Latest novel food authorisations, amendments, and extensions 2024

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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

What is changing and why?

The European Commission has authorised the novel foods listed in Table 1 to be placed on the EU market.

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).

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.

For more information see the full record on the AGRINFO website – where you can also view the latest AGRINFO Update newsletters and search the database.

Tables & 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

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