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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex I to Regulation (EU) No 10/2011 as regards the authorisation of the substance bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate (FCM No 1079)

Delegations will find attached document D089211/03.

Encl.: D089211/03



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/1364/2022 Rev.2
(POOL/E2/2022/1364/1364R2-EN.docx)
D089211/03
[...] (2023) **XXX** draft

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

of **XXX**

**amending Annex I to Regulation (EU) No 10/2011 as regards the authorisation of the
substance bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate (FCM No 1079)**

(Text with EEA relevance)

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

of **XXX**

amending Annex I to Regulation (EU) No 10/2011 as regards the authorisation of the substance bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate (FCM No 1079)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC¹, and in particular Article 5(1), second subparagraph, points (a), (e), and (i), and Article 11(3) thereof,

Whereas:

- (1) Commission Regulation (EU) No 10/2011² lays down specific rules as regards plastic materials and articles intended to come into contact with food. In particular, Annex I to that Regulation establishes a Union list of authorised substances that may be intentionally used in the manufacture of plastic materials and articles intended to come into contact with food.
- (2) On 11 December 2019, the European Food Safety Authority ('the Authority') adopted a favourable scientific opinion³ on the use of the substance bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate ('DEHCH', CAS No. 84731- 70- 4, FCM No 1079), as an additive (plasticiser) in poly(vinyl chloride) (PVC) at up to 25% w/w in contact with aqueous, acidic and low-alcohol foods for long-term storage at room temperature or below (refrigerated and frozen). Furthermore, based on a scientific study provided to the Authority, the Authority concluded that the substance does not raise a genotoxicity concern and noted that no adverse effects were observed up to the highest tested dose of 1000 mg/kg body weight (bw) per day in repeated dose toxicity studies. However, given uncertainty on the potential for accumulation of the substance in humans, it concluded that the migration of the substance should not exceed 0.05 mg/kg food, and the substance should only be used in PVC in contact with foods, for which simulants A (10% ethanol) and B (3% acetic acid) are assigned, at room temperature or below.
- (3) Therefore, it is appropriate to authorise the substance bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate .
- (4) Regulation (EU) No 10/2011 should be amended accordingly.

¹ OJ L 338, 13.11.2004, p. 4.

² Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

³ EFSA Journal 2020; 18(1):5973

- (5) 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 I to Regulation (EU) No 10/2011 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