycelia which are estimated based on food uses proposed for the pea and rice protein fermented by Shiitake mycelia.

Agricultural By-Products as a Substrate

Interesting from the perspective of biomass fermentation with mycelium is the use of different substrates. Fermentation with mycelium as a fermentation agent need carbon sources for mycelia biomass formation. Biomass is developed by degrading sugars under optimal conditions, often using agricultural by-products, although in submerged fermentation, the conditions require greater precision than in solid state fermentation.[112] The crucial consideration is the conversation ratio between the carbon sources (sugars) and the final protein product. Mycelium can be used in the fermentation of grains (corn, wheat), legumes, apples, wood, sometimes in combination. An increasing number of companies avoid using soy substrate for environmental reasons. Also, a number of companies strive to optimise the production process in a way that the resulting biomass is minimally processed.

The choice of the substrate may fundamentally alter the characteristics of the final product. Many laboratory experiments and proofs of concept have been dedicated to that matter. Some companies focus on the purchase of high-

[112] Larissa de Souza Kirsch, Ana Júlia Porto de Macedo and Maria Francisca Simas Teixeira, 'Production of Mycelial Biomass by the Amazonian Edible Mushroom Pleurotus Albidus' (2016) 47 Brazilian Journal of Microbiology 658.

quality materials for the substrate. Metabolism of fungi may produce different composition of the final product.

Another important consideration is the product standardisation. The biochemical quality of side streams may differ substantially making it too challenging to arrive at stable product. It is necessary to consider the complexities of storage, sterilisation and the avoidance of contamination. Also, side streams have limited shelf life. For other companies, agricultural by-products used as a substrate should be avoided for marketing purposes.

For these purposes, one must bear in mind the requirements for the novel food application concerning the product stability:

- Stability test on preferably at least 5, representative, independently produced batches of the novel food.
    - Test duration has to cover at least the end of the novel food shelf-life
    - Stability tests need to be performed to identify hazards which arise during storage and transports. This entails any monitoring constituents and parameters susceptible to changes during storage and having direct effect on safety, and also to effects of packaging, temperature and the environment. Often, proposed conditions of use are not considered and addressed properly.[113]
- Characterisation of the nature of degradation products
- Information on normal storage conditions of the novel food as well as information on the storage conditions under which the stability test was performed
- Physicochemical stability of the novel food under normal conditions of storage
- Biochemical stability of the novel food under normal conditions of storage
- Microbiological stability of the novel food under normal conditions of storage
- If the novel food is used as an ingredient added to other foods, characterisation of the stability of the novel food in real food matrixes or in relevant model systems (e.g. effect of processing temperature, pH)
- Information on ingredients added to the novel food to improve stability, if relevant

For the inclusion of agricultural by-products in production processes, one must also consider general and specific hygiene requirements per Article 4 of Regulation (EC) No 852/2004 [114] on the hygiene of foodstuffs as well as applicable national laws and regulations. Agricultural or food by-products in general may be considered a contamination hazard and be subject to good hygiene practice. This is usually done in the process of sterilisation or pasteurisation.

Food business operators carrying out primary production and those associated operations (storage) shall comply with general hygiene provisions laid down in part A of Annex I and any specific requirements provided for in

[113] Webinar on Scientific Aspects to consider when preparing a Novel Food Application, held by Prof. Marina Heinonen Dr. Inge Mangelsdor. Available at: https://www.efsa.europa.eu/sites/default/files/170615-p01.pdf.
[114] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1–54

Regulation (EC) No 853/2004 [115] . Food business operators shall, as appropriate, adopt specific hygiene measures, such as the compliance with microbiological criteria for foodstuffs. [116] This may also impact the use of agricultural by-products in compliance with EU law.

Agricultural waste is not an agricultural by-product. Per Article 5 of Directive 2008/98/EC[117] on waste, Member States shall take appropriate measures to ensure that a substance or object resulting from a production process the primary aim of which is not the production of that substance or object is considered not to be waste, but to be a by-product if the following conditions are met:

(a) further use of the substance or object is certain

This means that it is guaranteed that the material will be used, e.g. to meet the needs of economic operators other than the economic operator which produced it.[118]

(b) the substance or object can be used directly without any further processing other than normal industrial practice.

Those treatment techniques that address typical waste-related characteristics of the production residue, such as its contamination with components which are hazardous or not useful, would prevent classification as non-waste. On the other hand, if a production residue is treated with normal industrial practice, e.g. modification of size or shape by mechanical treatment, it can be regarded as a by-product.

(c) the substance or object is produced as an integral part of a production process; and

(d) further use is lawful, i.e. the substance or object fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts.

These tests are cumulative. A decision on whether a particular substance or object is a by-product must in the first instance be made by the producer of the substance or object, together with the competent national authorities, based on the applicable national legislation transposing the Waste Framework Directive.

As for d), it is important to note that where an agricultural by-product is used as fermentation or cultivation substrate, and the resulting product requires a novel food authorisation, the by-product does not fulfil all preconditions in the absence of such an authorisation and would be likely considered waste. A

[115] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, OJ L 139, 30.4.2004, p. 55–205

[116]

[117] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312, 22.11.2008, p. 3–30

[118] European Commission, Guidance on the interpretation of key provisions of Directive 2008/98/EC on waste. Available at. http://waste-prevention.gr/waste/wp-content/uploads/2015/10/2012_Guidance%20interpretation%20Directive%2098-2008-EC_EN.pdf

producer of mushroom or mycelium products should verify whether the substrate supplier complies with the regulatory requirements for by-products.

Food Additives Provisions Applicable to Mushrooms and Mycelium Products

Key messages

In the EU food additives and flavourings are subject to specific conditions of use.

Natural flavourings are regulated at the EU level.

When MMP are used to produce food additives and flavourings an authorisation is required.

Processing aids are defined at the EU level but, unless otherwise specified, their use is regulated in Member States national legislation.

This Chapter concerns legal provisions applicable to food additives and flavourings used in MMP. Since additives and flavourings can be derived from mushrooms and mycelia, we analyse requirements for food additives production and commercialization. We also clarify the difference between an additive and a processing aid and the definition of food enzymes.

