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 (Text with EEA relevance)

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

(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 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 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)] which establishes a Union list of authorised novel foods was adopted.

(3) On 29 February 2012, the company Sciotec Diagnostic Technologies, GmbH informed the Commission, pursuant to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council[(3)], 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 Regulation (EU) No 609/2013 of the European Parliament and of the Council[(4)], and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[(5)]. Therefore, protein extract from pig kidneys was included in the Union list of novel foods.

(4) On 14 May 2019, the company Dr Health Care España, S.L. made a request to the Commission to extend the conditions of use of the protein extract from pig kidneys within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to include enteric coated tablets 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 encapsulated pellets.

(5) The Commission did not request an opinion from the European Food Safety Authority, as the amendment of the conditions of use of the novel food protein extract from pig kidneys by including enteric coated tablets as an allowed form of protein extract from

pig kidneys to be used in foods for special medical purposes and in food supplements, is not liable to change the effects of this authorised novel food on human health.

(6) The maximum level of protein extract from pig kidneys as a novel food currently authorised to be used in enteric coated encapsulated pellets in foods for special medical purposes, and in food supplements, is 3 capsules/day, corresponding to 12,6 mg pig kidney extract a day. The proposed use of the enteric coated tablets form will not alter the currently authorised maximum level of the novel food. Therefore, it is appropriate to amend the section of the Union list on the conditions of use of protein extract from pig kidneys to authorise its use also in enteric coated tablets form at the same maximum authorised level as the already authorised forms of use of this novel food.

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

(8) 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

1 The entry in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283 referring to the 'protein extract from pig kidneys' shall be amended as specified in the Annex to this Regulation.

2 The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in 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, 6 July 2020.

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:

<table>
<tr><th>Authorised novel food</th><th colspan="2">Conditions under which the novel food may be used</th><th>Additional specific labelling requirements</th><th>Other requirements</th></tr>
<tr><td rowspan="3">'Protein extract from pig kidneys</td><td>Specified food category</td><td>Maximum levels</td><td rowspan="3"></td><td rowspan="3"></td></tr>
<tr><td>Food Supplements as defined in Directive 2002/46/EC</td><td rowspan="2">3 capsules or 3 tablets/day; equalising 12,6 mg pig kidney extract a day Diamine oxidase (DAO) content: 0,9 mg/day (3 capsules or 3 tablets with a content of DAO of 0,3 mg/capsule or 0,3 mg/tablet)'</td></tr>
<tr><td>Food for special medical purposes as defined in Regulation (EU) No 609/2013</td></tr>
</table>

(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 pig kidney extract is formulated as encapsulated enteric coated pellets or enteric coated tablets to reach the active sites of digestion. Basic Product: