FERMENTATION-PRODUCED SPECIALTY FOOD INGREDIENTS

EU specialty food ingredients

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CONTENTS

BACKGROUND

The purpose of this paper is to share information about fermentation as one of the many food technologies that are used to produce specialty food ingredients [1] considering a possible introduction of an EU Biotech Act [2], which may heighten focus on this technology. The paper also seeks to enhance fundamental understanding regarding the safety of fermentation-produced specialty food ingredients, their labelling requirements, their possible use in organic food products and their sustainability aspects.

1. Other types of ingredients may also be produced by fermentation.
2. European Commission Communication COM (2024) 137 final: Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU: https://research-and-innovation.ec.europa.eu/document/download/47554adc-dffc-411b-8cd6-b52417514cb3_en#:~:text=The%20EU%20has%20a%20broad,and%20now%20also%20the%20Strategic

FERMENTATION, ONE OF THE VARIOUS TECHNOLOGIES USED TO PRODUCE SPECIALTY FOOD INGREDIENTS

Specialty food ingredients are a broad category of ingredients that are added to foods and beverages for their nutritional and/or technological properties: fibres, vitamins, minerals, food additives, functional carbohydrates and special fats and proteins [3]. Some of them may be produced by fermentation [4].

Fermentation consists in the transformation of simple raw materials into a range of food ingredients by using the growth of microorganisms like bacteria, fungi and yeasts, or algae.

Food fermentation has a storied history, beginning as a means of preserving food, with early civilisations using this process to extend the shelf life of perishable items. Over time, fermentation evolved to encompass the transformation of raw materials into a variety of food products, such as cheese, yogurt, bread, and alcohol, highlighting its versatility. The process further advanced with the production of biomass, including yeast biomass, probiotics, and postbiotics, which became integral to both culinary and health contexts. The sophistication of fermentation technology has since escalated, enabling the production of high-value targeted ingredients by precision fermentation [5], exemplified by *Yarrowia* biomass, vitamins and human milk oligosaccharides (HMOs). This underscores the innovative strides made in this field, paving the way for groundbreaking advancements in food science and nutrition.

Schematically, the fermentation technology uses microorganisms to grow them on suitable fermentation substrates (or growth medium) in fermentation vessels (fermenter): the microorganisms "consume" and "convert" the substrate under controlled conditions to produce the food ingredients, which are then separated from the producing viable micro-organisms and the substrate residues and purified to the required level. These microorganisms are selected for their capacity to produce the targeted ingredients with high yields. They may be genetically modified for this purpose.

In other cases, the microorganisms grown on the substrate (the biomass) are consumed per se as food ingredients, either once the cells (biomass) have been inactivated (sometimes together with their components, i.e. postbiotics [6]) or as living microbial cells (e.g. probiotics) [7].

For example, fungal proteins have emerged as a sustainable and nutritionally valuable alternatives to traditional protein sources. *Fusarium venetatum*, a filamentous fungus widely known for its use in mycoprotein production (aerobic fermentation process from a carbohydrate substrate), exemplifies their potential [8].

Biomass can undergo further processing, such as ingredient extraction.

The fermentation process is different from the cell culture biomass production where the biomass is obtained through the multiplication of cells sourced from an animal or from botanicals [9, 10].

3. Detailed information about specialty food ingredients and their benefits are available in EU Specialty Food Ingredients' website: https://www.specialtyfoodingredients.eu/
4. Fermentation: process in which micro-organisms such as bacteria, fungi, yeasts and micro-algae are used to preserve and/or transform raw materials into e.g. food, feed, chemicals, pharmaceuticals, fuel, biomass.
5. Precision fermentation: using biotechnological approaches and innovations for the controlled cultivation of selected and/or modified microbial cells, to produce specific substances. These fermentation-derived products can be a single molecule, or a family of molecules purified from the fermentation broth or biomass.
6. A postbiotic is a preparation of inanimate microorganisms and/or their components that confers a health benefit on the host (ISAPP 2023)
7. Still the vast majority of probiotics and postbiotics are produced with non-genetically modified microorganisms.
8. More information about the technological, nutritional and sustainable value of fungal proteins as alternative protein sources is available in the following publication: Li et al. 2023. Nutritional Values and Bio-Functional Properties of Fungal Proteins – Applications in Foods as Sustainable Source. Foods, 12(4388), 1-18.
9. e.g., EFSA opinion on the safety of apple fruit cell culture biomass as a novel food pursuant to Regulation (EU) 2015/2283
10. Fermentation processes used for the production of specialty food ingredients should be clearly discriminated from eukariotic cell culture processes since microorganisms (e.g. bacteria, yeasts, filamentous fungi, or microalgae) rather than cells sourced from animal or plants are used.

