



2024/1821

27.6.2024

COMMISSION REGULATION (EU) 2024/1821

of 25 June 2024

**amending Annex II to Regulation (EC) No 1925/2006 of the European Parliament and of the Council
and Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards iron
milk caseinate added to foods and used in the manufacture of food supplements**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ⁽¹⁾, and in particular Article 4(5) thereof,

Having regard to 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 ⁽²⁾, and in particular Article 3(3) thereof,

Whereas:

- (1) Annexes I and II to Regulation (EC) No 1925/2006 establish the list of vitamin and mineral substances which may be added to foods and the forms in which they may be added.
- (2) Annexes I and II to Directive 2002/46/EC establish the list of vitamin and mineral substances which may be used in the manufacture of food supplements and the forms in which they may be added.
- (3) Commission Implementing Regulation (EU) 2023/949 ⁽³⁾ authorised iron milk caseinate as a novel food in, among other products, certain foods and food supplements subject to specific conditions.
- (4) During the process of authorisation, on 4 August 2022, the European Food Safety Authority ('the Authority') issued a scientific opinion ⁽⁴⁾ where it concluded that iron milk caseinate is safe under the proposed conditions of use and that it is a source from which iron is bioavailable.
- (5) Iron milk caseinate was on the basis of that scientific opinion included in the Union list of authorised novel foods provided for in the Annex to Commission Implementing Regulation (EU) 2017/2470 ⁽⁵⁾.
- (6) The Commission considers that the Authority's opinion gives sufficient grounds to establish that the use of iron milk caseinate as authorised by Implementing Regulation (EU) 2023/949, when used in foods and food supplements as specified therein, and excluding the use for infants and young children is not of safety concern as a source of iron.
- (7) Based on the Authority's favourable opinion and on the authorisation as a novel food as set out in Implementing Regulation (EU) 2023/949, iron milk caseinate should be included in Annex II Directive 2002/46/EC and in Annex II to Regulation (EC) No 1925/2006 as a form of iron.

⁽¹⁾ OJ L 183, 12.7.2002, p. 51.

⁽²⁾ OJ L 404, 30.12.2006, p. 26.

⁽³⁾ Commission Implementing Regulation (EU) 2023/949 of 12 May 2023 authorising the placing on the market of iron milk caseinate as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L 128, 15.5.2023, p. 60).

⁽⁴⁾ EFSA NDA Panel. Safety of iron milk proteinate as a novel food pursuant to Regulation (EU) 2015/2283 and bioavailability of iron from this source in the context of Directive 2002/46/EC (EFSA Journal 2022;20(9):7549).

⁽⁵⁾ 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).

- (8) The Advisory Group on the Food Chain and Animal and Plant Health was consulted and its comments were taken into consideration.
- (9) Annex II to Directive 2002/46/EC and Annex II to Regulation (EC) No 1925/2006 should therefore be amended accordingly.
- (10) 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

Annex II to Directive 2002/46/EC is amended in accordance with the Annex to this Regulation.

Article 2

Annex II to Regulation (EC) No 1925/2006 is amended in accordance with the Annex to this Regulation.

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*.

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

Done at Brussels, 25 June 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

1. In point 2 of Annex II to Regulation (EC) No 1925/2006, the following entry is inserted between the entry for 'elemental iron (carbonyl + electrolytic + hydrogen reduced)' and the entry for 'cupric carbonate':

'iron milk caseinate (*)

(*) As listed in the Union list of novel foods in 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).'

2. In Point B of Annex II to Directive 2002/46/EC, the following entry is inserted between the entry for 'ferric sodium EDTA' and the entry for 'iron (II) taurate':

'iron milk caseinate (*)

(*) As listed in the Union list of novel foods in Implementing Regulation (EU) 2017/2470.'