Food Additives and Flavouring Used in MMP

Grown mushrooms, either as fruiting bodies or mycelia can be consumed directly or processed further. Before marketing, however, MMP are treated for taste and aroma to appeal to consumers. Producers use "food additives" and "flavourings" to shape the raw material and enhance qualitative characteristics of their products.

Food Additives

Regulation (EC) No 1333/2008[119] on food additives (**FAR**) regulates food additives production and use. They are defined as:

"any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods;"[120]

According to the FAR, food additives shall, on the base of available scientific evidence, (1) pose no safety concerns at the level of use proposed; (2) serve a reasonable technological need that cannot be achieved in other ways, [121]

[119] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008, p. 16–33. (From here on: FAR)

[120] Ibid. Article 3(2)(a)

[121] Article 6(2) of the FAR specifies all the technological functions that food additives can serve, such as preserving the quality of the product, provide necessary ingredients or constituents for food manufactured for groups with special dietary

considering economic and technological considerations; (3) not mislead the consumer. Moreover, their use shall be set at the lowest level necessary to achieve the desired effect.[122]

Each food additive is linked to an E-number and is listed in the Annexes of the FAR. Annex II contains the "Union list of food additives approved for use in foods and conditions of use".

Which additives are permitted in MMP can be found in respective relevant food categories in Part E. The most relevant food categories are:

- *Category 0 - Food additives permitted in all categories of foods*[123]
- *Category 04 - Fruit and vegetables*
- *Category 12 – Salt, spices, soups, sauces, salads and protein products (sub-category 12.9 – Protein products)*
- *Category 13 - Foods intended for particular nutritional uses*
- *Category 14 - Beverages*
- *Category 15 - Ready-to-eat savouries and snacks*
- *Category 17 - Food supplements*

In principles, all food additives approved for these categories could be used in MMP preparations classified as such, unless otherwise specified. [124] When

needs, enhancing or ensuring the maintenance of the organoleptic properties, help in the processing, preparation, treatment, packing, transport or storage of the product.

[122] FAR. Article 11

[123] In relation to Category 0 restrictions for E 338-452 and E 551-559 are present. These additives can only be used in foods in dried powder form or tablet and coated tablet form, excluding the foods listed in Table 1 of Part A. The first category specified in Table 1 is "Unprocessed foods". Unprocessed foods are defined in article 3(2)(d) as: *foods which have not undergone any treatment resulting in a substantial change in the original state of the food, for which purpose the following in particular are not regarded as resulting in substantial change: dividing, parting, severing, boning, mincing, skinning, paring, peeling, grinding, cutting, cleaning, trimming, deep-freezing, freezing, chilling, milling, husking, packing or unpacking*. Simple mushrooms, cultivated or collected in the wild, and simple preparation prepared with or from them fall under the definition of unprocessed food. In MMP treated in a way other than the ones provided in the definition of unprocessed foods, the specified food additives are lawfully permitted, provided that all conditions set by the FAR are respected.

[124] Direct references to MMP are made for the following subcategories: 04.1.3- Frozen fruit and vegetables and 04.2.1 Dried fruit and vegetables in relation to additives E220-228 which can be used only for "*white vegetables including mushrooms and white pulses*"; 04.2.2 Fruit and vegetables in vinegar, oil, or brine for E 585 Ferrous lactate, which can be used only for "*mushroom Albatrellus ovinus used as a food ingredient in Swedish liver pâtés and olives darkened by oxidation*"; 04.2.3 Canned or bottled fruit and vegetables again for E 220-228 and E 585, for the same preparation as in the other subcategories, and E 385 Calcium disodium EDTA, to be used only with "*pulses, legumes, mushrooms and artichokes*" ; 04.2.4.1Fruit and vegetable preparations excluding compote also in relation to additives E 220-228 for "*only processed white vegetables and mushrooms*". In sub-category 12.9 references to meat analogues is made and the applicable exceptions must be kept into account.

MMP result in more complex preparations, the "carry over" principle shall also be taken into consideration.[125]

The classification of MMP in the various categories may be challenging since the FAR (Part D of Annex II) only list them by name, without further clarifications. The most efficient way to understand which products are covered by each category is to look at the specified "Restrictions/Exceptions".

Products obtained by processing of mushrooms (e.g. dried mushrooms) fall under *Category 04 - Fruit and vegetables* (see references made in the "Restrictions/Exceptions" of several sub-categories). One can also argue that products such as veggie burgers containing MMP would fall under *Category 12.9 – Protein product*, where "meat analogues based on vegetable origin" are mentioned. In additions, for MMP classified as novel foods, specifications of the novel food authorization may also help in finding the correct categories.

Food Flavourings

Regulation (EC) No 1334/2008[126] on flavourings and certain food ingredients with flavouring properties for use in and on food covers the production and use of flavourings in the EU. In MMP, flavourings can be employed provided that the conditions of use are respected. In Annex I of Regulation (EC) No 1334/2008, categories similar to the ones of food additives are used. The relevant categories that lists mushrooms specifically are:

- *4.2 - Processed fruit and vegetables*
- *12 - Salts, spices, soups, sauces, salads and protein products*
- *13 - Food intended for particular nutritional uses*
- *14.1 - Non-alcoholic beverages,*
- *15 Ready-to-eat savouries and snacks,*
- *17- Food supplements*

All flavourings approved for these Categories can be used.[127]

"Natural flavourings" are flavourings obtained by physical, enzymatic or microbiological processes from vegetables, animals or microorganisms, either

[125] Article 18 FAR introduces the "carry over" principle: The presence of a food additive shall be permitted: in a compound food (other than the ones referred to in Annex II), where the food additive is permitted in one of the ingredients. Same is valid for food enzymes and food flavourings, provided that all of them do not have technological function in the final food. Limits to the "Carry Over" principle are specified in Table 1 and Table 2 of Part A of Annex II.

[126] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC, OJ L 354, 31.12.2008, p. 34–50.

