COMMISSION IMPLEMENTING REGULATION (EU) 2022/1990

of 20 October 2022

cancelling the approval of tolylfluanid as an active substance for use in biocidal products of product-type 7 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 15(1) thereof,

Whereas:

(1) Tolylfluanid was approved as an active substance for use in biocidal products of product-type 7, film preservatives, as described in Annex V to Regulation (EU) No 528/2012, by Commission Implementing Regulation (EU) 2016/1087 ([2]), subject to compliance with certain conditions ('the approval').

(2) On 2 March 2020, Denmark requested that the Commission should initiate a review of the approval pursuant to Article 15(1) of Regulation (EU) No 528/2012, on the basis of significant indications that the use of the active substance in biocidal products or treated articles raises significant concerns about the safety of such biocidal products or treated articles. In more detail, a metabolite of tolylfluanid, dimethylsulfamid, has been found in a great number of Danish drinking water supplies, and these contaminations can be linked with use of paints treated with tolylfluanid. Where groundwater is ozonated in water treatment for the production of drinking water, dimethylsulfamid may turn into N-nitrosodimethylamine which is genotoxic, mutagenic and carcinogenic. Denmark therefore requested a revision of the evaluation of the groundwater risk assessment for tolylfluanid for product-type 7, with the view to restrict the use of tolylfluanid in outdoor paints treated with tolylfluanid.

(3) On 5 July 2021, the Commission announced to the initial applicant for approval of tolylfluanid its intention to start the procedure for the review of the approval of that active substance for product-type 7 in accordance with Article 15(1) of Regulation (EU) No 528/2012, and provided an opportunity for the initial applicant to submit comments. Moreover, the Commission made publicly available the information that it is carrying out this review on the website of the Directorate-General for Health and Food Safety in accordance with Article 15(1) of Regulation (EU) No 528/2012.

(4) On 7 October 2021, the initial applicant for the approval of tolylfluanid indicated that it stopped the production of the active substance and the placing on the market of biocidal products containing it, and will not seek the renewal of approval of the substance. The initial applicant for the approval of tolylfluanid is the only substance supplier within the meaning of Article 95(1), first subparagraph, of Regulation (EU) No 528/2012 included in the list referred to in that subparagraph, for that active substance and product-type, published on the European Chemicals Agency's website. Furthermore, no biocidal product containing tolylfluanid for product-type 7 is authorised in the Union.

(5) Given that there are no other suppliers of the substance, that no biocidal product containing tolylfluanid for product-type 7 is authorised in the Union and that the initial applicant will not seek the renewal of approval of the substance, the Commission did not consult the European Chemicals Agency pursuant to Article 15(2) of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Implementing Regulation (EU) 2016/1087 of 5 July 2016 approving tolylfluanid as an existing active substance for use in biocidal products of product-type 7 (OJ L 180, 6.7.2016, p. 18).

(6) After having reviewed the information provided, the Commission considers that the use of tolylfluanid in biocidal products and treated articles raises significant concerns about the safety of such biocidal products and treated articles. Given the fact that there are no other suppliers of the substance, that no biocidal product containing tolylfluanid for product-type 7 is authorised in the Union and that the initial applicant will not seek the renewal of approval of the substance, the Commission considers appropriate to cancel the approval of tolylfluanid as an active substance for use in biocidal products of product-type 7.

(7) Implementing Regulation (EU) 2016/1087 should therefore be repealed.

(8) As economic operators need time to adapt to the cancellation of the approval, it should be allowed to continue placing on the Union market treated articles treated with or incorporating tolylfluanid for product-type 7 for some time.

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

HAS ADOPTED THIS REGULATION:

Article 1

The approval of tolylfluanid as an active substance for use in biocidal products of product-type 7 is cancelled.

Article 2

Implementing Regulation (EU) 2016/1087 is repealed with effect from 10 November 2022.

Article 3

Treated articles treated with or incorporating tolylfluanid for product-type 7 shall not be placed on the Union market from 10 May 2023.

Article 4

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, 20 October 2022.

For the Commission
The President
Ursula VON DER LEYEN