SAFETY OF SPECIALTY FOOD INGREDIENTS PRODUCED BY FERMENTATION

Food, including specialty food ingredients, shall not be put on the market if it is unsafe [11].

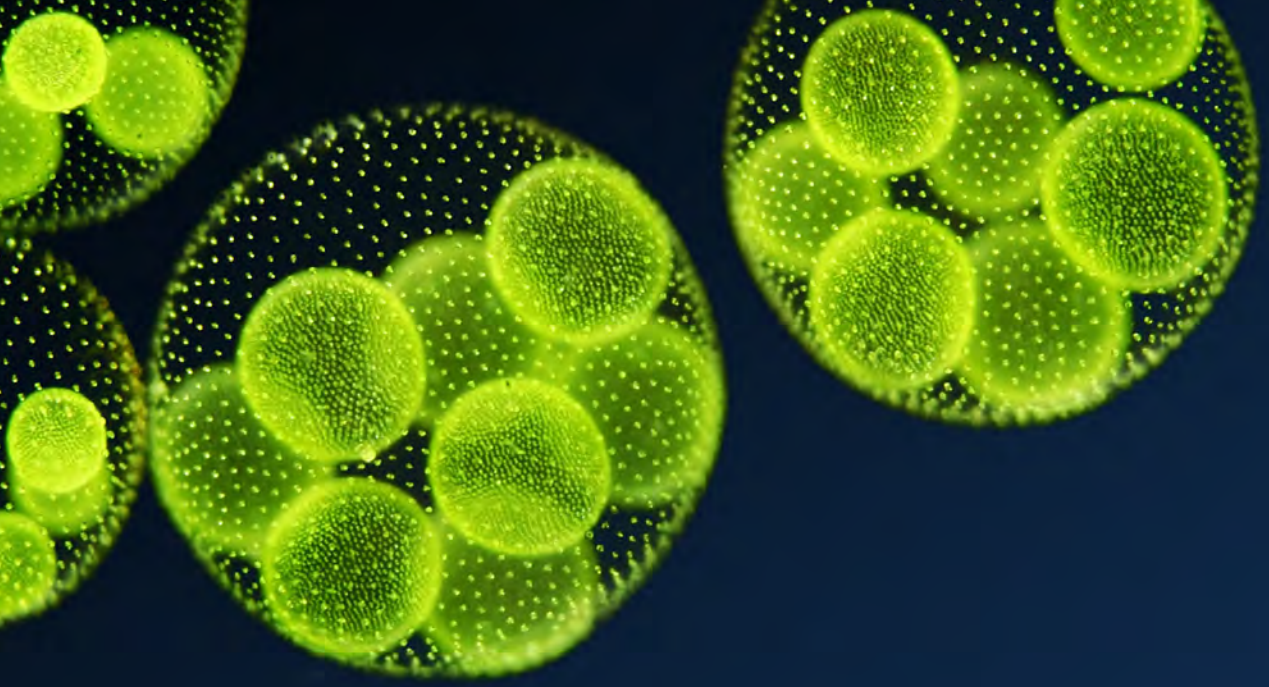
Like most of the specialty food ingredients produced through various technologies and sourced from botanical, animal, mineral, seaweed or chemical synthesis origins, fermentation-produced specialty food ingredients may be subject to a pre-market authorisation, on a case-by-case basis, considering factors such as the novelty of the microorganism, the QPS [12] list, and the origin of the product. Ingredients with a history of safe use are not subject to a pre-market authorisation, for example fermented oats, drinks and powders, which are considered not novel and therefore are not subject to a novel food authorisation procedure [13].

