

## COMMISSION IMPLEMENTING DECISION (EU) 2017/1387

of 24 July 2017

**authorising the placing on the market of an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council**

*(notified under document C(2017) 4975)***(Only the English text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients <sup>(1)</sup>, and in particular Article 7(1) thereof,

Whereas:

- (1) On 13 June 2012, the company DSM Food Specialties made a request to the competent authorities of France to place an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger*, on the Union market as a novel food ingredient within the meaning of point (d) of Article 1(2) of Regulation (EC) No 258/97. The target population is the general adult population.
- (2) On 31 July 2014, the competent food assessment body of France issued its initial assessment report. In that report it came to the conclusion that an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 11 November 2014, the Commission forwarded the initial assessment report to the other Member States.
- (4) Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.
- (5) On 25 November 2015, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* as a novel food ingredient in accordance with Regulation (EC) No 258/97.
- (6) On 13 December 2016, EFSA in its opinion on the safety of prolyl oligopeptidase as a novel food ingredient pursuant to Regulation (EC) No 258/97 concluded that the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* is safe for the proposed use and use levels <sup>(2)</sup>.
- (7) That opinion gives sufficient grounds to establish that the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* in the proposed use and use levels complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (8) Enzyme preparation of prolyl oligopeptidase falls outside the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council <sup>(3)</sup> on genetically modified food and feed as the genetically modified strain of *Aspergillus niger* is used as a processing aid and the material derived from the genetically modified microorganism is not present in the novel food.
- (9) Directive 2002/46/EC of the European Parliament and of the Council <sup>(4)</sup> lays down requirements on food supplements. The use of the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* should be authorised without prejudice to the provisions of that Directive.

<sup>(1)</sup> OJ L 43, 14.2.1997, p. 1.<sup>(2)</sup> EFSA Journal 2017; 15(2): 4681.<sup>(3)</sup> Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).<sup>(4)</sup> 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).

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

HAS ADOPTED THIS DECISION:

*Article 1*

Without prejudice to Directive 2002/46/EC, the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* as specified in Annex I to this Decision may be placed on the Union market as a novel food ingredient to be used in food supplements intended for the general adult population with a maximum dose established in Annex II to this Decision.

*Article 2*

The designation of the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* authorised by this Decision on the labelling of the foodstuffs shall be 'prolyl oligopeptidase'.

*Article 3*

This Decision is addressed to DSM Nutritional Products Ltd, Wurmisweg 576, 4303 Kaiseraugst, Switzerland.

Done at Brussels, 24 July 2017.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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## ANNEX I

**Specifications of the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger***

*Specification of the enzyme*

Systematic name	Prolyl oligopeptidase
Synonyms	Prolyl endopeptidase, proline-specific endopeptidase, endoprollylpeptidase
Molecular weight	66 kDa
Enzyme Commission number	EC 3.4.21.26
CAS number	72162-84-6
Source	A genetically modified strain of <i>Aspergillus niger</i> (GEP-44)

*Description:* Prolyl oligopeptidase is available as an enzyme preparation containing approximately 30 % maltodextrin.

*Specifications of the enzyme preparation of prolyl oligopeptidase*

Parameter	Specifications Limits
<b>Activity</b>	> 580 000 PPI ( <sup>1</sup> )/g (> 34,8 PPU ( <sup>2</sup> )/g)
<b>Appearance</b>	Microgranulate
<b>Colour</b>	Off-white to orange yellowish. The colour may change from batch to batch
<b>Dry Matter</b>	> 94 %
<b>Gluten</b>	< 20 ppm
<b>Heavy metals</b>	
Total heavy metals (as lead)	≤ 10 mg/kg
Lead	≤ 1,0 mg/kg
Arsenic	≤ 1,0 mg/kg
Cadmium	≤ 0,5 mg/kg
Mercury	≤ 0,1 mg/kg
<b>Microbiological specifications</b>	
Total aerobic plate count	≤ 10 <sup>3</sup> CFU/g
Total yeasts and moulds	≤ 10 <sup>2</sup> CFU/g
Sulphite reducing anaerobes	≤ 30 CFU/g
<i>Enterobacteriaceae</i>	< 10 CFU/g
<i>Salmonella</i>	Absent in 25 g

<i>Escherichia coli</i>	Absent in 25 g
<i>Staphylococcus aureus</i>	Absent in 10 g
<i>Pseudomonas aeruginosa</i>	Absent in 10 g
<i>Listeria monocytogenes</i>	Absent in 25 g
Antimicrobial activity	Absent
Mycotoxins	Below limits of detection: Aflatoxin B1, B2, G1, G2 (< 0,25 µg/kg), total Aflatoxins (< 2,0 µg/kg), Ochratoxin A (< 0,20 µg/kg), T-2 Toxin (< 5 µg/kg), Zearalenone (< 2,5 µg/kg), Fumonisin B1 and B2 (< 2,5 µg/kg)

(<sup>1</sup>) PPI — Protease Picomole International.

(<sup>2</sup>) PPU — Prolyl Peptidase Units or Proline Protease Units.

## ANNEX II

**Authorised uses of the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger***

Food category	Maximum dose
Food supplements as defined in Directive 2002/46/EC	120 PPU <sup>(1)</sup> /day (2,7 g of enzyme preparation/day) (2 × 10 <sup>6</sup> PPI <sup>(2)</sup> /day) for general adult population

<sup>(1)</sup> PPU — Prolyl Peptidase Units or Proline Protease Units.

<sup>(2)</sup> PPI — Protease Picomole International.