COMMISSION IMPLEMENTING DECISION (EU) 2023/1155

of 9 June 2023

on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Rapid Pro referred by France in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2023) 3666)

(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 36(3) thereof,

Whereas:

(1) On 7 October 2016, the biocidal product Rapid Pro ('the biocidal product') was authorised in France by mutual recognition in parallel of an authorisation granted by Belgium in accordance with Article 34 of Regulation (EU) No 528/2012. The biocidal product is a rodenticide, falling under product-type 14 and is placed on the market in pre-filled tamper-resistant bait boxes used for indoor control of mice by professionals. The biocidal product contains the approved active substance alphachloralose. The authorisation holder of the biocidal product is Rentokil Initial.

(2) In 2019, France was informed by the Netherlands and Finland that in 2018 a significant increase of cases of primary and secondary poisonings of cats and dogs with symptoms of alphachloralose poisoning had been reported by poison centres, pet owners and veterinary clinics. In France, the French veterinary poisoning centres had also reported an increase of alphachloralose poisoning of companion animals, mainly primary poisoning of dogs, in 2017 and 2018.

(3) On 9 December 2019, France amended the authorisation of the biocidal product in accordance with Article 48(1), point (a), of Regulation (EU) No 528/2012 to address the primary poisoning incidents involving dogs and secondary poisoning incidents involving cats.

(4) France amended the authorisation by requiring additional labelling on the biocidal product to indicate the risk for humans and non-target organisms and on the packaging to indicate the obligation to use the biocidal product only in bait boxes.

(5) Pursuant to Article 48(3), third subparagraph, read in conjunction with Article 35(2) of Regulation (EU) No 528/2012, on 15 April 2020, Germany referred to the coordination group objections to the amendment of the authorisation of the biocidal product made by France.

(6) The objection from Germany related to the legal basis under which the product can be authorised, as according to Germany, the product does not fully meet the conditions of Article 19(1) of Regulation (EU) No 528/2012 due to the risk of primary and secondary poisoning of animals and may therefore be authorised only under Article 19(5). France considered that the biocidal product complies with Article 19(1) of Regulation (EU) No 528/2012 and that therefore Article 19(1) is the correct legal basis for the amended authorisation.

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

(7) On 6 June 2020, the secretariat of the coordination group invited the other concerned Member States and the authorisation holder to submit written comments on the referral. The authorisation holder submitted written comments on 30 June 2020, 6 July 2020 and 23 July 2020. The referral was discussed in the coordination group on 6 and 23 July 2020 with the participation of the authorisation holder.

(8) As no agreement was reached in the coordination group, on 21 October 2020, France, as a reference Member State for the purposes of amending the authorisation under Article 48(1), first subparagraph, of Regulation (EU) No 528/2012, referred the unresolved objections to the Commission pursuant to Article 36(1) of that Regulation and provided the Commission with a detailed statement of the matter on which Member States were unable to reach an agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and to the authorisation holder.

(9) In May 2021, the Finnish Safety and Chemical Agency requested an opinion from the Finnish Food Authority and the Finnish Veterinary Association on the effects of biocidal products containing alphachloralose on pets and the need to restrict the use of such products. That opinion, which Finland shared with the Commission, stated that biocidal products containing alphachloralose cause significant harm and suffering to both pets and wildlife and that the number of pet poisonings reported to the Finnish Safety and Chemical Agency and the Finnish Food Authority is significant.

(10) In addition, the Swedish Chemical Agency obtained additional information in the form of blood sample analyses from the University Animal Hospital in Uppsala, Sweden, which confirmed the presence of alphachloralose in the blood of poisoned animals.

(11) According to Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, it is a condition for granting an authorisation that the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects.

(12) Article 19(5), first subparagraph, of Regulation (EU) No 528/2012 provides that a biocidal product may be authorised when the conditions laid down in Article 19(1), point (b)(iii), are not fully met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation. Furthermore, Article 19(5), second subparagraph, states that the use of a biocidal product authorised pursuant to that provision is to be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to that paragraph is to be restricted to Member States in which the condition set out in Article 19(5), first subparagraph, is met.

(13) The Commission has carefully examined the information submitted by the Member States and by the authorisation holder of the biocidal product, including the fact that incidents of animal poisoning by products containing alphachloralose were also reported in other Member States and in Norway. The Commission also takes into account the opinion from the Finnish Food Authority and the Finnish Veterinary Association, as well as the reports from the University Animal Hospital in Uppsala and the Swedish Veterinary Association, which strongly indicate that the biocidal product has unacceptable effects on animal health, and which confirm, by analytical tests conducted on the poisoned animals, that a significant number of incidents of secondary poisoning by alphachloralose involving cats had occurred, as well as all the information provided and the discussions held in the context of disagreements for other biocidal products containing alphachloralose that were referred to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012.