Where a pre-market authorisation is required, the process requires the assessment of their safety by the European Food Safety Authority (EFSA). Upon receiving authorisation by the EU legislators, they may be added to food and beverages for their nutritional and/or technological properties.

In the EU, there is no unique regulatory pathway for specialty food ingredients consisting of, isolated from or produced from microbiological sources, but different regulatory streams depending on their classification as, for example, food additives, novel food ingredients or nutrients. Nonetheless, a consistent factor in EFSA's evaluation of their safety remains the assessment of the safety of the microorganism and the assessment of the resulting food ingredient.

Examples of EFSA opinions on specialty food ingredients are provided in the Annex.

11. Article 14 of Regulation (EC) 178/2002 on General Food Law: Regulation - 178/2002 - EN - EUR-Lex
12. Qualified Presumption of Safety
13. 701a129c-800f-4a8f-a284-44872d9d0082_en



LABELLING OF SPECIALTY FOOD INGREDIENTS PRODUCED BY FERMENTATION

Food ingredient labelling in the EU is governed by Regulation (EU) 1169/2011 on the provision of food information to consumers [14]. This regulation should be considered alongside other specific legislation, notably Regulation (EC) 1333/2008 on food additives [15] and Regulation (EU) 2015/2283 on Novel Foods [16].

The labelling of specialty food ingredients is not technology-based, i.e., it is not required to mention in the ingredient list of a pre-packed food that the ingredient is obtained with the use of the fermentation technology. The labelling rules do not require either to indicate if the microorganism used for the production is genetically modified if the microorganism is not present anymore in the ingredient [17, 18].

Where a specialty food ingredient produced with fermentation technology has been granted a health claim in compliance with Regulation (EC) 1924/2006 [19], the labelling rules are similar to those applicable to any other food ingredient. For example, nine health claims are linked to riboflavin (vitamin B2), like "*contributes to normal energy-yielding metabolism" and 'normal functioning of the nervous system*".

Though Article 36 (3) b of Regulation (EU) 1169/2011 on the provision of food information to consumers lays down that the European Commission shall adopt implementing acts on the application of the requirements to the voluntary food information related to suitability of a food for vegetarians or vegans, this has not been adopted yet. Thus, private standards may apply regarding the use of vegan claims for ingredients produced with fermentation technology using Genetically Modified Microorganisms.

14. Regulation - 2011/1169 - EN - EUR-Lex
15. Regulation - 1333/2008 - EN - additives - EUR-Lex
16. Regulation - 2015/2283 - EN - EUR-Lex
17. GMMs used to produce ingredients through fermentation are exempt from GM legislation because, according to Regulation (EC) No 1829/2003, they are considered processing aids as long as they are thoroughly removed afterward.
18. If a genetically modified probiotic were brought to market, this would required labelling.
19. https://eur-lex.europa.eu/eli/reg/2006/1924/2014-12-13

ORGANIC FOODS

Articles 5 and 11 of Regulation (EU) 2018/848 on organic production and labelling of organic products [20] stipulate that organic production excludes the use of GMOs, products produced from GMOs, and products produced by GMOs, other than veterinary medicinal products.

For the purpose of this legislation, "produced by GMOs" means *derived by using a GMO as the last living organism in the production process* but not containing or consisting of GMOs nor produced from GMOs.

Operators using organic ingredients purchased from third parties shall require the vendor to confirm that those ingredients are not produced from GMOs or produced by GMOs.

20. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02018R0848-20230221&qid=1727093093408

SUSTAINABILITY DIMENSION OF SPECIALTY FOOD INGREDIENTS PRODUCED BY FERMENTATION

As with all food ingredients, where the environmental impact of fermentation-produced specialty food ingredients is evaluated, this should be done on a case-by-case basis. This assessment should follow established methodologies, such as the Product Environmental Footprint (PEF), which provides a multi-criteria measure of the environmental performance of a food ingredient throughout its life cycle.

