Collaboration

Novel foods authorised in the European Union: analysis and assessment of their specifications

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Abstract

In the European Union, the term novel food refers to foods that have not been used for human consumption to a significant degree within the Union before 15 May 1997. These novel foods require prior authorisation for placing on the market, based on an assessment of their safety for consumption. The authorisations for each novel food include, among other matters, the establishment of specifications with the main parameters characterising it and the limits to be respected.

This paper reviews and analyses the specifications established until 31 May 2023 for the novel foods included in the Union List, published in the Annex to Implementing Regulation (EU) 2017/2470. The specifications relate to compositional parameters, contaminants, microbiological criteria or the absence of genetically modified organisms.

The review and analysis carried out revealed a certain lack of uniformity in the criteria used to establish the specifications, both for novel foods authorised under the general procedure and for those authorised under the existing procedure for traditional foods from third countries. In some cases, the specifications do not include any parameter or do not specify the purity of some extracts.

Although the establishment of methods for the analysis of contaminants may be useful for the competent authorities when carrying out official controls and for operators, it would be more appropriate to refer to the criteria or conditions that these methods should meet rather than to the specific methods of analysis, since the progress in analytical techniques means that the specific methods established may become obsolete over time.

It is to be expected that, as the safety assessment has become a more centralised procedure through Regulation (EU) 2015/2283, with the European Food Safety Authority (EFSA) as the assessment authority, uniform criteria will be adopted for the establishment of specifications.

Key words

Novel food, specifications, Union List, composition, contaminants, microbiological criteria.

Translated from the original published in the journal: Revista del Comité Científico de la AESAN, 38, pp: 45-63.

1. Introduction

1.1 Novel foods. Concept and legislative framework

The legal concept of novel food was established in 1997 by Regulation (EC) No. 258/97 concerning novel foods and novel food ingredients (EU, 1997). Currently, this regulation has been replaced by Regulation (EU) 2015/2283 on novel foods, applicable as of 1 January 2018 (EU, 2015). This regulation defines the concept of novel food as "food which has not been used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of the Member States to the Union". All foods that have not been consumed in the European Union (EU) before this date, or for which there is no history of safe consumption, require pre-market authorisation based on a safety assessment.

Excluded from the scope of this regulation are Genetically Modified Organisms (GMO) (Regulation (EC) No. 1829/2003) (EU, 2003), food enzymes (Regulation (EC) No. 1332/2008) (EU, 2008a), food additives (Regulation (EC) No. 1333/2008) (EU, 2008b), food flavourings (Regulation (EC) No. 1334/2008) (EU, 2008c) and extraction solvents used or intended for use in the production of food or food ingredients (Directive 2009/32/EC (EU, 2009) transposed into Spanish law by Royal Decree 1101/2011 (BOE, 2011)), as they have their own regulation.

Regulation (EU) 2015/2283 includes ten food categories that fall under the concept of novel food, thus broadening the scope with the introduction of new categories compared to the previous Regulation (EC) No. 258/97.

1.2 Evaluation of novel foods and authorisation procedure for their placing on the market in the European Union

The authorisation procedure for a novel food requires a safety assessment prior to authorisation to place it on the EU market, taking into account that the novel food regulation is based on three fundamental principles: novel foods should be safe for consumers, should not mislead consumers and, if intended to replace another food, should not differ in such a way that consumption of the novel food would be nutritionally disadvantageous for the consumer (EU, 2015). This entailed a change in the regulatory framework, as the initial assessment was no longer carried out by the EU Member States, but by the European Food Safety Authority (EFSA), thus unifying the assessment criteria (Herrero et al., 2018).

As a step prior to starting the authorisation procedure, the applicant must establish the novel food status, i.e. verify whether the food they wish to place on the market falls within the scope of Regulation (EU) 2015/2283 (EU, 2015). For this purpose, if necessary, the applicant can submit a request for consultation to a Member State, the procedure for which is laid down in the Implementing Regulation (EU) 2018/456 (EU, 2018). The applicant can also consult the Novel Food Catalogue (EC, 2023), a list developed by the European Commission in cooperation with the Member States, which currently contains 739 foods and provides guidance on whether a product falls within the scope of the novel food Regulation.

