COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

authorising the placing on the market of glucosyl hesperidin as a novel food 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 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001[1], and in particular Article 12(1) thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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] has established a Union list of novel foods.

(3) On 26 March 2021, the company Nagase Viita Co., Ltd. ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place glucosyl hesperidin on the Union market as a novel food. The applicant requested for glucosyl hesperidin to be used in several hot beverages, non-alcoholic beverages and confectionery for the general population, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[3], excluding infants. Subsequently, on 14 May 2024, the applicant modified the initial request in the application for the use of glucosyl hesperidin to replace the proposed uses in several hot beverages, non-alcoholic beverages and confectionery with the use of the novel food in functional drinks at the same levels. As

[1] OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.

[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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

[3] 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, ELI: http://data.europa.eu/eli/dir/2002/46/oj).

this category alludes and can be interpreted by the consumers to be a nutrition claim according to the provisions of Regulation (EC) 1925/2006 of the European Parliament and of the Council[4], and in order to ensure clarity, it is appropriate that the designation of 'functional drink' should be replaced by 'soft drinks marketed in relation to physical exercise'. On XX September XXXX, the applicant withdrew the request for use in food supplements for young children from the application.

(4) On 26 March 2021, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data, namely, the certificates of analysis for glucosyl hesperidin[5], the HPLC-UV analysis, the NMR analyses for the determination of the identity of glucosyl hesperidin[6], the detailed description of the production process[7], the stability reports[8], the chromosome aberration test in cultured mammalian cells treated with glucosyl hesperidin[9], the micronucleus test of glucosyl hesperidin in mice[10], the bacterial reverse mutation test of glucosyl hesperidin[11], the *Salmonella typhimurium* and *Escherichia coli* reverse mutation assay[12], the composition of glucosyl hesperidin as tested in the 4-week oral toxicity study and the 90-day oral toxicity study[13], the 4-week oral toxicity study[14], the 90-day oral toxicity study in rats including the results of clinical biochemistry[15], the teratogenicity study of glucosyl hesperidin in rats[16].

(5) On 23 September 2021, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of glucosyl hesperidin as a novel food.

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4 Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. (OJ L 404, 30.12.2006, p. 26, ELI: http://data.europa.eu/eli/reg/2006/1925/oj).

5 Annex II_10_2_2_1_Conf_COA_GH_1K091 (unpublished); Annex_II_4_1_COA_5_Batches (unpublished); Annex_II_4_2_COA_5_Batches_Cadmium_Mercury (unpublished), Annex_II_4_3_1_Analytical Methods for MGH and HES (unpublished), Annex_II_10_1_COAs for GH samples (unpublished) Annex_II_4_MGH_HES_analysis (unpublished), Appendix_V_CoAs_raw_materials (unpublished), Appendix_VII_Compositional_analyses_of_GH (unpublished), Appendix_VII_updated_0123_GH_Compositional_analyses (unpublished), Annex_II_4_5_GH particle size distribution (unpublished).

6 Appendix_VII_1_HPLC Chromatogram_UV_detector (unpublished), Appendix_III_NMR_of_GH (unpublished), Appendix_II_NMR_of_Standards (unpublished).

7 Annex_II_3_1_Conf_Manufacturing_Process, (unpublished), Annex_II_3_1_1_Conf_HACCP_English_Translation (unpublished), Annex_II_3_1_2_Conf_Letters_of_consent_enzymes (unpublished).

8 Appendix_X_Stability_test_on_new_lot (unpublished)

9 Annex_II_10_2_1_Conf_Chromosome_aberration_test.pdf (unpublished)

10 Annex_II_10_2_2_Conf_Micronucleus_assay_0123; Annex_II_10_2_2_Conf_Micronucleus_assay.pdf (unpublished)

11 Annex_II_10_2_3_2_Conf_AMES_CoA (unpublished)

12 Annex_II_10_2_3_Conf_Bacterial_reverse_mutation_test_2.pdf

13 Annex II.10.2 (unpublished).

14 Annex_II_10_3_1_Conf_28_day_oral_toxicity_rat_study.pdf (unpublished)

15 Annex_II_10_3_2_Conf_90_day_oral_toxicity_rat_study.pdf (unpublished); Annex II.10.3.2.1.Conf (unpublished).

16 Annex_II_10_5_Conf_Teratogenicity.pdf (unpublished)

(6) On 25 June 2024, the Authority adopted its scientific opinion on Safety of glucosyl hesperidin as a Novel food[17] in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that glucosyl hesperidin is safe under the proposed conditions of use for the proposed target population. Therefore, that scientific opinion gives sufficient grounds to establish that glucosyl hesperidin, when used in soft drinks marketed in relation to physical exercise and in food supplements as defined in Directive 2002/46/EC, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on (i) detailed description of the production process; (ii) composition and stability of the novel food, and (iii) toxicological information including *in vitro* genotoxicity studies, 90-day subchronic toxicity study and teratogenicity study without which it could not have assessed the novel food and reached its conclusion.

