

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

EN

**ANNEX**

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted: *[OP, please insert in the EN version in alphabetical order.]*

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
Glucosyl hesperidin	Specified food category	Maximum levels	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Glucosyl hesperidin'.  2. The labelling of food supplements containing the novel		Authorised on <i>[OP please insert the date dd.mm.yyyy - 20th day following its publication]</i> . This inclusion is based on proprietary scientific evidence and scientific data protected in
	Soft drinks marketed in relation to physical exercise	525 mg/L			

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	Food supplements as defined in Directive 2002/46/EC excluding infants and young children	115 mg/day for children between 3 to 10 years of age 200 mg/day for general population older than 10 years of age	food shall bear a statement that they should only be consumed: (a) by children above 3 years of age (b) by a general population older than 10 years of age.		accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Nagase Viita Co., Ltd., Nihon-Seimei Okayama Bldg., II Shinkan, 1-1-3 Shimoishii, Kita-ku, Okayama, 700-0907, Japan.  During the period of data protection, the novel food glucosyl hesperidin is authorised for placing on the market within the Union only by Nagase Viita Co., Ltd., 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 Nagase Viita Co., Ltd..
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(1) in Table 2 (Specifications), the following entry is inserted: [OP, please insert in the EN version in alphabetical order.]

Authorised Novel Food	Specification
Glucosyl hesperidin	<p><b>Description/Definition:</b> The novel food consists of a pale yellow to yellow-brown powder produced enzymatically from hesperidin and dextrin. <u>Following the inactivation of the enzymes, the solution undergoes a multistep purification process that includes filtration, chromatographic separation, intermediate concentration and decolourisation. The purified solution is then concentrated by evaporation, micro-filtrated and spray-dried.</u></p> <p><b>Characteristics/composition:</b> Monoglucosyl hesperidin (MGH) (dry basis) 75-85% Hesperidin (dry basis) 10-20% Loss on drying &lt; 6% Residue on ignition &lt; 2%</p> <p><b>Heavy metals</b> Lead ≤ 2 mg/kg Arsenic ≤ 1.5 mg/kg</p> <p><b>Microbiological criteria</b> Total aerobic microbial count: ≤ 100 CFU/g <i>E. coli</i>: Not detected in 10 g <i>Salmonella</i> spp. Not detected in 25 g Yeast and moulds: &lt; 100 CFU/g CFU: colony forming units.</p>

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