Once the novel food status has been confirmed, there are two types of procedure for authorising the placing on the market of a novel food in the EU:

a) General procedure

The applicant must submit an application for authorisation to the European Commission in accordance with the requirements of Article 10 of Regulation (EU) 2015/2283 and may only place the novel food on the EU market after the EU has adopted a regulation authorising its placing on the market and it has been included in the so-called Union List of authorised novel foods established by the Implementing Regulation (EU) 2017/2470 (EU, 2017). On the basis of the information on the novel food provided by the applicant, EFSA will assess the safety of the novel food under the proposed conditions of use and adopt its opinion within 9 months. Within 7 months thereafter, the Commission will present a draft implementing act authorising the placing on the market of the novel food and updating the Union List, to be adopted by the Standing Committee on Plants, Animals, Food and Feed of the European Commission (EFSA, 2021a, b).

b) Procedure for traditional foods from third countries

In the case of traditional foods from third countries (non-EU), there is a simplified notification procedure in accordance with the requirements of Article 14, which aims to speed up the authorisation of the placing on the market of this type of novel food.

This procedure is limited to food of primary production for which there is evidence of safe consumption in the third country of origin for the last 25 years. Once the notification has been submitted, EFSA and Member States have the possibility to raise reasoned safety objections within 4 months. If such objections are raised, the applicant will submit an application for authorisation which will include, in addition to the information already provided, documented data on the safety objections raised in accordance with Article 16 of Regulation (EU) 2015/2283. This application shall be evaluated by EFSA (2021c).

Once a novel food has been authorised for placing on the market, it will be included in the Union List (EU, 2017). This List contains all novel foods authorised in the EU to date and includes information on the name and description of the novel food, the production process, compositional data, proposed uses, specific labelling requirements and specifications established for the novel food.

It also includes provisions on data protection so that an applicant can obtain an exclusive authorisation to place a novel food on the market, based on the latest scientific evidence and limited to 5 years.

2. Objectives

Based on the above, the general objective is to review the regulations, the guidelines for the preparation and submission of novel food applications and the safety assessments issued by EFSA, taking into account the following specific objectives:

1. To identify and analyse the specifications established for novel foods included in the Union List published in the Annex to the Implementing Regulation (EU) 2017/2470 (EU, 2017).
2. To analyse and compare the specifications established for some specific groups of novel foods.
3. To make a comparison between the microbiological criteria laid down in the specifications for novel foods and the microbiological criteria laid down in Regulation (EC) No. 2073/2005 (EU, 2005) on microbiological criteria for foodstuffs.

This is an adaptation of the final Master's Degree work of the same name carried out at the Spanish Agency for Food Safety and Nutrition (AESAN) and presented in the Master's Degree in Food Safety at the School of Government of the Complutense University of Madrid.

3. Materials and methods

The work presented in this report is mainly based on a review of the current legislation regulating novel foods and, in particular, the specifications established for them. A search for information was carried out using the websites of the Spanish Agency for Food Safety and Nutrition (AESAN), the European Food Safety Authority (EFSA) and the European Commission.

Several reports on the subject under study published in the Journal of the Scientific Committee of AESAN were also consulted, as well as numerous safety assessments published by EFSA and the scientific and technical guidance for applicants prepared by EFSA.

In addition, the EUR-Lex portal was used to access the regulations of interest for the development of this work, consulting in particular Regulation (EU) 2015/2283 (EU, 2015) on novel foods and Implementing Regulation (EU) 2017/2470 (EU, 2017) establishing the Union List of novel foods (consolidated version of 31/05/2023).

4. Analysis of novel food specifications

Following the adoption of Regulation (EU) 2015/2283 on novel foods, the European Commission requested EFSA to develop scientific and technical guidance documents for the preparation and submission of applications for authorisation of novel foods (EFSA, 2021a, b) and applications/notifications of traditional foods from third countries (EFSA, 2021c). These guidance documents have a common format and detail the type of information that applicants need to provide to facilitate EFSA's safety assessments of novel foods and the preparation of its respective scientific opinions.

The authorisation of each novel food involves, among other matters, the establishment of specifications. These specifications are initially established by the applicant and define the key parameters that characterise and underlie the identity of the novel food, as well as other relevant physicochemical, biochemical or microbiological parameters. In addition, these parameters must be accompanied by their respective limits, which will assist in the assessment to demonstrate the safety of the novel food to be placed on the market in the EU.

