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COMMISSION IMPLEMENTING DECISION (EU) 2023/2648

of 27 November 2023

not approving silver zeolite 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)

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 products ([1]), and in particular Article 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes silver zeolite (CAS No: 130328-18-6) for product-type 4.

(2) Sweden was designated as the rapporteur Member State. Silver zeolite 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. In the application for approval, the applicant submitted a representative biocidal product intended for two example uses: the incorporation into polymers used in food contact materials to reduce cross contamination of pathogens and the incorporation into materials used in water filters to control the growth of bacteria.

(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 Committee adopted the opinion of ECHA on 3 March 2021 ([3]), having regard to the conclusions of the evaluating competent authority.

(5) It results from the conclusions of the opinion of ECHA that, concerning the incorporation of silver zeolite into polymers used in food contact materials, sufficient efficacy has not been demonstrated. Furthermore, 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.

(6) As regards the incorporation of silver zeolite into materials used in water filters, ECHA identified unacceptable risks for infants (6 to 12 months old) consuming water filtered through materials treated with silver zeolite. The applicant proposed a risk mitigation measure in order to ensure that infants would not be exposed to silver zeolite above the acceptable threshold, namely to restrict the use of treated water filters to commercial, hospitality and institutional establishments and prohibit residential use, including also a mandatory labelling of filters. However, the Biocidal

([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).

([3]) Biocidal Products Committee Opinion on the application for approval of the active substance: silver zeolite, Product type: 4, ECHA/BPC/276/2021, adopted on 3 March 2021.

Products Committee found this measure insufficient, as it cannot be excluded that infants are exposed to unacceptable levels of silver zeolite via the consumption of filtered drinking water in restaurants and bars, especially when it comes to infants residing in the premises of bars and restaurants. There was no data submitted by the applicant in its dossier showing the sufficient risk reduction potential of such a measure. Data with respect to the in-house drinking water consumption of the general public versus outside the house (for example in restaurants and bars) or with respect to infants is lacking. There is no direct link between a warning given on the label, indicating that the impregnated water filter is for use in restaurants and bars only, and the objective of the measure (preventing the consumption by infants of drinking water which has passed through an impregnated filter). The Commission initiated a further consultation of Member States representatives on the matter in the Standing Committee on Biocidal Products, which further discussed the opinion of ECHA and additional arguments brought forward by the applicant on 3 May 2023. Member States representatives agreed with the opinion of ECHA and the Standing Committee on Biocidal Products concluded that there was not enough evidence to confirm that the risk mitigation measure proposed by the applicant would be sufficient to ensure that the risk to infants would be acceptable, while it could not identify any other adequate measure to mitigate the risk for infants for the use of water filters treated with silver zeolite.

(7) In conclusion, unacceptable risks to human health are identified for each of the example uses of the representative biocidal product submitted in the application, and no safe use could be identified. Therefore, biocidal products of product-type 4 containing silver zeolite are not expected to satisfy the criterion set out in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

(8) Silver zeolite has been also assessed pursuant to Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([4]). The European Food Safety Authority ('EFSA') adopted two opinions on 29 March 2005 ([5]) and on 4 February 2011 ([6]) evaluating the safety of silver zeolite A (silver zinc sodium ammonium alumino silicate), with a silver content of 2–5 %, for use in plastic food contact materials. In those opinions, EFSA concluded that there is no safety concern for the consumer if migration of silver ions from plastic food contact materials does not exceed a group-specific migration limit of 0,05 mg Ag/kg food. Although silver zeolite A 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 10/2011 ([7]).

(9) In the context of the evaluation of silver compounds under Regulation (EU) No 528/2012, EFSA and ECHA issued a joint document ([8]) in February 2020 (the '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.

(10) Taking into account the opinion of ECHA, as well as the joint EFSA-ECHA document, it is appropriate not to approve silver zeolite as an active substance for use in biocidal products of product-type 4.

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

([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]) Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 7th list of substances for food contact materials (Question N° EFSA-Q-2003-076, EFSA-Q-2004-144, EFSA-Q-2004-166, EFSA-Q-2004-082, EFSA-Q-2003-204, EFSA-Q-2003-205, EFSA-Q-2003-206) adopted on 29 March 2005 by written procedure. The EFSA Journal (2005)201, 1–28.

([6]) EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF); Scientific Opinion on the safety evaluation of the substance, silver zeolite A (silver zinc sodium ammonium alumino silicate), silver content 2–5 %, for use in food contact materials. EFSA Journal 2011;9(2):1999. [12 pp.] doi:10.2903/j.efsa.2011.1999.

([7]) 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).

([8]) 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.

HAS ADOPTED THIS DECISION:

Article 1

Silver zeolite (CAS No: 130328-18-6) 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, 27 November 2023.

For the Commission
The President
Ursula VON DER LEYEN