Official Journal
of the European Union

EN
L series

2024/2048

30.7.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2048

of 29 July 2024

amending Implementing Regulation (EU) 2017/2470 as regards the specifications and the conditions of use of the novel food protein extract from pig kidneys

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 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 ([1]), and in particular Article 12 thereof,

Whereas:

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

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ([2]) has established a Union list of novel foods.

(3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes protein extract from pig kidneys as an authorised novel food.

(4) Pursuant to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council ([3]), on 29 February 2012, the company Sciotec Diagnostic Technologies GmbH notified the Commission of its intention to place on the market protein extract from pig kidneys as a novel food ingredient to be used in foods for special medical purposes, which were subsequently defined in Article 2 of Regulation (EU) No 609/2013 of the European Parliament and of the Council ([4]), and in food supplements as defined in Article 2 of Directive 2002/46/EC of the European Parliament and of the Council ([5]). Based on that notification, protein extract from pig kidneys was included in the Union list of novel foods, when that list was established.

(5) Commission Implementing Regulation (EU) 2020/973 ([6]) amended the conditions of use of protein extract from pig kidneys to include enteric coated tablets as an allowed form of protein extract from pig kidneys to be used as food supplements as defined in Directive 2002/46/EC and as foods for special medical purposes as defined in Regulation (EU) No 609/2013, in addition to the authorised enteric coated encapsulated pellets.

([1]) OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.

([2]) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

([3]) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel foods ingredients (OJ L 43, 14.2.1997, p. 1, ELI: http://data.europa.eu/eli/reg/1997/258/oj).

([4]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35, ELI: http://data.europa.eu/eli/reg/2013/609/oj).

([5]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51, ELI: http://data.europa.eu/eli/dir/2002/46/oj).

([6]) Commission Implementing Regulation (EU) 2020/973 of 6 July 2020 authorising a change of the conditions of use of the novel food 'protein extract from pig kidneys' and amending Implementing Regulation (EU) 2017/2470 (OJ L 215, 7.7.2020, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2020/973/oj).

(6) Commission Implementing Regulation (EU) 2023/951 ([7]) amended the specifications of protein extract from pig kidneys to include a production process involving the use of a series of acetone wash steps of the pig kidneys, followed by heat-drying steps, milling and sieving, to result in a pale brown powder of the novel food which is formulated either in enteric coated capsules or as encapsulated enteric coated pellets or enteric coated tablets to reach the active sites of digestion, and the use of ultra-high performance liquid chromatography linked with fluorescent detection as an additional method to the currently authorised one for the determination of the enzymatic activity of diamine oxidase ('DAO') contained in the protein extracted from the pig kidneys.

(7) On 28 June 2023, the company Dr Healthcare España, S.L.U. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change in the specifications and in the conditions of use of the novel food protein extract from pig kidneys to include enteric coated microcapsules as an allowed form of protein extract from pig kidneys to be used in foods for special medical purposes and in food supplements, in addition to the currently authorised enteric coated pellets, capsules and tablets.

(8) The Commission considers that the requested update of the Union list is not liable to have an effect on human health. Evidence provided by the applicant and by previous applicants in support of the previous amendments in the specifications and conditions of use of the novel food indicate that the form of the novel food has no impact on its safety, provided that the maximum authorised levels of 12,6 mg pig kidney extract per day resulting in a maximum intake of 0,9 mg DAO per day and delivered in 3 doses with each dose containing a maximum of 0,3 mg of DAO are not exceeded in any of those forms. On that basis, rather than authorising enteric coated microcapsules as yet another form of this novel food, it is appropriate to amend the conditions of use and the specifications of the novel food to remove the specific forms of the novel food and to allow for the forms set out in Article 2 of Directive 2002/46/EC, and only refer to the maximum authorised levels of the pig kidney extract and of levels of DAO as these are the important components underpinning its safety and not the forms in which the novel food is to be made available to consumers. The maximum level of protein extract from pig kidneys as a novel food currently authorised is 12,6 mg pig kidney extract per day resulting in a maximum intake of 0,9 mg DAO per day and delivered in 3 doses with each dose containing a maximum of 0,3 mg of DAO.

(9) On 2 March 2023 the Court of Justice of the European Union ([8]) ruled, among other things, on the interpretation of Article 2 of Directive 2002/46/EC and Article 2(2), point (g), of Regulation No 609/2013 and concluded that the concepts of 'food supplement' and 'food for special medical purposes' are mutually exclusive and that it is necessary for Member States to determine on a case-by-case basis and according to the characteristics and conditions of use whether a product falls within one or the other of those categories. In light of that ruling, and the fact that the novel food pig kidney extract is currently authorised to be used in foods for special medical purposes as defined in Article 2 of Regulation (EU) No 609/2013, and in food supplements as defined in Article 2 of Directive 2002/46/EC at identical maximum use levels and dosage conditions, the Commission considers that it is appropriate to make a distinction in the conditions of use in the Union list between the two product categories.

([7]) Commission Implementing Regulation (EU) 2023/951 of 12 May 2023 amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food protein extract from pig kidneys (OJ L 128, 15.5.2023, p. 73, ELI: http://data.europa.eu/eli/reg_impl/2023/951/oj).

([8]) Case C-760/21 (2023/C 155/26), Kwizda Pharma: Judgment of the Court (Second Chamber) of 2 March 2023 (request for a preliminary ruling from the Verwaltungsgericht Wien – Austria) – Kwizda Pharma GmbH v Landeshauptmann von Wien (Reference for a preliminary ruling – Food safety – Food – Regulation (EU) No 609/2013 – Article 2(2)(g) – Concept of 'food for special medical purposes' – Other particular nutritional requirements – Dietary management – Modification of the diet – Nutrients – Use under medical supervision – Ingredients not absorbed or metabolised in the alimentary canal – Distinction in relation to medicinal products – Distinction in relation to food supplements (OJ C 155, 2.5.2023, p. 22).

(10) The information provided in the application and the available scientific evidence underpinning the authorisation of this novel food and previous authorisations of changes in the specifications to authorise the different forms of the novel food (enteric coated pellets, enteric coated capsules and enteric coated tablets), gives sufficient grounds to establish that the above-described changes to the specifications and the conditions of use of the novel food protein extract from pig kidneys are in accordance with the conditions laid down in Article 12 of Regulation (EU) 2015/2283 and should be approved.

(11) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 29 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the entry for 'Protein extract from pig kidneys' is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	*Maximum levels*		
'**Protein extract from pig kidneys**	Food supplements as defined in Directive 2002/46/EC	12,6 mg protein extract from pig kidney/day containing 0,9 mg/day diamine oxidase (DAO) taken in 3 doses per day, each dose containing a maximum of 0,3 mg DAO		
	Food for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended, but not higher than 12,6 mg protein extract from pig kidney/day containing 0,9 mg/day DAO'		

(2) in Table 2 (Specifications), the entry for 'Protein extract from pig kidneys' is replaced by the following:

Authorised novel food	Specification	
'**Protein extract from pig kidneys**	**Description/Definition:** The protein extract is obtained from homogenised pig kidneys through a combination of salt precipitation and high-speed centrifugation. The obtained precipitate contains essentially proteins with 7 % of the enzyme diamine oxidase (enzyme nomenclature E.C. 1.4.3.22) and is resuspended in a physiologic buffer system. The obtained protein extract from pig kidney is formulated in appropriate forms and dosage to reach the active sites of digestion.	**Description/Definition:** The protein extract is obtained from homogenised pig kidneys through a series of steps involving a number of acetone washes to defat and dehydrate the homogenized pig kidneys, followed by draining, drying, milling, and sieving to produce a powder containing essentially proteins with a 7-9 % (on average) content of the enzyme diamine oxidase (enzyme nomenclature E.C. 1.4.3.22). The protein extract from pig kidney is formulated in appropriate forms and dosage to reach the active sites of digestion.