As required by the guidance, a justification for the selected parameters should be provided and the specification should at least include contents and/or limits for parameters related to product identity, minimum purity and acceptable limits for impurities and degradation products, in particular those of toxicological or nutritional relevance. Specifications should include nutritionally or biologically active constituents and concentrations of major groups of constituents present in the food, such as amino acids and proteins, lipids, carbohydrates, inorganic ions, polyphenols, alkaloids, terpenes, lignin, saponins or chitin. In the absence of EU legislation, maximum levels for contaminants (e.g. microorganisms, mycotoxins, heavy metals, pesticide residues or polycyclic aromatic hydrocarbons) should be included (EFSA, 2021b).

Implementing Regulation (EU) 2017/2470 compiles all authorised novel foods, and its Annex has been updated by subsequent implementing regulations to include the latest authorisations and

amendments to authorisations or to make some corrections of errors. This Annex includes the Union List of novel foods, which lists 193 novel foods, of which 10 have been authorised through the traditional food route from third countries, and contains more than 3000 specifications.

The authorised novel foods correspond to very different products, and there is great variability in the number and type of parameters established for each of them in the specifications included in the Union List (Calderón et al., 2018). In addition, in some cases, specifications have been established for the different authorised forms of marketing of the same novel food.

In the light of the above, a preliminary assessment has revealed an apparent lack of uniformity in the criteria used to establish specifications for authorised novel foods in some cases. These specifications can be divided into the following categories: composition/characteristics, contaminants or undesirable substances (mainly heavy metals, mycotoxins, residual solvents, processing contaminants and dioxins and PCBs), microbiological criteria and analytical methods. However, it should be noted that some authorised novel foods do not contain these types of parameters mentioned above, but only a brief description of them (*Ajuga reptans* extract from cell cultures, *Cistus incanus* L. *Pandalis* herb, *Lippia citriodora* dry extract from cell cultures, *Echinacea angustifolia* extract from cell cultures and *Echinacea purpurea* extract from cell cultures).

The specifications relating to the absence of GMO in those novel foods where genetically modified strains were used in the production process were also evaluated.

4.1 Composition/characteristics specifications

They include aspects of the food itself, such as its description and composition: mainly moisture, dry matter, ash, pH, fibre, fat, protein and carbohydrates. Sometimes the definition itself refers to part of the sourcing process. In addition, other relevant information such as synonyms, chemical formula, chemical name or CAS (Chemical Abstracts Service) No. is occasionally included.

4.2 Specifications of contaminants or undesirable substances

Among the parameters related to undesirable substances or contaminants, heavy metals stand out, being present in the specifications of 81 of the 193 novel foods on the Union List (EU, 2017).

In particular, reference is made to the content of lead, arsenic, cadmium and mercury (Table 1). Limits have also been set for other metals: iron, copper, nickel, palladium, platinum, aluminium and chromium, among others.

Table 1. Heavy metal specifications in novel foods

Heavy metal	No. of specifications
Lead	85
Arsenic	69
Cadmium	67
Mercury	51

There are also 100 specifications regarding mycotoxins in 23 novel foods, mainly aflatoxins, ochratoxin A and deoxynivalenol. For residues of extraction solvents, 50 specifications were established in 15 novel foods, mainly for ethanol. In 12 of them, specifications were also set for dioxins and PCBs, pesticides (5 specifications) and process contaminants (9 specifications) such as polycyclic aromatic hydrocarbons, acrylamide or 3-monochloropropanediol and cyanotoxins (2 specifications), among others.

Occasionally, limits were set for the different forms of marketing of a novel food and only one case was identified where contaminant specifications were set according to the target population of the novel food: calcium L-methylfolate ("infants or young children" and "general population excluding infants and young children").

4.3 Microbiological criteria specifications

Microbiological criteria are present in the specifications of 90 novel foods. These include *Escherichia coli*, *Salmonella*, *Listeria*, enterobacteria, coliforms, moulds and yeasts (Table 2). These specifications are sometimes very general, referring to the "absence of pathogens". In other cases, similar expressions are used but with some nuance, such as "total aerobic microbial count", "total aerobic organisms on plate" or "total aerobic bacteria".