[127] The only direct reference to the use of flavourings in MMP is in Annex III "*Part B: Maximum levels of certain substances, naturally present in flavourings and food ingredients with flavouring properties, in certain compound food as consumed to which flavourings and/or food ingredients with flavouring properties have* been added": for the flavour 1-Allyl-4-methoxybenzene, Estragol there is a Maximum level mg/kg of 50 for Processed fruits, vegetables (incl. mushrooms, fungi …).

in the raw state or after processing under specified conditions.[128] There are no regulatory limits for their use. The requirements for the labelling of "natural flavouring" are also specified Regulation (EC) No 1334/2008.[129]

The start-ups we interviewed operate on both B2B and B2C markets. B2C companies prefer not to use food additives and flavourings in their products, particularly if they cannot be categorized as "natural". Contemporary marketing increasingly emphasizes the characteristics of raw materials in the communication about products which represent meat alternatives. These products are often highly processed; however, the new trend of preferring raw materials is the reflection of consumers' predilection for "clean" and "natural" products. This tendency is reflected in the debate on "clean labels" (see next Chapter).

Food Additives and Flavouring Derived from MMP

Food additives can be produced using mushrooms and mycelium. To be classified as such, they need to meet the food additive definition[130] and be

[128] Regulation (EC) No 1334/2008 (n 8). Article 3(2)(c) gives the definition of "natural flavourings", defined as flavourings *"obtained by appropriate physical, enzymatic or microbiological processes from material of vegetable, animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II. Natural flavouring substances correspond to substances that are naturally present and have been identified in nature".* Annex II therefore lists all traditional food preparation processes: Chopping, coating, cooling, Heating, cooking, baking, frying (up to 240 °C at atmospheric pressure) and pressure cooking (up to 120 °C), distillation, cutting, drying, emulsification, evaporation, extraction, grinding, infusion, maceration, mixing, peeling, percolation, pressing, refrigeration, pressing, roasting/grilling, squeezing, steeping but also microbiological processes and fermentation. The last two potentially gives the opportunity to derive "natural flavourings" from MMP.

[129] ibid. Article 16. In practice, the term 'natural' for the description of a flavouring may only be used if the flavouring component comprises only flavouring preparations and/or natural flavouring substances as defined in article 3(2)(c) (paragraph 2). The term '*natural flavouring substance(s)*' may only be used for flavourings in which the flavouring component contains exclusively natural flavouring substance (paragraph 3). The term 'natural' may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95 % by w/w from the source material referred to. The description shall then be read '*natural - food(s) or food category or* source(s) - *flavouring'.* (paragraph 4). The term 'natural - *food(s) or food category or source(s) - flavouring with other natural flavourings*' may only be used if the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised. (paragraph 5). Finally, the term '*natural flavouring'* may only be used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste. (paragraph 6)

[130] As seen, the definition of food additives set three specific conditions: the food additive shall not be normally consumed as a food itself, it shall serve a specific technological purpose, it is reasonable expected to be present as a component, directly or indirectly, in the final product.

approved under Regulation (EC) No 1331/2008[131] establishing a common authorisation procedure for food additives, food enzymes and food flavourings.[132] Similarly to novel foods, the authorization procedure reflects a risk analysis approach, with a risk assessment conducted by the scientific authority (EFSA) and the final authorization adopted by the Standing Committee on Plants, Animals, Food and Feed in the so-called comitology procedure.[133] Food additives are then classified in one or more functional classes of Annex I of the FAR.[134] MMP added to foods with nutritional purposes e.g. to increase the protein content of a drink and/or a snack, are not considered food additives.[135]

Annex I of the FAR lists the functional classes in which food additives are divided according to their uses. Classes (1) 'sweeteners',[136] (2) 'colours'[137] and (14) 'flavour enhancers'[138] are particularly interesting for food additives

[131] Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, OJ L 354, 31.12.2008, p. 1–6.
[132] Regulation (EC) No 1331/2008 sets the rules for updating Annexes II and III of the FAR, which list all approved food additives. The authorisation procedure mirrors other authorisation procedure in the EU e.g. novel foods. It can be initiated by the Commission or by an applicant and it is based on risk analysis, consisting in a risk assessment phase, conducted by EFSA on the base of the information present in the application, and on a risk management phase, with the final decision taken by the Standing Committee on the Food Chain and Animal Health on the proposal of the Commission.
[133] For an overview of the common authorization procedure: Common Authorisation Procedure , https://ec.europa.eu/food/safety/food-improvement-agents/common-authorisation-procedure_en
[134] Article 9 of the FAR further specifies that "allocating a food additive to a functional class shall not preclude it from being used for several functions", but the classification must be based on the principal technological function.
[135] FAR. Article 2(c).
[136] FAR. Annex I. Sweeteners are defined as "substances used to impart a sweet taste to foods or in table-top sweeteners". Article 7 FAR specifies that a food additive can be classified as sweetener only if it replaces sugars for the production of energy-reduced food, non-cariogenic food or food with no added sugars; or/and if it replaces sugars where this permits an increase in the shelf-life of the food; or/and it is used to produce food intended for particular nutritional uses, meaning "*foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability*."
[137] Ibid. Colours are defined as "substances which add or restore colour in a food, and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other edible natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of this Regulation". Article 8 specifies that colours shall restore the original appearance of food of which the colour has been affected by processing, storage, packaging and distribution, whereby visual acceptability may have been impaired; making food more visually appealing; giving colour to food otherwise colourless.
[138] Flavouring are added to impart or modify the flavour of a food (see the definition, article 3(2)(a) of Regulation (EU) 1334/2008), flavour enhancers simply increase the existing taste and/or odour and there are defined as: "substances which enhance the existing taste and/or odour of a foodstuff".

obtained from MMP, such as pigments or bitter blockers. It is important to note that MMP added to foods as nutrients are not food additives but simple food ingredients.[139]

Whenever there is a significant change in the production process or in employed starting materials of a food additive, a new authorisation is needed before placing the additive on the market.[140] Whenever MMP are innovatively used to produce an existing food additive, a new authorisation is required.[141] Food additives consisting, containing or produced from Genetically Modified Organisms (GMOs) should be authorised by both Regulation (EC) No 1829/2003[142] on genetically modified food and feed and the FAR.

The same reasoning applies for the authorisation of flavourings obtained from MMP, which also follow the provisions of Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

The Use of Processing Aids and Food Enzymes

In the FAR a processing aid is defined as a substance which:

(i) is not consumed as a food by itself;

(ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and

(iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;[143]

There are two differences between an additive and a processing aid. First, for processing aids the technological purposes are restricted to treatment and processing. Second, processing aids do not become a "component" of the final product. Only the technically unavoidable presence is acceptable and must not have a technological effect on the final product, in addition to not posing any risks to human health.

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[139] FAR. Article 2(c).
[140] FAR. Article 12
[141] The production methods to obtain food additives are not specified in the Annexes of the FAR, so there is no way to find out how many food additives are currently obtained by MMP.
[142] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, p. 1–23.
[143] FAR. Article 3

The use of processing aids is not regulated at the EU level but by national legislation.[144] Processing aids do not need to be labelled.[145]

Food enzymes may be products obtained from fungi or products thereof including a product obtained by a fermentation process using fungi. These products contain one or more enzymes capable of catalysing a specific biochemical reaction and they are added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods.[146] Food enzymes are currently regulated by national rules on the marketing and use of food enzymes and food produced with food enzymes. This will be the case until the Union List of approved food enzymes is established in accordance to Article 4 of Regulation (EC) No 1332/2008.[147]

Article 17 of Regulation 1332/2008 established a period (11 September 2011 to 11 March 2015) during which enzyme application were submitted to the Union List. Over 300 food enzyme applications were received. The Commission establishes a Register of all food enzymes' applications to be considered for inclusion in the first Union List. This register contains several food enzymes using fungi strains, such as *Aspergillus niger, Aspergillus oryzae, Trametes hirusta, Candida cylindracea, Hansenula polymorpha, Mucor javanicus* and others.

Fungi-derived enzymes can be potentially used to improve performance of alternative proteins by modifying their structure into better texture.[148]

The EFSA is mandated to establish safety of a food enzyme but in the safety assessment is not on the enzyme preparation. In October 2021, the EFSA published an updated Guidance on the Submission of a Dossier on Food Enzymes which is supposed to assist applicants in the preparation and presentation of dossiers for the safety evaluation of food enzymes.[149]

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[144] 'Food Additives' (*United States Mission to the European Union*), available at: <https://www.usda-eu.org/trade-with-the-eu/eu-import-rules/food-additives/>; DGCIS, 'Processing Aids' <https://www.entreprises.gouv.fr/files/files/directions_services/free-movement-goods/Processing-aids.pdf>; USDA, 'Food and Agricultural Import Regulations and Standards Country Report'.

[145] Food Safety Authority of Ireland, 'Labelling Requirements | Additives | FAQs |' available at: <https://www.fsai.ie/faq/additives/labelling_requirements.html>.

[146] Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 OJ L 354, 31.12.2008, p. 7–15. Article 3(2)

[147] The full Register can be accessed here: <https://ec.europa.eu/food/system/files/2020-06/fs_food-improvement-agents_enzymes_register.pdf>.

[148] Katy Askew. "Feeding plant-based innovation: 'Fermentation is the future of the alternative protein industry'". Food Navigator (2020). Available at: <https://www.foodnavigator.com/Article/2020/04/30/Feeding-plant-based-innovation-Fermentation-is-the-future-of-the-alternative-protein-industry>.

[149] EFSA. Guidance of the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food

The EFSA provides a detailed guidelines on the application for food enzymes that are of microbial origin. It explicitly includes filamentous fungi and yeasts in this category. To characterise these microorganisms, it is recommended to use whole genome sequence (WGS) analysis, including chromosome and extrachromosomal genetic elements, e.g. plasmids. According to the EFSA, "WGS data provide information for the characterisation of the strains regarding their functional traits of concern (e.g. virulence factors, production of or resistance to antimicrobials of clinical relevance of clinical relevance, production of known toxic metabolites)". Each microorganism should be cultivated before DNA extraction as a pure culture (for fungi, monosporic where possible). Total DNA should be extracted and subjected to WGS analysis according to an adequate protocol.

Different sequencing strategies can be employed. The sequencing reads can be also de novo assembled and annotated or mapped to a reference genome/database. If so, de novo assembly, including assembler software, version and parameters. For yeasts and filamentous fungi, contigs, (a series of overlapping DNA sequences used to make a physical map that reconstructs the original DNA sequence of a chromosome or a region of a chromosome) should be < 1,000. If a higher number of contigs is produced, a justification should be provided.

For yeasts and filamentous fungi genomes, the number of highly conserved genes, such as Benchmarking Universal Single-Copy Orthologs (BUSCO) genes, present in the assembly should be reported since this parameter indicates the completeness and quality of the assembly.[150] Ideally, > 90% complete matches to BUSCO gene set from the most closely related group of yeasts/filamentous fungi should be present in the assembly.

When WGS is available, taxonomic identification should be made by phylogenomic analysis (e.g. using a concatenation of several conserved sequences (e.g. Assembling the Fungal Tree of Life genes including 18S rDNA/ITS) to produce a phylogeny against available related genomes) or by alignment to a complete reference genome from the same species. When WGS is not available, identification may be made by comparing the 18S rRNA gene and/or internal transcribed spacer (ITS) regions and other characteristic genes (e.g. tubulin) with sequences deposited in databases.

The nomenclature and taxonomy of fungi, including yeasts, is covered by the International Code of Nomenclature for algae, fungi and plants (ICN). Applicants are referred to the website Mycobank.[151]

If the strain is genetically modified according to the definition in Directive 2001/18/EC, the genetic modification should be described. The characterisation of the structure of the genetic modification should be done using WGS data for yeasts and is recommended for filamentous fungi. For

Enzymes for Safety Evaluation, available at: https://www.efsa.europa.eu/en/efsajournal/pub/6851.

[150] See https://busco.ezlab.org/.

[151] See https://www.mycobank.org/.

filamentous fungi for which WGS is not available, all the steps to obtain the genetic modification should be described in order to identify all genetic material potentially introduced into the recipient/parental microorganism.

As for food enzymes, filamentous fungi and yeast, the guidance includes detailed requirements on microbiological purity. Where possible presence of compounds of known toxicity (e.g. mycotoxins) arising from the fermentation is indicated by literature searches or WGS analysis of the production strain, the applicant should determine the concentration of these compounds in the food enzyme. Filamentous fungi and yeast should not exceed 100 CFU/g in the food enzyme measured according to the prescribed standard.

This approach could also be possible to use in the applications in accordance to the Novel Food Regulation.

INFORMATIVE BOX #5 - UV light treatment in MMP

UV treated mushrooms of the species *Agaricus bisporus* were granted authorization as novel foods.[1] The UV treatment of the mushrooms increase their Vitamin D content. Consequently, it is likely that whenever MMP are treated with UV rays, they would result in a novel food under the EU legal framework. Among the interviewed start-ups, none of them uses UV rays in their products and almost all of them expressed little interest in the technique.

