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[...] (2023) **XXX** draft

COMMISSION IMPLEMENTING DECISION (EU) .../...

of **XXX**

not approving silver sodium hydrogen zirconium phosphate as an existing active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products¹, and in particular Article 89(1), third subparagraph, thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014² establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes silver sodium hydrogen zirconium phosphate (EC No: 422-570-3; CAS No: 265647-11-8) for product-type 4.
- (2) Sweden was designated as the rapporteur Member State. Silver sodium hydrogen zirconium phosphate has been evaluated by the competent authority of Sweden ('the evaluating competent authority') for use in biocidal products of product-type 4, food and feed area disinfectants, as referred to in Annex V to Regulation (EU) No 528/2012.
- (3) On 12 June 2017, the evaluating competent authority submitted the assessment report on the application together with the conclusions of its evaluation to the European Chemicals Agency ('ECHA'). ECHA discussed the assessment report and the conclusions in technical meetings.
- (4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of ECHA regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products

¹ OJ L 167, 27.6.2012, p. 1.

² Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

Committee adopted the opinion of ECHA on 3 March 2021³, having regard to the conclusions of the evaluating competent authority.

- (5) It results from the conclusions of the opinion of ECHA that sufficient efficacy has not been demonstrated for the use consisting in the incorporation of the reference biocidal product into food contact materials. Therefore, biocidal products of product-type 4 containing silver sodium hydrogen zirconium phosphate are not expected to satisfy the criterion set out Article 19(1), point (b)(i), of Regulation (EU) No 528/2012.
- (6) ECHA also concludes that unacceptable risks for human health have been identified from the consumption of food which has been in contact with treated polymers, and no adequate risk mitigation measure could be identified to mitigate those risks. Therefore, biocidal products of product-type 4 containing silver sodium hydrogen zirconium phosphate are not expected to satisfy the criterion set out Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.
- (7) Silver sodium hydrogen zirconium phosphate has been also assessed pursuant to Regulation (EC) No 1935/2004 of the European Parliament and of the Council⁴. The European Food Safety Authority ('EFSA') adopted an opinion evaluating the safety of silver sodium hydrogen zirconium phosphate for use in plastic food contact materials on 26 May 2004⁵. In that opinion, EFSA concluded that a restriction of 0.05 mg/kg of food (as silver) for silver sodium hydrogen zirconium phosphate would limit the intake to less than 12.5% of the human no observed adverse effect level, and therefore proposed a group-specific migration limit of 0.05 mg Ag/kg food. Although silver sodium hydrogen zirconium phosphate has not been authorised for use in plastic food contact materials at Union level, it has been included in a provisional list of additives which may be used in plastic food contact materials subject to national law, in accordance with Article 6(5) of Commission Regulation (EU) No 10/2011⁶.
- (8) In the context of the evaluation of silver compounds under Regulation (EU) No 528/2012, EFSA and ECHA issued a joint document⁷ in February 2020 ('joint EFSA-ECHA document'), in which they conclude that their respective opinions for the use of silver compounds in food contact materials are consistent within Regulation (EC) No 1935/2004 and Regulation (EU) No 528/2012, respectively, and that the differences in the risk assessment conclusions in their respective opinions are due to different objectives, datasets and methodologies.
- (9) Taking into account the opinion of ECHA, as well as the joint EFSA-ECHA document, it is appropriate not to approve silver sodium hydrogen zirconium phosphate as an active substance for use in biocidal products of product-type 4.

³ Biocidal Products Committee Opinion on the application for approval of the active substance: silver sodium hydrogen zirconium phosphate, Product type: 4, ECHA/BPC/278/2021, adopted on 3 March 2021.

⁴ 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/EEC (OJ L 338, 13.11.2004, p. 4).

⁵ EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food, 2004. Opinion of the Scientific Panel on Food Additives a 4th list of substances for food contact materials. EFSA Journal 2004; 2(6):65a, 17 pp. doi:10.2903/j.efsa.2004.65a.

⁶ 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).

⁷ Joint EFSA – ECHA document of February 2020. Comparison of the evaluations performed on silver compounds used as biocidal active substances in food contact materials (FCM) by EFSA and ECHA.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Silver sodium hydrogen zirconium phosphate (EC No: 422-570-3; CAS No: 265647-11-8) is not approved as an active substance for use in biocidal products of product-type 4.

Article 2

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN