COMMISSION IMPLEMENTING REGULATION (EU) 2018/1122

of 10 August 2018

authorising the placing on the market of pyrroloquinoline quinone disodium salt 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 6 December 2012, the company Mitsubishi Gas Chemical Company, Inc. ('the Applicant') made a request to the competent authority of Ireland to place pyrroloquinoline quinone disodium salt produced from the bacterium *Hyphomicrobium denitrificans*, 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 pyrroloquinoline quinone disodium salt 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 concerning novel foods and novel food ingredients, 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 pyrroloquinoline quinone disodium salt 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 8 July 2016, the competent authority of Ireland issued its initial assessment report. In that report, it came to the conclusion that an additional assessment is required for pyrroloquinoline quinone disodium salt with regards to its safety following long-term consumption at the levels proposed in the application, in accordance with Article 6(3) of Regulation (EC) No 258/97.

(8) On 2 August 2016, the Commission forwarded the initial assessment report to the other Member States. The Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 agreed with the initial assessment report of Ireland.

(9) In view of the initial assessment report conclusions issued by Ireland, to which the other Member States agreed, on 13 October 2016, the Commission consulted the European Food Safety Authority ('the Authority') asking it to carry out an additional assessment for pyrroloquinoline quinone disodium salt as a novel food ingredient in accordance with Regulation (EC) No 258/97.

([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 food ingredients (OJ L 43, 14.2.1997, p. 1).

(10) On 24 October 2017, the Authority adopted 'Scientific Opinion on the safety of pyrroloquinoline quinone disodium salt as a novel food pursuant to Regulation (EC) No 258/97' ([1]). This opinion, although elaborated and adopted by the Authority 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 pyrroloquinoline quinone disodium salt 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 24 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, a bacterial reverse mutation test study ([2]), an *in vitro* chromosomal aberration test in human blood lymphocytes study ([3]), an *in vitro* chromosomal aberration test in Chinese hamster lung fibroblasts study ([4]), an *in vivo* micronucleus test study ([5]), a 14-day oral toxicity and a 90-day oral toxicity studies ([6]), and a 28-day renal toxicity study ([7]).

(13) On 18 February 2018, the Authority considered ([8]) that in elaborating its opinion on pyrroloquinoline quinone disodium salt as a novel food, the data from the bacterial reverse mutation test and from the *in vivo* micronucleus test studies served as basis to alleviate concerns with respect to the potential genotoxity of pyrroloquinoline quinone disodium salt, and the 14-day oral, the 28-day renal toxicity, and the 90-day oral toxicity studies served as a basis to assess the toxicity profile of pyrroloquinoline quinone disodium salt and to establish the related No Observed Adverse Effect Level (NOAEL). Therefore, it is considered that the conclusions on the safety of pyrroloquinoline quinone disodium salt, could not have been reached without the data from the unpublished reports of these studies.

(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 study reports, which were unpublished at the time the application was made, 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 bacterial reverse mutation test, the *in vivo* micronucleus test studies, the 14-day oral toxicity, the 28-day renal toxicity, and the 90-day oral toxicity studies 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 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 pyrroloquinoline quinone disodium salt should be appropriately labelled.

(19) Directive 2002/46/EC of the European Parliament and of the Council ([9]) lays down requirements on food supplements. The use of pyrroloquinoline quinone disodium salt should be authorised without prejudice to that Directive.

([1]) *EFSA Journal* 2017; 15(11):5058.
([2]) Mitsubishi Gas Chemical Company Inc., 2005b (unpublished report).
([3]) Mitsubishi Gas Chemical Company Inc., 2008b (unpublished report).
([4]) Mitsubishi Gas Chemical Company Inc., 2006d (unpublished report).
([5]) Mitsubishi Gas Chemical Company Inc., 2006c (unpublished report).
([6]) Mitsubishi Gas Chemical Company Inc., 2005a (unpublished report).
([7]) Mitsubishi Gas Chemical Company Inc., 2006b (unpublished report).
([8]) EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies, Minutes of the 83rd Plenary held on 7-8 February 2018 and agreed on 18 February 2018.
([9]) 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).

(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. Pyrroloquinoline quinone disodium salt 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: Mitsubishi Gas Chemical Company, Inc.

Address: Mitsubishi Building 5-2 Marunouchi 2-chome, Chiyoda-ku, Tokyo 100-8324, Japan

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 Mitsubishi Gas Chemical Company, Inc.

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 Mitsubishi Gas Chemical Company, Inc.

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

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) the following last column is added in Table 1 (Authorised novel foods):

'Data Protection'

(2) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'**Pyrroloquinoline quinone disodium salt**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Pyrroloquinoline quinone disodium salt". Food supplements containing Pyrroloquinoline quinone disodium salt shall bear the following statement: This food supplement should be consumed by adults only excluding pregnant and lactating women		Authorised on 2 September 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Mitsubishi Gas Chemical Company, Inc., Mitsubishi Building 5-2 Marunouchi 2-chome, Chiyoda-ku, Tokyo 100-8324, Japan. During the period of data protection the novel food Pyrroloquinoline quinone disodium salt is authorised for placing on the market within the Union only by Mitsubishi Gas Chemical Company, Inc., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Mitsubishi Gas Chemical Company, Inc. End date of the data protection: 2 september 2023'
	Food Supplements as defined in Directive 2002/46/EC intended for the adult population, excluding pregnant and lactating women	20 mg/day			

(3) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
'**Pyrroloquinoline quinone disodium salt**	**Definition:** Chemical name: disodium 9-carboxy-4,5-dioxo-1*H*-pyrrolo[5,4-f]quinoline-2,7-dicarboxylate Chemical formula: $C_{14}H_4N_2Na_2O_8$ CAS No: 122628-50-6 Molecular weight: 374,17 Da

Authorised Novel Food	Specification
	Description Pyrroloquinoline quinone disodium salt is a reddish–brown powder produced by the non-genetically modified bacterium *Hyphomicrobium denitrificans* strain CK-275. **Characteristics/Composition** Appearance: Reddish-brown powder Purity: ≥ 99,0 % (dry weight) UV absorbance (A322/A259): 0,56 ± 0,03 UV absorbance (A233/A259): 0,90 ± 0,09 Moisture: ≤ 12,0 % **Residual Solvent** Ethanol: ≤ 0,05 % **Heavy metals** Lead: < 3 mg/kg Arsenic: < 2 mg/kg **Microbiological criteria:** Total viable cell count: ≤ 300 CFU/g Mould/yeast: ≤ 12 CFU/g Coliforms: absent in 1 g *Hyphomicrobium denitrificans*: ≤ 25 CFU/g CFU: Colony Forming Units'