Labelling of Mushrooms and Mycelium Products

Key messages

In the EU "food information" is a broader concept than the simple label. It covers a product's accompanying material and any other technological means or verbal communication.

Information is mandatory or voluntary.

In labelling of MMP, using descriptive names is recommended.

Nutrition and health claims must respect sever conditions of use.

There is no legal definition of vegan and vegetarian.

The organic certification is harmonized at the EU level.

Voluntary information on sustainability aspects are regulated by private standards.

This Chapter clarifies which information must be offered to consumers in relation to MMP. First, we elaborate on how MMP shall be named, particularly when derived from mycelium, and we identify which mandatory information must be indicated on the labels. Afterwards we focus on the use of health and nutrition claims. Finally, we provide an overview of other voluntary information that food businesses might be willing to provide, starting with the concept of clean labelling and then looking into the definition of vegan/vegetarian, the organic certification requirements, and the role of voluntary sustainability standards.

Labelling Requirements for MMP

Considering the critical role of information to consumers, labelling of MMP is one of the most challenging aspect of compliant marketisation for this new industry.

Regulation (EU) No 1169/2011 on the provision of food information to consumers establish the mandatory requirements for food labelling in the

EU.[152] Under the Regulation, the following mandatory particulars must be provided to the consumers:[153]

1) Name of the food
2) List of ingredients
3) Any ingredients derived from substances which might cause allergic reaction, present in the manufacturing of the product and still present in the food even in altered form[154]
4) Quantity of certain ingredients and categories of ingredients
5) Net quantity of a food
6) Date of minimum durability and "use by" date
7) Special storage conditions and/or condition of use
8) The name of the business name and address of the food business operator responsible for the food information
9) Country of origin or place of provenance, when required[155]
10) Instructions for use when not immediately understandable
11) Nutrition declaration

When providing mandatory particulars, but also voluntary indications to consumers, the definition of food information must be considered. In the EU, food information covers not only the label but also other accompanying material and any other technological means of communication or verbal communication to consumers.[156]

[152] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ L 304, 22.11.2011, p. 18–63. (hereafter: FIR)

[153] ibid. Article 9(1). In addition to the ones listed, the alcoholic strength is also mandatory for alcoholic beverages.

[154] Regarding allergen indications, Annex II of Regulation (EU) 1169/2011 lists 14 allergens that must be indicated in the label of a food products. Mushrooms are not in the list. In general, companies working on MMP tend to claim an absence of allergens in their products. It is always wise to support such claims with appropriate studies. Although not being considered of high-level risks, allergic reactions from mushrooms might still occur. If a substantial risk is identified during the novel food application, labelling might be required among the Conditions of Use.

[155] The country of origin is required where failure to indicate this might mislead the consumer as to the true country of origin or place of provenance of the food, in particular if the information accompanying the food or the label as a whole would otherwise imply that the food has a different country of origin or place of provenance and when the country of origin or place of provenance of the primary ingredient is different than the one associated to the food by means of food information.(Article 26(2)(a) of Regulation (EU) No 1169/2011). For more information see the website of the European Commission "Origin Labelling": https://ec.europa.eu/food/food/labelling-and-nutrition/food-information-consumers-legislation/origin-labelling_en

[156] Regulation (EU) No 1169/2011. Article 2(2)(b)

Food information shall not be misleading as regards the characteristics of the food[157] and shall be accurate and easy to understand.[158] The responsibility of providing the correct information lays on the food business operator under whose name the product is marketed or imported in the EU.[159]

When assessing whether the information given to the consumers is misleading or not, the so-called "average consumer" benchmark is employed. Derived from CJEU case law, the definition of average consumers stipulates that a consumer shall be reasonably well informed and reasonably observant and circumspect.[160] This means that in the EU, consumers are expected to read the label and understand it, in particular considering the list of ingredients. Recent court cases have however widened the concept. Alone, a precise list of ingredients is no more considered enough to balance the general feeling derived from a label.[161]

Correct denomination of MMP

The correct labelling of MMP can be challenging. Commonly consumed mushrooms are labelled with the name of mushroom species or the generic name under which consumers know them, or both. For example, shiitake mushrooms can be labelled as "Shitake mushrooms" or as "*Lentinula edodes*" or both.

When it comes to processed products, the situation is different. First of all, the legal name of the food may differ from the marketing name of the product. The marketing name of the product is the denomination chosen by the company for marketing reasons, while the legal name of the food provides information on the actual nature of the product. The legal name of the food cannot be substituted by the name of the product,[162] shall be displayed on the label and shall either be its name as prescribed by the law (e.g. the name "milk chocolate" is regulated at the EU level[163]), a customary name, comprehensible to the

[157] ibid. Article 7(1), which states that "*Food information shall not be misleading as regards to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production; identify, composition, properties, by suggesting that the food possesses characteristics that are common to all similar foods, by attributing effects that do not exist, by suggesting the presence of a particular ingredients when it is not present*"
[158] ibid. Article 7(2)
[159] ibid. Article 8
[160] *C-210/96 - Gut Springenheide and Tusky v Oberkreisdirektor des Kreises Steinfurt* [1998] Court of Justice of the European Union ECLI:EU:C:1998:369 96. Paragraph 37; *C-470/93 - Verein gegen Unwesen in Handel und Gewerbe Köln v Mars* [1995] Court of Justice of the European Union ECLI:EU:C:1995:224. Paragraph 24;
[161] *C-195/14 - Teekanne* [2015] Court of Justice of the European Union ECLI:EU:C:2015:361. Paragraphs from 39 to 44.
[162] Regulation (EU) No 1169/2011. Article 17(4)
[163] Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption, OJ L 197, 3.8.2000, p. 19–2. Annex I.

consumers without being misleading (e.g. caesar salad), or a descriptive name (e.g. baked bread with ham and cheese).[164]

As an example, a veggie soup containing mushrooms might bear the marketing name "Farmer´s life" while the legal name would be a descriptive one, like "Soup made with vegetables, barley, potatoes and mushrooms" since there is no legal definition or customary denomination for such a soup. In the list of ingredients, the specific mushroom must be indicated, and it is recommended to use both the scientific and the generic name of the species.

