This draft has not been adopted nor 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.

WORKING DOCUMENT

Status: Commission internal procedures not yet launched

COMMISSION REGULATION (EU) …/…

of XXX

amending the Annex to Regulation (EU) No 231/2012 as regards neohesperidine dihydrochalcone (E 959)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[1], and in particular Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[2], and in particular Article 7(5) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.

(2) Commission Regulation (EU) No 231/2012[3] lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) The specifications for food additives may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council, either on the initiative of the Commission or following an application from a Member State or an interested party.

(4) Neohesperidine dihydrochalcone (E 959) is the food additive authorised in accordance with Annex II to Regulation (EC) No 1333/2008.

(5) Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the European Food Safety Authority ('the Authority').

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1 OJ L 354, 31.12. 2008, p.16, ELI: http://data.europa.eu/eli/reg/2008/1333/oj.

2 OJ L 354, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1331/2021-03-27.

3 Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/231/oj).

(6) On 17 November 2022, the Authority issued an opinion on the re-evaluation of neohesperidine dihydrochalcone (E 959) as food additive[4], which established an acceptable daily intake (ADI) of 20 mg/kg body weight (bw) per day for neohesperidine dihydrochalcone. The 95th percentile exposure estimates for chronic exposure to neohesperidine dihydrochalcone (E 959) were below the ADI in all populations, indicating that there is no safety concern.

(7) Neohesperidine dihydrochalcone (E 959) is obtained by catalytic hydrogenation of neohesperidin. Based on available information, the source material neohesperidin is a flavanone naturally occurring in bitter oranges (*Citrus aurantium*) that is isolated by alcohol extraction. Therefore, the Authority recommended including a definition of the source of the starting material and how this starting material is obtained in the existing specifications of neohesperidine dihydrochalcone (E 959). In addition, the CAS number for neohesperidine dihydrochalcone (E 959) and information on specific rotation of this food additive should be added into the specifications of this food additive. The Authority further recommended lowering the maximum limits for arsenic and lead in the EU specifications of neohesperidine dihydrochalcone (E 959) to ensure that the food additive will not be a significant source of exposure to those toxic elements through food, taking into account the scientific opinion of the Authority and the level which is currently achievable by the application of good manufacturing practices.

(8) Regulation (EU) No 231/2012 should therefore be amended accordingly.

(9) Considering that the Authority did not identify an immediate health concern linked to the current specifications for neohesperidine dihydrochalcone (E 959) and to allow the food business operators, including small and medium enterprises, to adapt to the new more stringent specifications laid down in this Regulation, the application of this Regulation should be deferred and a transitional period should be provided for the use of this additive lawfully placed on the market before the date of application of this Regulation.

(10) For the same reasons, a transitional period should be provided for foods, to which neohesperidine dihydrochalcone (E 959) that have been lawfully placed on the market before the date of application of this Regulation is added.

(11) 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

The Annex to Regulation (EU) No 231/2012 is amended in accordance with the Annex to this Regulation.

Article 2

1. The food additive neohesperidine dihydrochalcone (E 959) that has been lawfully placed on the market before [*6 months after the date of entry into force of this Regulation*] may be added to food in accordance with Annex II to Regulation (EC) No 1333/2008 until the exhaustion of stocks.

2. Foods, to which neohesperidine dihydrochalcone (E 959) that has been lawfully placed on the market before [*6 months after the date of entry into force of this Regulation*]

4 *EFSA Journal, 2022;20(11):7595*.

has been added, may be placed on the market until their date of minimum durability or 'use-by date'.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*6 months after the date of entry into force of this Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
[…]

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ANNEX

In the Annex to Regulation (EU) No 231/2012, the entry for food additive E 959 NEOHESPERIDINE DIHYDROCHALCONE is amended as follows:

(1) The entry 'Definition' is replaced by:

'Definition	Neohesperidine dihydrochalcone is obtained by catalytic hydrogenation of neohesperidin. The starting material neohesperidin is extracted in a hydroalcoholic solution from bitter oranges (*Citrus aurantium*) and purified.'

;

(2) new entry is inserted after the entry 'Definition':

‘CAS number	20702-77-6’

;

(3) new entry is inserted after the entry ‘Identification’:

‘Specific rotation	Between -85° and -86°’

;

(4) the entries for ‘Arsenic’ and ‘Lead’ are replaced by the following:

‘Arsenic	Not more than 0,05 mg/kg (expressed on dry weight basis)
Lead	Not more than 0,1 mg/kg mg/kg (expressed on dry weight basis)’

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