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COMMISSION IMPLEMENTING DECISION (EU) 2024/2402

of 12 September 2024

not renewing the approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18 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 14(4), first subparagraph, point (b), thereof,

Whereas:

(1) Sulfuryl fluoride was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) as an active substance for use in biocidal products of product-types 8 and 18. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved until 31 December 2018 for use in biocidal products of product-type 8 and until 30 June 2021 for use in biocidal products of product-type 18 under that Regulation subject to the requirements set out in Annex I to Directive 98/8/EC.

(2) On 28 June 2017, applications were submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18 ('the applications'). The applications were evaluated by the competent authority of Sweden ('the evaluating competent authority').

(3) On 14 February 2018, the evaluating competent authority informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the applications was necessary. In accordance with Article 14(2) of that Regulation, where the evaluating competent authority decides that a full evaluation of an application is necessary, the evaluation is to be carried out in accordance with Article 8(1), (2) and (3), of that Regulation.

(4) Pursuant to Commission Implementing Decision (EU) 2018/1479 ([3]), the expiry date of approval of sulfuryl fluoride for use in biocidal products of product-type 8 has been postponed to 30 June 2021, in order to allow sufficient time for the examination of the application. Commission Implementing Decision (EU) 2021/713 ([4]) further postponed the expiry date of the approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18 to 31 December 2023. That expiry was again postponed by Commission Implementing Decision (EU) 2023/2101 ([5]) to 31 December 2024.

(5) On 12 December 2022, the evaluating competent authority submitted recommendations on the renewal of the approval of sulfuryl fluoride to the European Chemicals Agency ('the Agency').

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p.1, ELI: http://data.europa.eu/eli/dir/1998/8/oj).
([3]) Commission Implementing Decision (EU) 2018/1479 of 3 October 2018 postponing the expiry date of approval of sulfuryl fluoride for use in biocidal products of product-type 8 (OJ L 249, 4.10.2018, p. 16, ELI: http://data.europa.eu/eli/dec_impl/2018/1479/oj).
([4]) Commission Implementing Decision (EU) 2021/713 of 29 April 2021 postponing the expiry date of approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18 (OJ L 147, 30.4.2021, p. 21, ELI: http://data.europa.eu/eli/dec_impl/2021/713/oj).
([5]) Commission Implementing Decision (EU) 2023/2101 of 28 September 2023 postponing the expiry date of the approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 241, 29.9.2023, p. 147, ELI: http://data.europa.eu/eli/dec_impl/2023/2101/oj).

(6) In accordance with Article 14(3) of Regulation (EU) No 528/2012, on 13 September 2023 the Agency adopted the opinions [6], [7] formulated by its Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(7) In its opinions the Agency concluded that the information provided in the applications was not sufficient to assess whether sulfuryl fluoride meets the criteria set out in Article 5(1), point (c), of Regulation (EU) No 528/2012, with regard to reproduction toxicity, and Article 5(1), point (d), of that Regulation, with regard to endocrine-disrupting properties that may cause adverse effects in humans. Furthermore, the information provided in the applications was not sufficient to assess whether sulfuryl fluoride meets the condition for being considered a candidate for substitution set out in Article 10(1), point (e), of Regulation (EU) No 528/2012 with regard to endocrine-disrupting properties that may cause adverse effects in non-target organisms.

(8) Pursuant to Article 8(2) and Article 6(2), second subparagraph, of Regulation (EU) No 528/2012, the evaluating competent authority requested the applicant to provide sufficient data in order to make it possible to determine whether sulfuryl fluoride meets the criteria referred to in Article 5(1), points (c) and (d), of Regulation (EU) No 528/2012. However, the requisite information and data have not been submitted by the applicant within the period prescribed by the evaluating competent authority. Therefore, Article 6(2), second subparagraph, of Regulation (EU) No 528/2012 has not been complied with, making it impossible to determine whether sulfuryl fluoride meets the criteria referred to in Article 5(1), points (c) and (d), of that Regulation, and subsequently it is not possible to determine whether sulfuryl fluoride may meet the conditions set out in Article 5 of that Regulation.

(9) Since the applicant did not submit the requisite information and data requested by the evaluating competent authority within the period prescribed with regard to Article 5(1), point (d), of Regulation (EU) No 528/2012, concerning endocrine-disrupting properties that may cause adverse effects in humans, the evaluating competent authority did not make a further request for data needed to assess whether sulfuryl fluoride meets the condition for being considered a candidate for substitution set out in Article 10(1), point (e), of that Regulation with regard to endocrine-disrupting properties that may cause adverse effects in non-target organisms.

(10) Furthermore, due to the missing information, it is not possible to evaluate the risks for both human health and the environment for the representative biocidal products containing sulfuryl fluoride for use in biocidal products of product-types 8 and 18 in order to determine if sulfuryl fluoride still meets the conditions of approval laid down in Article 4(1) of Regulation (EU) No 528/2012. Therefore, it has ultimately not been demonstrated that the representative biocidal products containing sulfuryl fluoride for use in biocidal products of product-types 8 and 18 may be expected to not have unacceptable effects themselves, or as a result of their residues, on human health and on the environment, and thus that they may be expected to satisfy the criteria set out in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012.

(11) Consequently, given the opinions of the Agency, taking into account that the applicant did not provide the requisite information and data prescribed by the evaluating competent authority needed to assess whether sulfuryl fluoride meets the criteria referred to in Article 5(1), points (c) and (d), of Regulation (EU) No 528/2012 and subsequently to assess whether sulfuryl fluoride may meet the conditions set out in Article 5 of that Regulation, and since it has not been demonstrated that the criteria laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012 are met, it cannot be determined whether the conditions laid down in Article 4(1) of that Regulation are still satisfied. Thus, the condition for renewal of the approval of an active substance set out in Article 12(1) of Regulation (EU) No 528/2012 is not fulfilled.

(12) It is therefore appropriate not to renew the approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18.

[6] Biocidal Products Committee (BPC) opinion on the application for renewal of the approval of the active substance: sulfuryl fluoride, Product type: 8, ECHA/BPC/389/2023, adopted on 13 September 2023.

[7] Biocidal Products Committee (BPC) opinion on the application for renewal of the approval of the active substance: sulfuryl fluoride, Product type: 18, ECHA/BPC/390/2023, adopted on 13 September 2023.

(13) 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

The approval of sulfuryl fluoride as an active substance for use in biocidal products of product-types 8 and 18 is not renewed.

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, 12 September 2024.

For the Commission
The President
Ursula VON DER LEYEN