Latest novel food authorisations, amendments, and extensions 2024

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Novel food authorisations, amended uses, and extensions adopted January–July 2024

Authorisations

Commission Implementing Regulations 2024/2036, 2024/2049, 2024/2061, 2024/2090, 2024/2101

Amendments

Commission Implementing Regulations 2024/2044, 2024/2046, 2024/2048, 2024/2062, 2024/2102

Update

This report summarises recent EU decisions to authorise, amend, or extend the specifications or conditions of use of existing novel foods:

- 2'-FL obtained by microbial fermentation using a derivative strain of Escherichia coli by Kyowa Hakko Bio Co.
- LNFP-I/2'-FL mixture obtained by microbial fermentation using a derivative strain of E. coli
- Schizochytrium limacinum (TKD-1) oil
- Schizochytrium sp. (CABIO-A-2) oil
- Ashitaba stem juice.

The EU has authorised the following changes:

- extension of use of the novel food Yarrowia lipolytica yeast biomass to meal replacements for weight control intended for the adult population
- labelling requirements ‘Partially hydrolysed protein from barley and rice’ for foods containing partially hydrolysed protein from spent barley and rice
- specifications and conditions of use of protein extract from pig kidneys will only refer to the maximum authorised levels; its different forms are removed from the specifications
- lower levels of docosahexaenoic acid (DHA) in specifications of the novel food Schizochytrium sp. oil rich in DHA and eicosapentaenoic acid (EPA)

- authorised levels of 2'-FL will increase from current levels authorised in both infant formulae and follow-on formulae
- authorised levels of residual endotoxins for 2'-FL produced from derivative strain E. coli BL-21 will be aligned to levels already authorised under the same conditions of use for 2'-FL from E. coli K-12, and other milk oligosaccharides at similar residual levels in infant formulae and follow-on formulae.

Impacted products

Milk products (pasteurised, sterilised, UHT), fermented milk-based products, flavoured beverages, cereal bars, infant formula, follow-on formula, processed cereal-based food and baby food, diet replacement foods (for weight control), special medical foods, food supplements

What is changing?

The European Commission has authorised the novel foods listed in Table 1 to be placed on the EU market. These foods will be included in the Union list of novel foods (Regulation 2017/2470). For certain novel foods, only the company applicants that were granted authorisation are permitted to sell them on the EU market over the next 5 years, unless they permit other companies to sell them, or if another company obtains a novel food authorisation without reference to the protected scientific data used by the original applicant (see footnote to Table 1).

The Commission has also authorised some changes to the specifications and conditions of use for certain novel foods that are already authorised and available on the EU market (see Table 2).

Why?

Only novel foods authorised and included in the Union list of novel foods may be placed on the market within the EU (Regulation 2015/2283).

The European Food Safety Authority (EFSA) evaluates novel food applications to ensure their safety under the proposed conditions and/or levels of use [see Resources 1–6].

Timeline

The newly authorised novel foods may be placed on the EU market from the date indicated in Table 1.

Changes to specifications and conditions apply from the dates shown in Table 2.

Background

For further information on the novel food authorisation process, see Novel foods explained.

Resources

European Commission: Union list of novel foods

Regulation (EU) 2017/2470 (Union list of novel foods)

Regulation (EU) 2015/2283 on novel foods

Regulation No 1169/2011 on the provision of food information to consumers

Opinions published by the European Food Safety Authority (EFSA) on the safety/efficacy of the following novel foods:

1. EFSA (2023) Safety of 2′■fucosyllactose (2′■FL) produced by a derivative strain (Escherichia coli SGR5) of E. coli W (ATCC 9637) as a Novel Food pursuant to Regulation (EU) 2015/2283. EFSA Journal, 21(11): 8333.
2. EFSA (2023) Safety of the extension of use of 2′-fucosyllactose (2′-FL) as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal, 21(11): e8334.
3. EFSA (2023) Safety of an extension of use of Yarrowia lipolytica yeast biomass as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal, 21(11): e8416.
4. EFSA (2023) Safety of lacto-N-fucopentaose I/2'-fucosyllactose (LNFP-I/2'-FL) mixture as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal, 21(12): e8412.
5. EFSA (2023) Safety of oil from Schizochytrium limacinum (strain TKD■1) for use in infant and follow■on formula as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal, 21(12): e8414.
6. EFSA (2023) Safety of oil from Schizochytrium sp. (strain CABIO■A■2) for use in infant and follow■on formula as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal, 21(12): e8415.