The same would theoretically apply for mycelium products. However, such products trigger the Novel Food Regulation requirements. The legal names, the correct wording for the list of ingredients and other specific labelling requirements e.g. claims alerting consumers of potential allergenic reactions, will all be specified in the authorisation.

Our interviewees are divided in two groups on how they label mycelium products, both as regards the legal names and the list of ingredients. Biomass producers tend to prefer wordings such as "mycelium of … (generic name and/or scientific name of the species)" or "fungal mycelium of ... (generic name and/or scientific name of the species)". Start-ups which instead focus on the production of proteins, further processing the mycelium's biomass, generally employ the term "mycoprotein"[165] or a more generic description, such as "protein extracted from mycelium biomass of ….".

Plant based or fungi based?

The companies we interviewed are interested in using the wording "plant based" for marketing names of the products and in descriptive legal names. At the moment, there is no legal definition of the claim "plant-based" under EU law. The claim is widely employed for the labelling of meat alternatives. Considering that consumers shall have the opportunity to make an "informed choice", one might say that MMP are not "plants" since they are part of the kingdom "Fungi" and not "Plantae". It might be possible to argue that an average consumer looking for a meat alternative does not necessarily have a specific knowledge of biology, neither he/she has an interest in it. He/she is instead focusing on the purchase of products that do not contain animal derivates. Therefore, the term "plant based" could be used in the labelling of MMP.[166] However, there could be also an opposing view according to which,

[164] ibid. Article 2(2)(m)(n)(o) specify the definitions of legal name, customary name and descriptive name. Article 17 illustrates the rules to correctly name the food.
[165] The term "mycoprotein" is already used in the EU and the US by recognized brands, but US authorities required a more complete indication of what it pertains, after cases of allergic reaction (see Gaynor Selby, 'Quorn Explains Mycoprotein "Mold" Origin as US Labeling Case Is Settled', available at : *foodingredientsfirst.com/* <https://fif.cnsmedia.com/a/hSeo1yBC37Q=>). Considering the EU policy on food information, it is likely that the same might happen in the future in the EU, with the growth of the market.
[166] Despite the prohibition of using dairy-related words for plant products resembling dairy products (e.g. soy milk), the European Parliament has recently clarified that wording like "veggie burgers" or "plant based sausages" are still permitted. See European Parliament, 'Are Veggie Burgers, Tofu Steaks or the Use of

fungi and plants are strictly separated, and therefore, the use of the term "plant based" for fungi products could be considered misleading. In that case, a wording like "fungi based" or "mushroom based" seems more suitable to avoid any possible confusion on the part of the consumer.

NUTRITION AND HEALTH CLAIMS

In addition to the mandatory information, EU food law allows food businesses to offer consumers voluntary information, such as nutrition and health claims.

Per Regulation (EC) No 1924/2006[167] on nutrition and health claims, "claim" means any message or representation which is not mandatory under EU law, including graphic, pictorial or symbolic representation which imply that a product has some particular characteristics.[168] This entails not only the label of the product but also advertisement materials, webpages or TV spots.[169]

Nutrition and health claims are two separate types of claims. Nutrition claims focus on the nature of the products, while health claims are based on the effects the products have. In other words, nutrition claims are related to the product composition from a nutritional point of view, e.g. "high in protein".[170] Health claims instead imply a connection between the product composition and health. For example, the claim "essential fatty acids are needed for normal growth and development of children".[171] Health claims must not suggest that a human disease is treated cured or prevented by eating a food.

Authorized nutrition claims are listed in the Annex of Regulation (EC) No 1924/2006. Anyone can use them, provided that their products meet the specified conditions. A product can bear the claim "high in protein" if 20% of its energy value is provided by protein, while the claim "high in fibre" requires at least 6 g of fibre per 100 g of product, or at least 3 g of fibre per 100 kcal. Health claims instead shall be authorized first, [172] and be included in the Union Register, where the conditions of use are specified.[173] In addition, health claims

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Yogurt Pots Going to Be Banned? | News | European Parliament' <https://www.europarl.europa.eu/news/en/press-room/20201019BKG89682/eu-farm-policy-reform-as-agreed-by-the-parliament-and-council/7/are-veggie-burgers-tofu-steaks-or-the-use-of-yogurt-pots-going-to-be-banned>.

[167] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404, 30.12.2006, p. 9-25

[168] ibid. Article 2(2)(1)

[169] ibid. Article 3. "*Claims cannot be false, ambiguous or misleading, raise doubts about the safety and nutritional adequacy of other foods, encourage or condone the excess consumption of an food, imply that a balanced diet does not provide all necessary nutrients and refer to bodily functions to exploit consumers´ fears*".

[170] ibid. Article 2(2)(4)

[171] ibid. Article 2(2)(5). There are three types of health claims: function health claims, (article 13) reduction of disease risk claims Article 14(1)(a), claims referring to children's development and health Article 14(1)(b)

[172] ibid. Article 15, 16, 17

[173] Ibid. Article 20(2). The EU Register for Nutrition and Health claims can be found at the following link: https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event

shall always be accompanied by other mandatory particulars.[174] For example, "Betaine contributes to normal homocysteine metabolism" can only be used for food which contains at least 500 mg of betaine per quantified portion and shall bear the indications: "the beneficial effect is obtained with a daily intake of 1,5 g of betaine" and "a daily intake in excess of 4 g may significantly increase blood cholesterol levels".

Nutrition and health claims could be theoretically made only on those foods that meet a nutrient profile awaiting to be prepared by the European Commission under Regulation (EC) No 1924/2006.[175] Nutrient profiles were supposed to avoid the use of nutrition and health claims on products matching their conditions of use but otherwise categorised as unhealthy. However, such nutrient profiles have never been presented.

All companies we interviewed showed interest in nutrition and health claims, and almost all of them already use such claims in their websites and advertising materials. B2B companies should consider that their customers might require evidence to substantiate nutrition and health claims in the final products.

