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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 saccharins (E 954)

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 additives¹, 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 flavourings², 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 231/2012³ 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) Saccharins (E 954) are food additives authorised in accordance with Regulation (EC) No 1333/2008.

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>).

- (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').
- (6) On 15 November 2024, the Authority issued a scientific opinion on the re-evaluation of saccharin and its sodium, potassium and calcium salts (E 954) as food additives⁴, which established an acceptable daily intake (ADI) of 9 mg/kg body weight (bw) per day for saccharins. The 95th percentile exposure estimates for chronic exposure to saccharins (E 954) were below the ADI in all populations, indicating that there is no safety concern.
- (7) To improve clarity, the name of the food additives saccharins and its sodium, potassium and calcium salts (E 954), as currently mentioned in Commission Regulation (EU) No 231/2012, should be aligned with the name of these food additives as mentioned in Regulation (EC) No 1333/2008.
- (8) Saccharins (E 954) can be manufactured by two different processes. Since the Authority received information on production of saccharins using the Remsen-Fahlberg process only, the evaluation on toxicological elements and potential impurities was performed for this process only. Therefore, the Authority recommended including a definition for saccharins (E 954) in the EU specifications, restricted to the manufacturing with the Remsen-Fahlberg process. In addition, the Authority recommended including the CAS numbers and indicating that the numbers refer to the anhydrous substances. The Authority also recommended increasing the purity of calcium saccharin (E 954(iii)) from 95 to 99 % and removing the parameter 'readily carbonisable substances' from the EU specifications of saccharins (E 954). The Authority further recommended lowering the maximum limits for lead and arsenic in the EU specifications of saccharins (E 954) 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.
- (9) Regulation (EU) No 231/2012 should therefore be amended accordingly.
- (10) Considering that the Authority did not identify an immediate health concern linked to the current specifications for saccharins (E 954) 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.
- (11) For the same reasons, a transitional period should be provided for foods, to which saccharins (E 954) that have been lawfully placed on the market before the date of application of this Regulation is added.
- (12) 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.

⁴ EFSA Journal, 2024; 22:e9044.

Article 2

1. The food additives saccharins (E 954) that have 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 saccharins (E 954) that have been lawfully placed on the market before *[6 months after the date of entry into force of this Regulation]* 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
[...]

ANNEX

In the Annex to Regulation (EU) No 231/2012, the entry for food additive E 954 SACCHARIN AND ITS Na. K AND Ca SALTS is amended as follows:

- (1) The title 'E 954 SACCHARIN AND ITS Na. K AND Ca SALTS' is replaced by '**E 954 SACCHARINS**';
- (2) The point '(i) SACCHARIN' is replaced by '**E 954(i) SACCHARIN**';

(3) The table below point (i) SACCHARIN is amended as follows:

(a) The entry for 'Definition' is replaced by:

'Definition	Manufactured by the Remsen-Fahlberg process'
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;

(b) A new entry is inserted after the entry 'Definition':

'CAS number	81-07-2'
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;

(c) The entry 'Readily carbonisable substances' is deleted;

(d) The entry 'Arsenic' is replaced by:

'Arsenic	Not more than 0,2 mg/kg (expressed on dry weight basis)'
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;

(e) The entry 'Lead' is replaced by:

'Lead	Not more than 0,5 mg/kg (expressed on dry weight basis)'
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(4) The point '(ii) SODIUM SACCHARIN' is replaced by 'E 954(ii) SODIUM SACCHARIN';

(5) The table below point (ii) SODIUM SACCHARIN is amended as follows:

(a) The entry for 'Definition' is replaced by:

'Definition	Manufactured by the Remsen-Fahlberg process'
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(b) A new entry is inserted after the entry 'Definition':

'CAS number	128-44-9 (anhydrous)'
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;

(c) The entry 'Einecs' is replaced by:

'Einecs	204-886-1 (anhydrous)'
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(d) The entry 'Readily carbonisable substances' is deleted;

(e) The entry 'Arsenic' is replaced by:

'Arsenic	Not more than 0,2 mg/kg (expressed on dry weight basis)'
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;

(f) The entry 'Lead' is replaced by:

'Lead	Not more than 0,5 mg/kg (expressed on dry weight basis)'
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(6) The point '(iii) CALCIUM SACCHARIN' is replaced by 'E 954(iii) CALCIUM SACCHARIN';

(7) The table below point (iii) CALCIUM SACCHARIN is amended as follows:

(a) The entry for 'Definition' is replaced by:

'Definition	Manufactured by the Remsen-Fahlberg process'
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(b) The entry 'Einecs' is replaced by:

'Einecs	229-349-9 (anhydrous)'
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(c) The entry 'Assay' is replaced by:

'Assay	Not less than 99 % of $C_{14}H_8CaN_2O_6S_2$ on the anhydrous basis'
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(d) The entry 'Readily carbonisable substances' is deleted;

(e) The entry 'Arsenic' is replaced by:

'Arsenic	Not more than 0,2 mg/kg (expressed on dry weight basis)'
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;

(f) The entry 'Lead' is replaced by:

'Lead	Not more than 0,5 mg/kg (expressed on dry weight basis)'
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(8) The point '(iv) POTASSIUM SACCHARIN' is replaced by 'E 954(iv) POTASSIUM SACCHARIN';

(9) The table below point (iv) POTASSIUM SACCHARIN is amended as follows:

(a) The entry for 'Definition' is replaced by:

'Definition	Manufactured by the Remsen-Fahlberg process'
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;

(b) A new entry is inserted after the entry 'Definition':

‘CAS number	10332-51-1 (anhydrous)’
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;

(c) The entry ‘Readily carbonisable substances’ is deleted;

(d) The entry ‘Arsenic’ is replaced by:

‘Arsenic	Not more than 0,2 mg/kg (expressed on dry weight basis)’
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(e) The entry ‘Lead’ is replaced by:

‘Lead	Not more than 0,5 mg/kg (expressed on dry weight basis)’
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