Table 2. Microbiological criteria specifications for novel foods

Microorganism/Endotoxin	No. of specifications	Microorganism/Endotoxin	No. of specifications
Salmonella, *Salmonella* sp. and *Salmonella* spp.	90	Yeast	21
Yeasts and moulds	83	Moulds/Fungi	21
Escherichia coli	66	Coagulase-positive staphylococci	18
Aerobic count	60	Sulfite-reducing anaerobes	17
Enterobacteriaceae	53	Endotoxins	15
Listeria spp. and *L. monocytogenes*	41	Mesophil count	14
Staphylococcus and *S. aureus*	34	*Pseudomonas* and *P. aeruginosa*	8
Coliforms	32	*Cronobacter* spp. and *Cronobacter sakazaki*	7
Total counts	32	Clostridia	4
Bacillus cereus	27	Others	12

4.4 Analytical specifications

The specification of methods of analysis for the determination of some parameters is not very common, as they are present in only 35 of the 193 novel foods authorised. In addition, it should

be borne in mind that advances in analytical techniques may render fixed methods obsolete over time.

The inclusion of analytical methods is only envisaged for the determination of some parameters related to the composition of the novel food or the presence of contaminants. In some cases, they are defined in more general terms, such as the Kjeldahl method for the determination of nitrogenous constituents in shiitake mushroom (*Lentinula edodes*) mycelium extract or the Karl Fischer method for the determination of water in tomato lycopene oleoresin. In other cases, they are specified more precisely by indicating the chromatographic conditions and the type of column (as in the case of alpha-cyclodextrin or trehalose) or by referring to a specific method or to a method published in a scientific journal (as in the case of the determination of nattokinase activity in fermented soya bean extract using the method described by Takaoka et al.).

In the case of egg membrane hydrolysate, specific commercial methods for the determination of collagen and elastin content are also included, raising the question whether the use of other similar commercially developed assays would be valid or whether these are still marketed today.

On the contrary, the specifications of microbiological parameters do not refer to standardised methods, although in this type of determinations the influence of the analytical method is decisive for the detection or quantification of a microorganism.

4.5 Specifications regarding the absence of GMO

Some authorised novel foods have been obtained by a process involving the use of genetically modified microorganisms. According to Regulation (EC) No. 1829/2003, food and feed produced with the use of a genetically modified processing aid, as in this case, fall outside the scope of this Regulation, as the material derived from this microorganism is not present in the final product (EU, 2003). Of the 16 novel foods containing GMO, only 2 lay down specific specifications for demonstrating their absence: ice structuring protein type III HPLC 12 ("DNA: not detectable") and L-alanylglutamine ("*Escherichia coli*: absence") (López-Rodríguez, 2023).

5. Comparison of specifications for similar novel food groups

The Union List contains a wide variety of products for which different specifications have been established (EU, 2017). Below is a summary of selected novel food cases grouped by food type.

5.1 Insects

Among the recent authorisations, the inclusion of some insect species as novel foods stands out. Currently, the Union List contains 6 authorisations for four insect species (Table 3): *Acheta domesticus* or house cricket, *Alphitobius diaperinus* or dung beetle, *Locusta migratoria* or migratory locust and *Tenebrio molitor* or mealworm. Some of these novel foods are intended to be commercialised in different forms.

Table 3. Insect species authorised as novel foods	
Insect species	**Novel food authorised**
Acheta domesticus	Frozen, dried and powdered form
	Partially defatted powder
Alphitobius diaperinus	Frozen, paste, dried and powdered form
Locusta migratoria	Frozen, dried and powdered form
Tenebrio molitor	Dried larvae
	Frozen, dried and powdered form

In this case, the criteria used to establish the specifications are homogeneous. In all cases, the specifications contain a complete definition of the novel food, including aspects related to the processing of the product, as well as parameters related to its composition. Parameters with similar values have also been established for some contaminants (heavy metals, mycotoxins and dioxins and dioxin-like PCBs) and microbiological criteria.

The microbiological criteria established for all authorised insect species are the same, with the exception of anaerobic sulfite-reducing microorganisms, which are only included in the frozen, dried and powdered forms of *Acheta domesticus* and *Locusta migratoria*. Small differences have also been found in the values established for heavy metals.

5.2 Extracts

Among the novel foods authorised, the 26 authorised extracts stand out (López-Rodríguez et al., 2022). Among them, the Union List (EU, 2017) includes 2 authorisations for cocoa extract *(Theobroma cacao* L.): defatted cocoa powder extract and low fat cocoa extract. Although the name of the novel food itself refers to fat content, the specifications do not detail this parameter. It does not include parameters related to contaminants or microbiological criteria either.