Clean Labels and Voluntary, Indications

Clean labels are increasingly important for consumers.[176] Clean labels are labels which ideally lists only a few, recognizable ingredients prepared using traditional processes. They reflect the consumers´ rejection of highly-processed products with dozens of ingredients, colourants, aromas and flavourings identified with strange numbers or long chemical names. In the broadest sense, clean labels are the reflection of changes in perception which affected consumers, particularly in developed countries, and the increased interest for healthy, natural and sustainable products.[177] In practice, clean labels give consumers a feeling that a food they are consuming is free of those components that, in their perception, makes it unnatural and unhealthy.[178] Examples of clean labels include "No GMOs", "Made with all natural

=register.home. Health claims authorised on the basis of proprietary data are recorded in a separate Annex to the Register: https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=getListOfPropClaims

[174] Regulation (EC) No 1924/2006 (n 22). Article 10(2). In particular, a statement on the importance of a varied and balanced diet and a healthy lifestyle, the quantity of the food and the pattern of consumption required to obtain the beneficial effect; a statement addressed to persons who should avoid the food, if applicable; an appropriate warning for products that are likely to present a health risk.

[175] ibid. Article 4(1)

[176] Flora Southey, '"Mega Trends" in Clean Label Revealed: "It's What's Not on the Label That's Important"' *Food Navigator* , available at: <https://www.foodnavigator.com/Article/2020/11/26/Mega-trends-in-clean-label-revealed-It-s-what-s-not-on-the-label-that-s-important>.

[177] Daniele Asioli and others, 'Making Sense of the "Clean Label" Trends: A Review of Consumer Food Choice Behavior and Discussion of Industry Implications' (2017) 99 Food Research International 58.

[178] ibid.

ingredients", "Free from palm oil", "Eco Friendly", "Local", "Like your grandma used to make it" could be classified as such.

There is no mandatory obligation to have a "clean" label. However, during our interviews, we noticed a strong interest in voluntary indications which reflect the clean labelling trend and might play a role in the future marketing of MMP.

Vegan/vegetarian

There is no legal definition of "vegan" and "vegetarian" in EU law,[179] despite stakeholders lobbying for it.[180] Some Member States define "vegan" or "vegetarian" in their national legislation.[181] In the absence of legal definition, private bodies provide independent certification for vegetarian and vegan products, via associations like the European Vegetarian Union.[182]

As all claims, vegan/vegetarian claims, even if certified by a private entity, are subject to general labelling rules, namely that they must not be misleading and must respect all applicable provisions, including national rules. In other words, provided that EU and national rules are respected, and information is not false, ambiguous or misleading, food businesses can freely label their products as vegan and vegetarian.

MMP may be considered vegetarian whenever they are not accompanied by or contain ingredients derived from meat, and vegan if they are free from every ingredient of animal origin. However, production processes, the use of additives, possible contaminations must all be taken into account, as it is specified for example in private standards developed by the European Vegetarian Union.[183]

The ideal path to label products as vegan/vegetarian is to work with recognized partners and seek appropriate certification under trustworthy private schemes like the European Vegetarian Union or Vegan Action. Evidence must be appropriately recorded to prove that the claims are not misleading.

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[179] Neli Sochirca, 'The European Legal Framework on Vegan and Vegetarian Claims' (2018) 13 European Food and Feed Law Review 514.
[180] Niamh Michail, 'EU to Set Legal Definition of Vegetarian and Vegan Food' *Food Navigator,* available at: <https://www.foodnavigator.com/Article/2017/11/03/EU-to-set-legal-definition-of-vegetarian-and-vegan-food> .
[181] Germany was the first EU country that defined vegan/vegetarian: Ministerium für Klimaschutz, Umwelt, Landwirtschaft, Natur- und Verbraucherschutz des Landes Nordrhein-Westfalen (2016) Definitionen vegan-vegetarisch. For an analysis of the German law, see Marielle Gerke and Meike Janssen, 'Vegan Foods: Labelling Practice' (2017) 64 Ernährungs Umschau 51.
[182] European Vegetarian Union, 'V-Label', available at: <https://www.euroveg.eu/v-label/>.
[183] European Vegetarian Union, 'Definitions of "Vegan" and "Vegetarian" in Accordance with the EU Food Information Regulation', available at: <https://www.euroveg.eu/wp-content/uploads/2021/02/072019_EVU_PP_Definition.pdf>.

Organic certification and labelling

Organic production is regulated by Regulation (EU) No 848/2018 [184] on organic production and labelling of organic products. [185] It is defined as an agricultural method that aims to produce food using natural substances and processes, [186] minimizing the environmental impact and encouraging the responsible use of soil, water and resources, the protection of biodiversity and the preservation of ecological balance.[187]

If production requirements set by Regulation (EU) No 848/2018 are respected throughout the entire supply chain, [188] and businesses are certified by accredited control bodies and authorities, the organic logo can be used on the packaging of products.[189] If MMP companies desire to be certified as organic, the production should follow the provisions specified in the Annexes of the Regulation (EU) No 848/2018.[190]

Organic production must take place on the soil and therefore innovative production systems as vertical farming cannot be certified as such.[191] The use of substrates for mushroom production is permitted as long as these substrates are organic and respect certain conditions. [192] In the case of

[184] Regulation (EU) No 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007, OJ L 150, 14.6.2018, p. 1–92.
[185] European Commission, 'The Future of Organics', available at: <https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/future-organics_en>. The Regulation should have become applicable starting 1 January 2021 but its implementation was postponed for one year due to the Covid 2019 situation.
[186] European Commission, 'Organics at a Glance', available at; <https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/organics-glance_en> .
[187] Regulation (EU) No 2018/848. Article 4, 5
[188] ibid. Article 2(2)
[189] ibid. Article 33. The logo can only be used on products if they contain at least 95% of organic ingredients and additionally respect further strict conditions for the remaining 5%. The same ingredient cannot be present in organic and non-organic form. Single ingredients can still be labelled as organic, only in the list of ingredients, if the organic percentage is in total less than 95% (Article 30). Following the same approach held for information and claims, a product is considered to be labelled as organic if specific terms or wording e.g. bio are used, either on the labels or in every other accompanying materials.
[190] ibid. Annex II Part I specifies rules applicable to Plant Production, the category under which MMP would fall. In particular see Section 2.1, in which requirements applicable to the substrates for mushrooms´ production are specified.
[191] Politico, 'Vertical Farming's Sky-High Ambitions Cut Short by Eu Organic Rules', available at: <https://www.politico.eu/article/vertical-farming-eu-organic-rules-startups/>.
[192] Regulation (EU) No 2018/848. Annex 2.1. Rules on mushroom production For the production of mushrooms, substrates may be used if they are composed only of the following components: (a) farmyard manure and animal excrement: (i) either from organic production units or from in-conversion units in their second year of conversion; or (ii) referred to in point 1.9.3, only when the product referred to in point (i) is not available, provided that that farmyard manure and animal excrement do not exceed 25 % of the weight of total components of the substrate, excluding the covering material and any added water, before composting; (b) products of agricultural origin, other than those referred to in point (a), from organic production

companies which employ such organic substrates and then sell the final product as organic, it is important to work with trustworthy suppliers, keep records of certification and certify the final product. The same is valid for those companies which acquire organic-processed mushroom and mycelium from third parties to include them in their own final products.