Sources

Commission Implementing Regulations:

2024/2036 authorising the placing on the market of 2'-Fucosyllactose produced by a derivative strain of *Escherichia coli* W (ATCC 9637) as a novel food

2024/2044 as regards the specifications and the conditions of use of the novel food *Yarrowia lipolytica* yeast biomass

2024/2046 as regards the specific labelling requirements for the novel food partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)

2024/2048 as regards the specifications and the conditions of use of the novel food protein extract from pig kidneys

2024/2049 authorising the placing on the market of *Schizochytrium limacinum* (TKD-1) oil as a novel food

2024/2061 authorising the placing on the market of the juice of the stems of the *Angelica keiskei* plant (Ashitaba stem juice) as a novel food

2024/2062 as regards the specifications of the novel food *Schizochytrium* sp. oil rich in DHA and EPA

2024/2090 authorising the placing on the market of Lacto-N-fucopentaose I and 2'-Fucosyllactose mixture produced using a derivative strain of *Escherichia coli* K-12 DH1 as a novel food

2024/2101 authorising the placing on the market of *Schizochytrium* sp. (CABIO-A-2) oil as a novel food

2024/2102 as regards the conditions of use of the novel food 2'-Fucosyllactose and as regards the specifications of the novel food 2'-Fucosyllactose produced with a derivative strain of *Escherichia coli* BL-21

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Table & Figures

Table 1
Latest novel food authorisations (July 2024)

Regulation	Novel food	Use	Applicant	Applies from[1]
2024/2036	2'-Fucosyllactose (2'-FL) from *Escherichia coli* W (ATCC 9637)	Milk-based drinks and similar products intended for young children	Kyowa Hakko Bio Co., Ltd[2]	19 Aug 2024
2024/2049	*Schizochytrium limacinum* (TKD-1) oil	Infant formula and follow-on formula	ATK Biotech Co., Ltd	20 Aug 2024
2024/2061	Ashitaba (*Angelica keiskei*) stem juice	Food supplements for adult population excluding pregnant and lactating women	Japan Bio Science Laboratory (JBSL)-USA, Inc. [2]	20 Aug 2024
2024/2090	Lacto-N-fucopentaose I and 2'-fucosyllactose mixture from *Escherichia coli* K-12 DH1	Infant formula and follow-on formula; unflavoured pasteurised and unflavoured sterilised (including UHT) milk products; unflavoured and flavoured fermented milk-based products including heat-treated products; cereal bars, milk-based drinks and similar products; processed cereal-based food and baby food for infants and young children; food for special medical purposes; beverages (flavoured drinks excluding those pH <5); total diet replacement for weight control; food supplements intended for general population	Glycom A/S[2]	19 Aug 2024
2024/2101	*Schizochytrium* sp. (CABIO-A-2) oil	Infant formula and follow-on formula	CABIO Biotech (Wuhan) Co., Ltd	20 Aug 2024

1. Foods may be placed on the market from this date.
2. During the period of data protection, the novel food is authorised for placing on the market within the EU only by this named applicant unless a subsequent applicant obtains authorisation for the same without reference to the proprietary scientific evidence or scientific data protected, or with the agreement of the applicant.

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Source: based on Regulations 2024/2036, 2024/2049, 2024/2061, 2024/2090, 2024/2101

Table 2
Extended uses, changes in specifications or conditions of use (July 2024)

Regulation	Novel food	Change	Applicant	Applies from
2024/2044	*Yarrowia lipolytica* yeast biomass	Extension of use to meal replacements for weight control intended for adult population	Skotan SA	19 Aug 2024
2024/2046	Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)	Change of specific labelling requirements to 'Hydrolysed protein from barley and rice'	Evergrain LLC	19 Aug 2024
2024/2048	Protein extract from pig kidneys	Specifications and conditions of use will only refer to the maximum authorised levels (12.6 mg/day) and maximum authorised levels of diamine oxidase (DAO) (0.9 mg/day); its different forms (enteric coated pellets, enteric coated capsules, enteric coated tablets) are removed from the specifications	Dr Healthcare España, SLU	19 Aug 2024
2024/2062	*Schizochytrium* sp. oil rich in docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA)	Changes to allow lower levels of DHA (from ≥22.5 to ≥15.0%)	DSM Nutritional Products Ltd	20 Aug 2024
2024/2102	2'-Fucosyllactose (2'-FL) from *Escherichia coli* BL-21	Maximum authorised levels will increase from 1.2 g/L in both infant formulae and follow-on formulae to 3.0 g/L in infant formulae and 3.64 g/L in follow-on formulae	Chr. Hansen A/S	20 Aug 2024
		New authorised levels of residual endotoxins: ≤10 endotoxin units (EU)/mg for powder form; ≤10 EU/µl for liquid form		

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Source: based on Regulations 2024/2044, 2024/2046, 2024/2048, 2024/2062, 2024/2102