The List also includes different authorisations for cell culture extracts: *Lippia citriodora* dry extract, *Echinacea angustifolia* extract and *Echinacea purpurea* extract, where the specifications, as mentioned above, are limited only to a brief description without including any specific parameters.

Regarding algae extracts, the marketing of fucoidan extract from the seaweed *Fucus vesiculosus* and fucoidan extract from the seaweed *Undaria pinnatifida* is authorised. Both novel foods have two types of extracts (extract 1 and extract 2) with similar compositional values except for the polyfloroglucinol content, which is significantly higher in extract 2 of *Fucus vesiculosus* seaweed. In both cases, the same limits were set for heavy metals and microbiological criteria.

It should be noted that, of the above extracts, specifications were only established for the purity of the low-fat cocoa extract and the fucoidan extracts from seaweeds, which raises the question of whether the use of a higher purity than that evaluated could pose a safety problem.

5.3 Oils

Oils also account for a significant number of novel foods, with a total of 25 oils authorised. Among the oils of animal origin, *Euphausia superba* Antarctic krill oil and *Euphausia superba* Antarctic krill oil rich in phospholipids stand out, both characterised by their combined maximum concentrations of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) of 9 % and 5 %, respectively. However, they differ in their phospholipid content, which exceeds 60 % in the oil rich in this compound. Other parameters common to both oils are the saponification index and the peroxide index. In no case were parameters of possible contaminants or microbiological criteria established.

The marketing of 6 oils obtained from different strains of the microalgae *Schizochytrium* sp. and another from *Ulkenia* sp. is also authorised. Similar specifications have been established for all of them, with slight differences. There are a number of common specifications among them: peroxides index, unsaponifiables, *trans* fatty acids and DHA content (Table 4). In no case have parameters related to contaminants or microbiological criteria been considered.

Table 4. Microalgae oils approved as novel foods

Novel food authorised	Peroxide value (meq/kg oil)	Unsaponifiables (%)	*Trans* fatty acids (%)	DHA content (%)
Oil of *Schizochytrium* sp. rich in DHA and EPA	≤5.0	≤4.5	≤1.0	≥22.5
Oil of *Schizochytrium* sp. (ATCC PTA-9695)	≤5.0	≤3.5	≤2.0	≥35.0
Oil of *Schizochytrium* sp. (FCC-3204)	≤5.0	≤4.5	≤1.0	≥32.0
Oil of *Schizochytrium* sp.	≤5.0	≤4.5	≤1.0	≥32.0
Oil of *Schizochytrium* sp. (T18)	≤5.0	≤3.5	≤2.0	≥35.0
Oil of *Schizochytrium* sp. (WZU477)	≤5.0	≤4.5	≤1.0	≥32.0
Oil from the microalgae *Ulkenia* sp.	≤5.0	≤4.5	≤1.0	≥32.0

It should be noted that Antarctic krill oils from *Euphausia superba* and *Schizochytrium* sp. rich in DHA and EPA are the only cases of novel foods whose specifications have established the need to test the oxidative stability in all final products containing the novel food by an appropriate nationally and internationally recognised analytical method, such as the Association of Analytical Communities (AOAC).

5.4 Microalgae

In addition to the algae-based products mentioned in the previous sections (algae extracts and oils), the marketing of freeze-dried microalgae *Tetraselmis chuii* and dried microalgae *Euglena gracilis* and *Odontella aurita* is also permitted in the EU. The specifications regarding composition are much more detailed in the freeze-dried microalgae *Tetraselmis chuii* compared to those of the microalgae *Odontella aurita*, which only includes the content of silica and crystalline silica as an impurity. Only

parameters related to heavy metals and microbiological criteria have been established for dried *Euglena gracilis*. It should also be noted that *Tetraselmis chuii* freeze-dried microalgae is the only authorised microalgae species whose specifications include iodine content and the only case of a novel food for which a specification has been established for its genetic identification, in this case by means of an 18 S rDNA nuclear marker (analysed sequence of no less than 1600 base pairs) against the National Center for Biotechnology Information (NCBI) database.

