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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards iron hydroxide adipate tartrate used in the manufacture of food supplements

Delegations will find attached document D090704/02.

Encl.: D090704/02



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2344/2022
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[...](2023) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards iron hydroxide adipate tartrate used in the manufacture of food supplements

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards iron hydroxide adipate tartrate 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 supplements¹, and in particular Article 4(5) thereof,

Whereas:

- (1) Annexes I and II to Directive 2002/46/EC establish the list of vitamin and mineral substances, and for each of them the forms, which may be used in the manufacture of food supplements.
- (2) Pursuant to Article 14 of Directive 2002/46/EC, provisions on vitamin and mineral substances in food supplements that may have an effect upon public health are to be adopted after consultation with the European Food Safety Authority ('the Authority').
- (3) Following a request from the European Commission to deliver an opinion on iron hydroxide adipate tartrate as a novel food pursuant to Regulation (EU) 2015/2283 of the European Parliament and of the Council² and as a source of iron in the context of Directive 2002/46/EC, on 27 October 2021 the Authority adopted a scientific opinion on the matter³.
- (4) It follows from that opinion that iron hydroxide adipate tartrate used in food supplements is not of safety concern provided that certain conditions are respected which are set out in Commission Implementing Regulation (EU) 2022/1373.⁴ Based on the Authority's favourable opinion and on the authorisation as novel food ingredient as set out in Implementing Regulation (EU) 2022/1373, iron hydroxide adipate tartrate should be included in the list set out in Annex II to Directive 2002/46/EC in order to allow its use as a source of iron in food supplements.

¹ OJ L 183, 12.7.2002, p. 51.

² Regulation (EU) 2015/2283 of the 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 (OJ L 327, 11.12.2015, p. 1).

³ EFSA NDA Panel. Safety of iron hydroxide adipate tartrate as a novel food pursuant to Regulation (EU) 2015/2283 and as a source of iron in the context of Directive 2002/46/EC, EFSA Journal 2021;19(12):6935.

⁴ Commission Implementing Regulation (EU) 2022/1373 of 5 August 2022 authorising the placing on the market of iron hydroxide adipate tartrate as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L 206, 8.8.2022, p. 28).

- (5) Directive 2002/46/EC should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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

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