Commission Implementing Regulation (EU) 2018/1123 of 10 August 2018 authorising the placing on the market of 1-methylnicotinamide 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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1123

of 10 August 2018

authorising the placing on the market of 1-methylnicotinamide 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

(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 may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283 the Commission Implementing Regulation (EU) 2017/2470[(2)] was adopted, which establishes a Union list of authorised novel foods.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on updating the Union list.

(4) On 18 September 2013, the company Pharmena SA (‘the Applicant’) made a request to the competent authority of the United Kingdom to place synthetic 1-methylnicotinamide chloride on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council[(3)]. The application requests for 1-methylnicotinamide chloride to be used in food supplements for the general adult population, excluding pregnant and lactating women.

(5) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not

been taken before 1 January 2018, shall be treated as an application submitted under Regulation (EU) 2015/2283.

(6) While the request for placing 1-methylnicotinamide chloride on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.

(7) On 26 November 2015, the competent authority of the United Kingdom issued its initial assessment report. In that report, it came to the conclusion that 1-methylnicotinamide chloride meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

(8) On 11 December 2015, the Commission forwarded the initial assessment report to the other Member States. 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 with regard to the safety and tolerance of 1-methylnicotinamide chloride, and in particular on the effects on consumer health of the long-term intake of 1-MNA, especially when taking into account the intake of niacin from the diet, including food supplements.

(9) In view of the objections raised by the other Member States, on 11 August 2016, the Commission consulted the European Food Safety Authority ('the Authority') asking it to carry out an additional assessment for 1-methylnicotinamide chloride as novel food ingredient in accordance with Regulation (EC) No 258/97

(10) On 20 September 2017, the Authority adopted 'Scientific Opinion on the safety of 1-methylnicotinamide chloride as a novel food pursuant to Regulation (EC) No 258/97'[(4)]. This opinion, although elaborated and adopted by EFSA under Regulation (EC) No 258/97 is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(11) That opinion gives sufficient grounds to establish that 1-methylnicotinamide chloride in the proposed uses and use levels when used as an ingredient in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.

(12) On 25 January 2018, the Applicant made a request to the Commission for protection of proprietary data for a number of studies submitted in support of the application namely, the methods of analysis[(5)], an animal toxicity and pharmacokinetic study[(6)], a human pharmacokinetic study[(7)], an *in vitro* micronucleus test with human lymphocytes study[(8)], a human lipid metabolism study[(9)], a 90-day sub chronic oral toxicity study[(10)], and a single dose human bioavailability study[(11)].

(13) On 18 February 2018, the Authority considered that in elaborating its opinion on 1-methylnicotinamide chloride as a novel food, the methods of analysis served as the basis to assess the specifications and the composition of 1-methynicotinamide, the *in vitro* micronucleus test study with human lymphocytes served as the basis to conclude that there were no concerns with respect to the genotoxicity of 1-methylnicotinamide chloride, and the 90-day oral toxicity study served as the basis to establish a reference point and to assess whether the margin of exposure in relation to the proposed maximum intake of 1-methylnicotinamide chloride by humans is sufficient.

(14) Following the receipt of the Authority's opinion, the Commission requested the Applicant to further clarify the justification provided with regard to their proprietary claim over the studies, which were unpublished at the time the application was submitted, and to clarify their claim to an exclusive right of reference to those studies, as referred to in Article 26(2)(a)(b) of Regulation (EU) 2015/2283.

(15) The Applicant has also declared that, at the time the application was submitted, they held proprietary or exclusive rights of reference to the studies under national law and that therefore third parties could not lawfully access or use those studies. The Commission assessed all the information provided by the Applicant and considered that the Applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283.

(16) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the methods of analysis of 1-methylnicotinamide chloride, the *in vitro* micronucleus test with human lymphocytes study, and the 90-day sub chronic oral toxicity study contained in the Applicant's file should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the Applicant for a period of five years.

(17) However, restricting the authorisation of this novel food and of the reference to the studies contained in the Applicant's file for the sole use of the Applicant, does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information available outside the Applicant's file supporting the authorisation under this Regulation.

(18) Taking into account of the intended use in food supplements for the general adult population, and the fact that the request for authorisation excludes pregnant and lactating women, food supplements containing 1-methylnicotinamide chloride should be appropriately labelled.

(19) Directive 2002/46/EC of the European Parliament and of the Council[(12)] lays down requirements on food supplements. The use of 1-methylnicotinamide chloride should be authorised without prejudice to that Directive.

(20) 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 1-methylnicotinamide chloride as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2 For a period of five years from the date of entry into force of this Regulation only the initial Applicant:

Company: Pharmena SA

Address: ul. Wolczanska 178, 90 530 Lodz, Poland

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Pharmena SA.

3 The entry in the Union list referred to in the first paragraph shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

4 The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the applicant as proprietary and without which the data protection could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Pharmena SA.

Article 3

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

Article 4

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, 10 August 2018.

For the Commission

The President

Jean-Claude JUNCKER