5.5 Noni fruit derivatives

There are 5 authorisations for the noni fruit (*Morinda citrifolia*) for different forms of marketing: noni fruit juice, noni fruit juice powder, noni fruit puree and concentrate, noni leaves and noni fruit powder. Despite belonging to the same food category, it was noted that noni juice and noni juice powder did not have compositional parameters established and their specifications were limited to a brief description. The other novel foods derived from noni fruit have different compositional parameters such as moisture, protein, fat and carbohydrate, among others. However, none of them include parameters for possible contaminants or undesirable substances, nor microbiological criteria.

All of them, with the exception of noni juice powder, consider the presence of different types of anthraquinones depending on the product (Table 5). In the case of noni juice, this specification was added after its authorisation when the Union List was published in 2017 (EU, 2017), due to the appearance of some scientific publications that seemed to link the consumption of this juice with cases of hepatotoxicity. Although EFSA concluded that no such association could be established between the consumption of noni juice and the described cases of hepatitis, specifications regarding the presence of anthraquinones were eventually added (EFSA, 2006).

Table 5. Specifications for the presence of anthraquinones in products derived from noni fruit

Novel food authorised	**Anthraquinones**			
	Rubiadin	**Lucidin**	**Alizarin**	**5,15-dimethylmorindol**
Noni fruit juice	≤10 µg/kg	≤10 µg/kg	-	-
Noni fruit juice powder	-	-	-	-
Noni fruit puree*	n.d.**	n.d.	n.d.	-
Concentrate of noni fruits*	-	-	-	≤0.254 µg/ml
Noni leaves	n.d. (≤10 µg/kg)	n.d. (≤10 µg/kg)	-	<47 mg/kg
Noni fruit powder	-	-	-	≤2.0 µg/ml

*Noni fruit puree and noni fruit concentrate are part of the same authorisation. **n.d.: not detected.

5.6 Oligosaccharides present in human milk

There are several oligosaccharides in human milk approved for industrial production, such as 2'-fucosyl-lactose (synthetic and microbial source), 3-fucosyl-lactose (microbial source) and a 2'-fucosyl-lactose/difucosyl-lactose mixture (microbial source) (Table 6), as well as several sources of lacto-N-tetraose and lacto-N-neotetraose.

The main difference lies in the source of the novel food, which can be synthetic or microbial. For those obtained by microbial synthesis, the strain used is indicated.

Table 6. Authorisations for oligosaccharides present in human milk I

Novel food authorised	**Source**
2'-Fucosyl-lactose (synthetic)	Chemical synthesis
2'-Fucosyl-lactose (microbial source)	Genetically modified strain of *E. coli* K12
	Genetically modified strain of *E. coli* BL21
	Genetically modified strain of *Corynebacterium glutamicum* ATCC 12032
2'-Fucosyl-lactose/difucosyl-lactose (2'-FL/DFL) mixture (microbial source)	Genetically modified strain of *E. coli* K12 DH1
3-Fucosyl-lactose (3-FL) (microbial source)	Genetically modified strain of *E. coli* K12
3-Fucosyl-lactose (3-FL) (produced by a strain derived from *E. coli* BL21 (DE3))	Genetically modified strain of *E. coli* BL21 (DE3)

With regard to the different authorisations listed in Table 6, a definition with chemical name, chemical formula, CAS No. and molecular weight is included in all cases, except for the 2'-FL/DFL mixture, which only contains a short description. However, microbiological criteria are included in all cases, although the number of parameters varies.

In addition, heavy metal specifications have been included, except for the 2'-FL from microbial source *E. coli* K12 strains and for 2'-FL/DFL. Mycotoxins have also been included in the following cases: 2'-FL from microbial source (*E. coli* BL21 and *Corynebacterium glutamicum* ATCC 12032 strains), 3-FL from microbial source and 3-FL (*E. coli* BL21 (DE3) strain).

In the case of lacto-N-neotetraose and lacto-N-tetraose oligosaccharides, there are 4 authorisations (Table 7). All have similar specifications, including composition and microbiological criteria. However, criteria for heavy metals (arsenic) and mycotoxins (aflatoxin M1) have only been established for lacto-N-tetraose produced by strains derived from *E. coli* BL21 (DE3).

Table 7. Authorisations for oligosaccharides present in human milk II	
Novel food authorised	**Source**
Lacto-N-neotetraose (synthetic)	Chemical synthesis
Lacto-N-neotetraose (microbial source)	Genetically modified strain of *E. coli* K12
	Combination of genetically modified strains PS-LNnT-JBT and DS-LNnT-JBT of *E. coli* BL21 (DE3)
Lacto-N-tetraose (LNT) (microbial source)	Genetically modified strain of *E. coli* K12 DH1
Lacto-N-tetraose (LNT) (produced by strains derived from *E. coli* BL21 (DE3))	Two genetically modified strains (one production strain and one optional degradation strain) of *E. coli* BL21 (DE3)

5.7 Bases for chewing gum

There are 2 product authorisations for chewing gum base obtained by chemical synthesis: monomethoxypolyethylene glycol and vinyl methyl ether copolymer with maleic anhydride. Both have a definition, a CAS No. and a different composition depending on the chewing gum base obtained. It should be noted that although they belong to the same food category and both originate from a chemical source, microbiological criteria are established only in the second case.

5.8 Products treated with ultraviolet radiation

One of the categories included in the scope of novel foods is foods derived from a new production process not previously used. In this context, the Union List (EU, 2017) includes 7 foods that have been subjected to an ultraviolet (UV) irradiation process with the aim of increasing the vitamin D content in the final product: mushrooms (*Agaricus bisporus*), baker's yeast (*Saccharomyces cerevisiae*), bread, milk and 3 mushroom powder (*Agaricus bisporius*).

Although they belong to the same category of novel foods, there are some differences in the specification. All of them refer to the vitamin D content in the final product (Table 8). However, only in mushrooms, bread and milk the wavelength value used in the irradiation process is specified.

Table 8. Novel foods treated with ultraviolet radiation

Novel food authorised	Wavelength (nm)	Vitamin D
Mushroom (*Agaricus bisporus*)	200-800	5-20 µg vitamin D_2/100 g
Baker's yeast (*Saccharomyces cerevisiae*)	-	200-875 µg vitamin D_2/g
Bread	240-315	0.75-3 µg vitamin D_2/100 g
Whole milk Semi-skimmed milk	200-310	0.5-3.2 µg vitamin D_3/100 g 0.1-1.5 µg vitamin D_3/100 g
Mushroom powder with vitamin D_2 I	-	1000-1300 µg vitamin D_2/g
Mushroom powder with vitamin D_2 II	-	580-595 µg vitamin D_2/g
Mushroom powder with vitamin D_2 III	-	125-375 µg vitamin D_2/g

The presence of contaminants or undesirable substances is only considered in mushroom powders. With regard to parameters related to potential contaminants, the same limits have been set for heavy metals (lead, cadmium, mercury and arsenic). In addition, the sum of aflatoxins B1, B2, G1 and G2 (<4 µg/kg) is considered in all three cases, and aflatoxin B1 is added in powders II and III, but with very different maximum limits (≤0.10 µg/kg and ≤2 µg/kg, respectively). Microbiological criteria are laid down for mushroom powder and yeast.

5.9 Engineered nanomaterials

The category of foods containing engineered nanomaterials is one of the new categories introduced by Regulation (EU) 2015/2283 (EU, 2015). Nanotechnology has great potential to improve the quality of food and to create new ingredients and additives with different functionalities, allowing innovation and improvement in food production. Therefore, despite the fact that only one novel food based on this technology is currently authorised, it was considered relevant to include it in this work due to its relevance and future expectations.

The only engineered nanomaterial currently authorised by the Union List (EU, 2017) is Iron Hydroxide Adipate Tartrate (IHAT). It includes specifications on compositional parameters, heavy metals (arsenic and nickel), microbiological criteria (total aerobic microbial count and total yeast and mould count) and residual solvents (ethanol). It also states that when other forms of food supplements (such as tablets, lozenges, powder sachets, gums, syrups, etc.) are used in combination with adipate, tartrate and sodium chloride or in combination with other substances, or when other substances are used in food supplements in capsule form containing the novel food, it must be ensured that the authorised particle size of the IHAT particles is maintained. The phase distribution (soluble, nano and micro) and the primary particle size are also specified.

6. Case study: comparison of the microbiological criteria laid down in novel food specifications with the maximum limits laid down in Regulation (EC) No. 2073/2005

Novel food specifications are part of European legislation and therefore compliance with them is mandatory if these products are to be marketed in the EU. In addition, it should be noted that there are already regulations on contaminants and microbiological criteria, among others, in certain foods or food groups.

