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

(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 as 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]). On the basis of that notification, the 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 specifications of the novel food protein extract from pig kidneys to include enteric coated tablets as an allowed form of protein extract from pig kidneys to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council and in 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.

([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).

([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).

([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).

([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).

([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).

(6) On 11 July 2022, the company Bioiberica, S.A.U ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the specifications of the novel food 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 final form 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. The applicant also requested the use of Ultra High Performance Liquid Chromatography linked with Fluorescent Detection ('UHPLC-FLD') 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. This method results in the activity of DAO being expressed in measurement units ('MU') that are different from the currently authorised ones. The applicant justified their request for the addition of a new production process on the fact that their production process besides being robust and consistent in producing the novel food in line with the authorised specifications, it is not protected by third party patents as the currently authorised novel food production process is thereby preventing the applicant and other food business operators from making use of it. The applicant justified their request for the use UHPLC-FLD method to measure the DAO activity as being a well-known method that is easy to validate and implement while being equally reliable to the currently authorised Radio Extraction Assay ('REA') method.

(7) The Commission considers that the requested update of the Union list is not liable to have an effect on human health, and that a safety evaluation by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The production process using the acetone wash method followed by heat-drying steps, milling and sieving results in the production of a novel food that complies with all the authorised specifications and only differs in its form (powder) and colour (pale brown). The changes in the physical form and appearance of the novel food obtained by the acetone wash method are not expected to impact the safety of the novel food if the authorised conditions of use and specifications are respected. The use of capsules is currently authorised for the enteric coated pellet form of the novel food and their use for the powder form of the novel food is also not liable to change the safety profile of this authorised novel food.

(8) Acetone as a solvent used in the preparation of foods is authorised by Directive 2009/32/EC of the European Parliament and of the Council ([7]), and levels up to 5 000 mg/kg of acetone have been assessed by the Authority in the context of the safety assessment of the application for the authorisation of nicotinamide riboside chloride as a novel food ([8]) that involved identical proposed uses and resulting anticipated intakes to the uses and intakes of the protein extract from pig kidneys. The Commission however considers that, as an additional safety reassurance element, acetone should be added as a parameter in the specifications of the protein extract from pig kidneys produced by the acetone wash production process, at the same levels (≤ 5 000 mg/kg) that have been assessed by the Authority and are included in the specifications of the novel food nicotinamide riboside chloride authorised by Commission Implementing Regulation (EU) 2020/16 ([9]).

(9) The Commission also considers that the inclusion in the Union list of the UHPLC-FLD method for the determination of the enzymatic activity of DAO, and the expression of its resulting activity in different measurement units in addition to the currently authorised method and measurement units, will offer food business operators and Member State enforcement authorities another method to verify the performance and quality of the novel food placed on the market.

([7]) Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3).

([8]) EFSA Journal 2019; 17(8):5775.

([9]) Commission Implementing Regulation (EU) 2020/16 of 10 January 2020 authorising the placing on the market of nicotinamide riboside chloride as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 7, 13.1.2020, p. 6).

(10) The information provided in the application gives sufficient grounds to establish that the changes to the specifications of the novel food protein extract from pig kidneys are in accordance with the conditions of 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, 12 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Table 2 (Specifications) of the Annex to Implementing Regulation (EU) 2017/2470, 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 pig kidney extract is formulated as encapsulated enteric coated pellets or enteric coated tablets to reach the active sites of digestion. **Basic Product:** Specification: pig kidney protein extract 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 Radioextractionassay)) **Microbiological criteria:** Brachyspira spp.: negative (Real Time PCR) Listeria monocytogenes: negative (Real Time PCR) Staphylococcus aureus: < 100 CFU/g	**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 pig kidney extract powder is formulated either in enteric coated capsules or as encapsulated enteric coated pellets or enteric coated tablets to reach the active sites of digestion. **Basic Product:** Specification: pig kidney protein extract with natural content of Diamine oxidase (DAO): Physical condition: powder Colour: pale brown Enzymatic activity: ≥ 0,10 mU/mg (UHPLC-FLD (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

	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/10g Bile salt resistant enterobacteriaceae: < 10^4 CFU/g **Final product:** Specification pig kidney protein extract with natural content of DAO (E.C. 1.4.3.22) in an enteric coated formulation: Physical condition: solid Colour: yellow grey Appearance: micropellets or tablets Enzymatic activity: 110-220 kHDU DAO/g pellet or g tablet (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 pellet or g tablet (DAO REA (DAO Radio Extraction Assay)) Humidity: < 10 % **Microbiological criteria:** *Staphylococcus aureus*: < 100 CFU/g *Escherichia coli*: < 10 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/10g Bile salt resistant enterobacteriaceae: < 10^2 CFU/g *Listeria monocytogenes*: absence in 25 g **Final product:** Specification pig kidney protein extract with natural content of DAO (E.C. 1.4.3.22) in an enteric coated formulation: Physical condition: solid Colour: pale brown Appearance: micropellets, capsules, or tablets Enzymatic activity (micropellets, capsules or tablets): 2,29 – 4,6 mU/g pellet or g tablet or g capsule (UHPLC-FLD (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 pellet or g tablet or g capsule (UHPLC-FLD (Ultra High Performance Liquid Chromatography linked with Fluorescent Detection)) Humidity: < 10 % **Microbiological criteria:** *Staphylococcus aureus*: < 100 CFU/g

	Total aerobic microbiological count: < 10^4 CFU/g Total combined yeasts/moulds count: < 10^3 CFU/g *Salmonella*: Absence/10g Bile salt resistant enterobacteriaceae: < 10^2 CFU/g PCR: Polymerase Chain Reaction; HDU (Histamine Degrading Units);	*Escherichia coli*: < 10 CFU/g Total aerobic microbiological count: < 10^4 CFU/g Total combined yeasts/moulds count: < 10^3 CFU/g *Salmonella*: Absence/10g 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 Detection (UHPLC-FLD) (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.’