ELI: http://data.europa.eu/eli/reg_impl/2024/2048/oj

	Basic product: Specification: Protein extract from pig kidney with natural content of diamine oxidase (DAO): Physical condition: liquid Colour: brownish Appearance: slightly turbid solution pH value: 6,4-6,8 Enzymatic activity: > 2 677 kHDU DAO/ml (DAO REA (DAO Radio Extraction Assay)) **Microbiological criteria:** *Brachyspira* spp.: negative (Real Time PCR) *Listeria monocytogenes*: negative (Real Time PCR) *Staphylococcus aureus*: < 100 CFU/g Influenza A: negative (Reverse Transcription Real Time PCR) *Escherichia coli*: < 10 CFU/g Total aerobic microbiological count: < 10^5 CFU/g Yeasts/moulds count: < 10^5 CFU/g *Salmonella*: Absence/10 g Bile salt resistant enterobacteriaceae: < 10^4 CFU/g **Final product:** Specification protein extract from pig kidney with natural content of DAO (E.C. 1.4.3.22) in appropriate forms and dosage to reach the active sites of digestion:	**Basic product:** Specification: Protein extract from pig kidney with natural content of diamine oxidase (DAO): Physical condition: powder Colour: pale brown Enzymatic activity: ≥ 0,10 mU/mg (ultra-high performance liquid chromatography linked with fluorescent detection) Humidity: < 10 % **Residual solvents:** Acetone: < 5 000 mg/kg **Microbiological criteria:** *Staphylococcus aureus*: < 100 CFU/g *Escherichia coli*: < 10 CFU/g Total aerobic microbiological count: < 10^4 CFU/g Total combined yeasts/moulds count: < 10^3 CFU/g *Salmonella*: Absence/10 g Bile salt resistant enterobacteriaceae: < 10^2 CFU/g *Listeria monocytogenes*: absence in 25 g **Final product:** Specification protein extract from pig kidney with natural content of DAO (E.C. 1.4.3.22) in appropriate forms and dosage to reach the active sites of digestion: Physical condition: solid

	Physical condition: solid Colour: yellow grey Enzymatic activity: 110-220 kHDU DAO/g (DAO REA (DAO Radio Extraction Assay)) Acid stability 15 min 0,1M HCl followed by 60 min Borat pH = 9,0: > 68 kHDU DAO/g (DAO REA (DAO Radio Extraction Assay)) Humidity: < 10 % **Microbiological criteria:** *Staphylococcus aureus*: < 100 CFU/g *Escherichia coli*: < 10 CFU/g Total aerobic microbiological count: < 10^4 CFU/g Total combined yeasts/moulds count: < 10^3 CFU/g *Salmonella*: Absence/10 g Bile salt resistant enterobacteriaceae: < 10^2 CFU/g PCR: Polymerase Chain Reaction; HDU (Histamine Degrading Units)	Colour: pale brown Enzymatic activity: 2,29-4,6 mU/g (ultra-high performance liquid chromatography linked with fluorescent detection). Acid stability 15 min 0,1M HCl followed by 60 min Borat pH = 9,0: > 1,4 mU DAO/g (ultra-high performance liquid chromatography linked with fluorescent detection) Humidity: < 10 % **Microbiological criteria:** *Staphylococcus aureus*: < 100 CFU/g *Escherichia coli*: < 10 CFU/g Total aerobic microbiological count: < 10^4 CFU/g Total combined yeasts/moulds count: < 10^3 CFU/g *Salmonella*: Absence/10 g Bile salt resistant enterobacteriaceae: < 10^2 CFU/g *Listeria monocytogenes*: absence in 25 g mU: milliUnit (expressed in mU/mg) measures nanomols (nmol) of histamine degraded by the DAO per minute using ultra-high performance liquid chromatography linked with fluorescent fetection (O. Comas-Basté et al. Analytical and Bioanalytical Chemistry 411:7595-7602 (2019)). 1 mU corresponds to 48 000 HDU of the DAO Radio Extraction Assay (REA) method.'

ELI: http://data.europa.eu/eli/reg_impl/2024/2048/oj