(9) The applicant declared that they held proprietary and exclusive rights of reference to the scientific studies and data at the time they submitted the application.

(10) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific studies and data, namely, the certificates of analysis for glucosyl hesperidin[18], the HPLC-UV analysis, the NMR analyses for the determination of the identity of glucosyl hesperidin[19], the detailed description of the production process[20], the stability reports[21], the chromosome aberration test in cultured mammalian cells treated with glucosyl hesperidin[22], the micronucleus test of glucosyl hesperidin in mice[23], the bacterial reverse mutation test of glucosyl hesperidin[24], the *Salmonella typhimurium* and *Escherichia coli* reverse mutation assay[25], the composition of glucosyl hesperidin

17 DOI: 10.2903/j.efsa.2024.8911.

18 Annex II_10_2_2_1_Conf_COA_GH_1K091 (unpublished); Annex_II_4_1_COA_5_Batches (unpublished); Annex_II_4_2_COA_5_Batches_Cadmium_Mercury (unpublished), Annex_II_4_3_1_Analytical Methods for MGH and HES (unpublished), Annex_II_10_1_COAs for GH samples (unpublished) Annex_II_4_MGH_HES_analysis (unpublished), Appendix_V_CoAs_raw_materials (unpublished), Appendix_VII_Compositional_analyses_of_GH (unpublished), Appendix_VII_updated_0123_GH_Compositional_analyses (unpublished), Annex_II_4_5_GH particle size distribution (unpublished).

19 Appendix_VII_1_HPLC Chromatogram_UV_detector (unpublished), Appendix_III_NMR_of_GH (unpublished), Appendix_II_NMR_of_Standards (unpublished).

20 Annex_II_3_1_Conf_Manufacturing_Process (unpublished), Annex_II_3_1_1_Conf_HACCP_English_Translation (unpublished) Annex_II_3_1_2_Conf_Letters_of_consent_enzymes (unpublished)

21 Appendix_X_Stability_test_on_new_lot (unpublished)

22 Annex_II_10_2_1_Conf_Chromosome_aberration_test.pdf (unpublished)

23 Annex_II_10_2_2_Conf_Micronucleus_assay_0123; Annex_II_10_2_2_Conf_Micronucleus_assay.pdf (unpublished)

24 Annex_II_10_2_3_2_Conf_AMES_CoA (unpublished)

25 Annex_II_10_2_3_Conf_Bacterial_reverse_mutation_test_2.pdf

as tested in the 4-week oral toxicity study and the 90-day oral toxicity study[26], the 4-week oral toxicity study[27], the 90-day oral toxicity study in rats including the results of clinical biochemistry[28], the teratogenicity study of glucosyl hesperidin in rats[29] should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place glucosyl hesperidin on the market within the Union during a period of five years from the entry into force of this Regulation.

(11) However, restricting the authorisation of glucosyl hesperidin and the reference to the scientific studies and data contained in the applicant's file for the sole use by them does not prevent subsequent 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 such an authorisation.

(12) It is appropriate that the inclusion of glucosyl hesperidin as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

(13) Glucosyl hesperidin should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(14) 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. Glucosyl hesperidin is authorised to be placed on the market within the Union.

Glucosyl hesperidin shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

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

Article 2

Only the company Nagase Viita Co., Ltd.[30] is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from [*the date of entry*

26 Annex II.10.2 (unpublished).

27 Annex_II_10_3_1_Conf_28_day_oral_toxicity_rat_study.pdf (unpublished)

28 Annex_II_10_3_2_Conf_90_day_oral_toxicity_rat_study.pdf (unpublished); Annex II.10.3.2.1.Conf (unpublished).

29 Annex_II_10_5_Conf_Teratogenicity.pdf (unpublished)

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into force of this Regulation] [*OP please insert the date*], unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Nagase Viita Co., Ltd.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 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 Nagase Viita Co., Ltd.

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,

For the Commission
The President
Ursula VON DER LEYEN