In relation to MMP, the most important aspect to consider is whether start-ups producing biomass by mycelium fermentation can satisfy the production rules for processed food under Article 16 of Regulation (EU) No 2018/848. First, it is unclear whether fermentation of hydrocarbon-based substrates with mycelium is to be considered food processing. The General Food Law distinguishes between production, processing and distribution of food.[193] It does not define food processing, however, primary production is defined as the production, rearing or growing of primary products including harvesting, milking and farmed animal productions prior to slaughter. This also includes hunting and fishing and the harvesting of wild products. This would mean that mushroom picking and production would be considered primary production. However, the position is not clear as regards mycelium fermentation. If mycelium fermentation is to be classified as food processing, on the other hand, detailed production rules for organic processed food set out in Part IV of Annex II of Regulation (EU) No 2018/848 would apply. These rules prescribe that "*in the processing of food, preparations of microorganisms and food enzymes normally used in food processing may be used, provided that food enzymes to be used as food additives have been authorised pursuant to Article 24 for use in organic production*". It is debatable whether fungal mycelium of different fungal strains belong to microorganisms normally used in food processing or whether it can be categorized as microorganism at all.

The organic market in the EU is continuously growing.[194] When seeking for the certification, some aspects need to be considered. First of all, genetically modified organisms are prohibited in organic production and only approved additives, flavourings and processing aids can be used.[195] Second, a conversion period to modify production processes from conventional to organic is granted to food business operators willing to engage with organic production.[196] Finally, Regulation (EU) No 848/2018 terminates all recognitions of equivalences previously granted to 'organic' labelling schemes in third countries and requires compliance with EU rules for organic products imported from third countries.[197] This is particularly relevant for organic

units; (c) peat, not treated with chemical products; (d) wood, not treated with chemical products after felling; (e) mineral products referred to in point 1.9.3, water and soil.

[193] Article 3, point 2.

[194] IFOAM, 'European Organic Market Grew to €45 Billion in 2019', available at: <https://www.organicseurope.bio/content/uploads/2021/02/fibl-press-release-EUROPE-2021-02-17-english-FINAL.pdf?dd> .

[195] Regulation (EU) No 2018/848. Article 5 (iii) and Article 16. GMOs for veterinary use are permitted.

[196] ibid. Article 10

[197] ibid. Article 45 to 49. Under the previous organic regulatory framework, recognition to other organic certification systems in third countries was easily

producers of MMP planning to export their products to the EU and sell them as organic.

Voluntary Sustainability Labels

Voluntary Sustainability Labels **(VSL)** are defined as "*rules that producers, traders, manufacturers, retailers or service providers may be asked to follow so that the things they make, grow or do don't hurt people and the environment. These standards help keep workers healthy and safe, protect communities and land, and uphold human rights, as well as moderating the environmental impacts of production and consumption*."[198]

At the moment, labelling of sustainability indications is not harmonised. Regulation of sustainability labels rely largely on existing EU competition and internal market law.[199] The EU Commission is expected to bring forward a proposal for a front-of-pack labelling scheme which will include information on the sustainability of food products by 2022.[200]

Currently, VSL are based on standards developed by private entities, e.g. industry consortium, consumer associations or private citizens initiatives. VSL aim at raising the market value of products, filling a legislation gap and meeting consumers' demands.[201] They reflect a general commitment to certain product features, such as social equity and environmental protection.

The power of VSL lies in the impact of their logo, which can be placed on the product when a standard's provisions are respected. The more a VSL is recognizable by consumers, the more value it has. However, the choice of VSL must also consider that consumers negatively respond to an overload of stimuli: it is better to have one, recognized logo on the label than a few symbols

granted. As a consequence, organic producers in a third country could import in the EU and label their product as organic if they were certified as such in the country of origin. All these recognitions expire in 2022. This means that either a new recognition agreement is reached, or producers in third countries will have to comply with Regulation (EU) No 848/2018 and be certified by control bodies recognized by the EU.

[198] UNFSS, 'United Nations Forum on Sustainability Standards' available at: <https://unfss.org/>.

[199] Hanna Schebesta, "Control in the Label: Self-Declared, Certified, Accredited?" in: Peter Rott (ed.), Certification – Trust, Accountability, Liability (Springer, 2019), 143 (145).

[200] Gerardo Fortuna, 'Food Labelling Proposal Will Be Data-Led, Commission Says' (2021), available at: *www.euractiv.com* <https://www.euractiv.com/section/agriculture-food/news/food-labelling-proposal-will-be-data-led-commission-says/>.

[201] Alessandro Monaco, 'Nagoya Protocol and Private Standards' (Wageningen University & Research 2020) <https://edepot.wur.nl/517207?_ga=2.161734207.229147649.1627633856-103920773.1622532635>.

that could confuse customers.[202] Suitable options can be found in databases collecting all existing VSL private certification schemes.[203]

[202] Sun-Jung Moon, John P Costello and Dong-Mo Koo, 'The Impact of Consumer Confusion from Eco-Labels on Negative WOM, Distrust, and Dissatisfaction' (2017) 36 International Journal of Advertising 246. VSL themselves, in order to avoid such effects, tend to merge to increase their impact. See for example: Rainforest Alliance, 'The Rainforest Alliance and UTZ to Merge, Forming New, Stronger Organization', available at: <https://www.rainforest-alliance.org/articles/rainforest-alliance-utz-merger>.

[203] As an example, see the International Trade Centre 'Standards Map' <https://standardsmap.org/> To be included in the Standards Map, standards need to address at least one of the pillars of sustainable development (social, environmental or economic), have to present a published set of criteria and an implementation system.

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