

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising a change of the conditions of use of the novel food ʽprotein extract from pig kidneysʼ 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]](#footnote-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]](#footnote-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]](#footnote-3), of its intention to place on the market “protein extract from pig kidneys” as a novel food ingredient. 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 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 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 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

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.

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,

For the Commission

The President

Ursula VON DER LEYEN

1. OJ L 327, 11.12.2015, p. 1. [↑](#footnote-ref-1)
2. Commission Implementing Regulation (EU) No 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). [↑](#footnote-ref-2)
3. Regulation (EC) No 258/1997 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p.1). [↑](#footnote-ref-3)