In this context, Regulation (EC) No. 2073/2005 (EU, 2005) on microbiological criteria for foodstuffs establishes two types of microbiological criteria for different food categories: food safety criteria and process hygiene criteria (Table 9). Depending on the type of criterion, the stage at which it is applied is specified.

Table 9. Microbiological criteria established by Regulation (EC) No. 2073/2005

Food safety criteria	
Microoorganisms, their toxins and metabolites	**Food group**
Cronobacter spp. *Escherichia coli* Shiga toxin-producing *Escherichia coli* (STEC) O157, O26, O111, O103, O145, O104:H4 Staphylococcal enterotoxins Histamine *Listeria monocytogenes* *Salmonella* *Salmonella* Typhimurium *Salmonella* Enteriditis	Ready-to-eat food Dried infant formulae, follow-on formulae and dried dietary foods for special medical purposes for infants under six months of age Meat and products thereof Fishery products Vegetables, fruit and products thereof Milk and dairy products Egg products
Process hygiene criteria	
Microorganisms	**Food group**
Bacillus cereus (presumed) *Campylobacter* spp. *Escherichia coli* Enterobacteriaceae Coagulase-positive staphylococci Aerobic colony count *Salmonella* *Salmonella* spp.	Meat and products thereof Milk and dairy products Egg products Fishery products Vegetables, fruit and products thereof

It should be borne in mind that correct sampling can be decisive for the representativeness of the analytical results and thus for their validity. In this respect, Chapter 3 of Annex I lays down the rules for sampling and sample preparation. In addition, for each microbiological criterion, this Regulation establishes the microbiological limits and the sampling plan based on a standardised analytical method according to an ISO (International Organization for Standardization) standard. However, the novel food specifications for microbiological criteria do not specify the type of criterion, the sampling plan or the reference analytical method.

On the other hand, most of the novel foods included in the Union List (EU, 2017) do not fall within the scope of the limits established by Regulation (EC) No. 2073/2005, such as oils, extracts, fungi,

insects, micro-algae, seeds or products of chemical synthesis, among others. Some others, such as noni juice or milk treated with ultraviolet radiation, could be included in some of the categories of this Regulation.

At present, Regulation (EC) No. 2073/2005 does not set limits to ensure the safety of foods susceptible to viral contamination. On the other hand, the specifications for novel foods only consider the presence of influenza A virus (negative) in the protein extract of porcine kidney by real-time reverse transcriptase PCR.

Due to the differences described above, it is difficult to make a comparison between the microbiological criteria set for different foods in the two Regulations, and it is not possible to establish a relationship between the microbiological criteria for conventional foods and novel foods. Therefore, there seems to be a different approach to the setting of microbiological criteria between Regulation (EC) No. 2073/2005 and novel food specifications, as the latter can be considered as limits rather than criteria in the absence of indications on the sampling plan and methods of analysis.

Conclusions

1. An analysis of the specifications laid down for novel foods has revealed a certain lack of uniformity in the criteria used to define them.
2. It is difficult to ensure full identification of novel foods that do not contain parameters. In this regard, the absence of a specification regarding the purity of some extracts, such as, for example, *Echinacea angustifolia* and *Echinacea purpurea* extracts from cell cultures, is noteworthy.
3. Although the establishment of methods for the analysis of contaminants may be useful for the competent authorities when carrying out official controls and for operators, it would be more appropriate to refer to the criteria or conditions that these methods should meet rather than to the specific methods of analysis, since the progress in analytical techniques means that the specific methods established may become obsolete over time.
4. No differences were found between the criteria used to establish specifications for novel foods authorised under the general procedure and those authorised under the traditional food from third countries procedure.
5. Despite the existence of novel food legislation since 1997 and the evaluation criteria laid down in Regulation (EC) No. 258/97, there has been some variation in the criteria used to establish specifications. However, the experience gained during the period of validity of Regulation (EC) No. 258/97 has provided an important basis for entering a new phase with the implementation of Regulation (EU) 2015/2283 from 2018, in which the efficiency of the authorisation procedure can be improved, as it is a simplified and centralised process managed by the European Commission, and transparency, as EFSA is the only evaluating body and also publishes all its safety assessments.

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