For example [21]:

- Today virtually all vitamin B2 on the global food market is produced by fermentation using a one-step fermentation process vs. a traditional chemical process that took multiple steps. Compared to the traditional process, production using vegetable oil as a starting point and the fungus *Ashbya gossypii* for fermentation decreased energy consumption by 25%, Global Warming Potential (GWP) by as much as 33%, and it also reduced air emissions. Production using a renewable Carbon-source and the bacteria *Bacillus subtilis* for fermentation reduced the usage of fossil raw materials by 75%. In addition, it resulted in a reduction of 67% of waste water and 50% of waste gas with no hazardous waste produced anymore.
- Omega-3 DHA (docosahexaenoic acid), is a nutrient that has been granted several health claims in relation to its role in human nutrition. It is traditionally obtained from fish oil, but it can also be produced from microalgae grown in closed fermentation tanks on sugars' substrate. This reduces pressure on limited marine pelagic fishery stocks, preventing 1.5 million metric tons of fish from being caught over the last five years for DHA production by a specialty food ingredients manufacturer. Moreover, the production of microalgae is fully circular: bagasse, a by-product of a nearby sugar mill, is used as a renewable energy source to power both the microalgae facility and the sugar mill. The proximity to sugar cane fields allows all water from the microalgae facility to be reused for irrigation, thus helping responsible water management.

21. Examples are not exhaustive. More information about the role of sustainable innovation in the field of specialty food ingredients is available at: https://www.specialtyfoodingredients.eu/ingredients-and-benefits/sustainable-innovation/

ANNEX – EXAMPLES OF EFSA OPINIONS ON THE SAFETY OF SPECIALTY FOOD INGREDIENTS PRODUCED WITH FERMENTATION TECHNOLOGY

	INGREDIENT	MICRO-ORGANISM	PRODUCTION PROCESS (information from EFSA opinions)
FOOD ADDITIVES	**Curdlan**	*Rhizobium radiobacter*	Curdlan is a polysaccharide produced by pure-culture fermentation from a non-genetically modified strain of the bacteria *Rhizobium radiobacter*, for use as a firming agent, gelling agent, stabiliser and thickener. DOI: https://doi.org/10.2903/j.efsa.2024.8985
	Soy leghemoglobin	*Komagataella phaffii*	Soy leghemoglobin is intended to be used as a colour in meat analogue products. The yeast *Komagataella phaffii* has been genetically modified to produce soy leghemoglobin. The safety of the genetic modification and the safety of the resulting ingredient have been assessed separately: • in May 2024, EFSA concluded on the safety of the use of soy leghemoglobin as a new food additive at the proposed use and use level. • In November 2024, EFSA concluded on the safety of the genetic modification. DOI: https://doi.org/10.2903/j.efsa.2024.8822 DOI: https://doi.org/10.2903/j.efsa.2024.9060
NOVEL FOOD INGREDIENTS/ NUTRIENTS Human-identical milk oligosaccharides	**2'-fucosyllactose/ difucosyllactose (2'-FL/DFL) mixture**	*Escherichia coli K12*	2'-fucosyllactose/difucosyllactose (2'-FL/DFL) mixture is a powdered mixture mainly composed of two oligosaccharides, 2'-FL and DFL, which are produced together by fermentation with a genetically modified strain of *Escherichia coli K12*. It is intended to be used for nutritional purposes in a variety of foods, including infant and follow-on formula, foods for infants and young children, foods for special medical purposes and food supplements. DOI: https://doi.org/10.2903/j.efsa.2019.5717
	6'-Sialyllactose (6'-SL) sodium salt	*Escherichia coli*	6'-Sialyllactose (6'-SL) sodium salt produced with the use of genetically modified strain of *Escherichia coli*, for nutritional use in infant formula and follow-on formula, foods for infants and toddlers, foods for special medical purposes and food supplements. DOI: https://doi.org/10.2903/j.efsa.2020.6097

	INGREDIENT	MICRO-ORGANISM	PRODUCTION PROCESS (information from EFSA opinions)
NOVEL FOOD INGREDIENTS/ NUTRIENTS Biomass-based	**Yeast biomass**	*Yarrowia lipolytica*	*Yarrowia lipolytica* yeast biomass primarily consists of proteins (about 50%) and dietary fibre (about 25%), for use as food supplement in the form of capsules, tablets or powder. DOI: https://doi.org/10.2903/j.efsa.2019.5594
	Selenium-enriched yeast	*Saccharomyces cerevisiae*	The production process for selenium yeast involves culture of the yeast under optimum fermentation conditions and a defined source of selenium. Following harvest, the selenium-enriched yeast cream is pasteurised and then spray dried or dried by other appropriate drying methods. The inactivated and spray dried product may be blended with inactive dehydrated baker's yeast to standardize selenium content. The ingredient is for use as source for selenium added for nutritional purposes in foods. DOI: https://doi.org/10.2903/j.efsa.2008.766
NOVEL FERMENTED FOOD INGREDIENTS / EXTRACTS	**Pea and rice protein fermented by Shiitake mycelia**	*Lentinula edodes*	The novel food ingredient, to be used as ingredient in specific food categories, is produced by the fermentation with Shiitake mycelia of pea and rice protein and consists of ⩾ 75% protein on a dry basis and an estimated level of Shiitake mycelia biomass of < 0.1 weight (wt) % DOI: https://doi.org/10.2903/j.efsa.2022.7205
	Fermented black bean extract (Touchi extract)	*Aspergillus oryzae*	Fermented black beans are derived from the small soybean grown in the Sichuan province of China. The soybeans are steamed and fermented using the fungus *Aspergillus oryzae.* The fermented black beans are milled, suspended in water, heated at boiling temperature and extracted into the aqueous phase. Following centrifugation and filtration the dialysate is concentrated and spray dried to give the final product, "fermented black bean extract", as a pale brown powder for food supplements for adults. DOI: https://doi.org/10.2903/j.efsa.2011.2136
	Vitamin K2 added for nutritional purposes in food	*Bacillus subtilis natto*	The form is a sunflower oil suspension of a vitamin K2-rich extract obtained from the fermentation of soybean protein isolate and corn starch in the presence of *Bacillus subtilis natto.* The manufacturing process includes fermentation, ethanol extraction, filtration and purification steps, degumming and the addition of sunflower oil. DOI: https://doi.org/10.2903/j.efsa.2008.822

TO KNOW MORE ABOUT SPECIALTY FOOD INGREDIENTS

Brochures and infographics

- Selected specialty food ingredients & their benefits for gut microbiome and health
- Benefits of selected specialty food ingredients for gut health
- Specialty Food Ingredients: innovating to meet consumer needs
- Everything you ever wanted to know about health ingredients
- Specialty food ingredients: sustainable solutions for the food systems
- Everything you always wanted to know about food additives
- Specialty food ingredients: additives in the safety spotlight
- "Synthetic" food ingredients: debunking the myths with facts
- Specialty food ingredients and processed & "ultra-processed" foods: debunking the myths with facts
- Did you know? Facts about processed and "ultra-processed" foods
- Questions & Answers

Animated videos

- Our life with specialty food ingredients
- What are specialty food ingredients?
- How can I be sure that food additives are safe?
- Should I be afraid of processed food?
- How can food reformulation help achieve healthier diets?
- Are there food ingredients solutions to meet individual dietary needs?
- What is the contribution of specialty food ingredients to sustainable food systems?
- Can specialty food ingredients help reduce food waste?

DISCLAIMER

This document is designed to provide insights about specialty food ingredients produced with fermentation technology. As such this document is not and should not be construed as a guarantee or warranty, nor a part of any contractual or other legal obligations on behalf of EU Specialty Food Ingredients and its member companies. This information is offered solely for the consideration, investigation and verification of interested parties.

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