(14) The Commission recognises that it is technically and scientifically impossible to link the reported secondary poisoning cases to a specific biocidal product, as it is not possible to identify which of the specific products was ingested by the mouse that was ingested by the cat. It is only possible to detect the presence of the active substance alphachloralose in the tissue of the animals and sometimes in the carcases of dead rodents in the stomach of poisoned cats. However, it is clear that those poisoning incidents were linked to biocidal products containing alphachloralose, including the biocidal product.

(15) Based on similar considerations, the Commission has recently adopted, in respect of similar products containing alphachloralose, Commission Implementing Decisions (EU) 2022/1005 ([2]), (EU) 2022/1006 ([3]) and (EU) 2022/1388 ([4]).

(16) The Commission considers that, while the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 are not fully met due to the unacceptable risks for animal health arising from the use of the biocidal product, no objection was referred to the coordination group on the rest of the conditions laid down in Article 19(1), point (b), and, regarding the risks to animal health identified, the risk mitigation measures applied by Member States are likely to reduce the risk of primary and secondary poisoning.

(17) The Commission therefore considers that, due to the risk of primary and secondary poisoning of dogs in France and of cats in several Member States, the biocidal product does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

(18) Therefore, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the biocidal product may only be authorised in Member States who consider that not authorising it would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

(19) Also, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the use of the biocidal product is to be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised.

(20) The active substance alphachloralose was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([5]) for use in biocidal products of product-type 14, and is therefore, pursuant to Article 86 of Regulation (EU) No 528/2012, deemed to have been approved under that Regulation, subject to the specifications and conditions set out in Annex I to Directive 98/8/EC.

(21) On 24 December 2019, pursuant to Article 13(1) of Regulation (EU) No 528/2012, an application for renewal of the approval of the active substance alphachloralose was submitted to the European Chemicals Agency. On 15 October 2020, the evaluating competent authority of Poland informed the Commission that it had decided, pursuant to Article 14(1) of that Regulation, that a full evaluation of the application for renewal was necessary.

(22) For reasons beyond the control of the applicants, the approval of alphachloralose for use in biocidal products of product-type 14, which was to expire on 30 June 2021, would have expired before a decision would have been taken on its renewal. Therefore, the expiry date of the approval of alphachloralose was postponed to 31 December 2023 by Commission Implementing Decision (EU) 2021/333 ([6]), to enable the examination of the application.

([2]) Commission Implementing Decision (EU) 2022/1005 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Grain referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 168, 27.6.2022, p. 86).

([3]) Commission Implementing Decision (EU) 2022/1006 of 24 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Pasta referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 168, 27.6.2022, p. 90).

([4]) Commission Implementing Decision (EU) 2022/1388 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Pat'Appât Souricide Canadien Foudroyant referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 208, 10.8.2022, p. 7).

([5]) 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).

([6]) Commission Implementing Decision (EU) 2021/333 of 24 February 2021 postponing the expiry date of approval of alphachloralose for use in biocidal products of product-type 14 (OJ L 65, 25.2.2021, p. 58).

(23) The risk of primary and secondary poisoning of animals due to the use of biocidal products containing alphachloralose, the differences in the occurrence of primary and secondary poisoning incidents among Member States and the necessary risk mitigation measures to be applied to reduce that risk to an acceptable level should be also assessed in the context of the evaluation of the application for renewal of the approval of alphachloralose and should subsequently be duly taken into account by Member States in the authorisation of biocidal products containing alphachloralose.

(24) The Commission therefore considers that risk mitigation measures to address the risk of primary and secondary poisoning from the use of the biocidal product should, exceptionally, until the conclusion of the evaluation of the application for renewal of the approval of alphachloralose, take into account the particular circumstances and available scientifically validated evidence of the occurrence of primary and secondary poisoning incidents in the individual Member States.

(25) On 26 October 2022, the Commission provided the authorisation holder with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The authorisation holder provided comments, which have been considered by the Commission.

(26) 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 biocidal product identified by the asset numbers AT-0016213-0000, BE-0011978-0000, CH-0016234-0000, DE-0015430-0000, DK-0012634-0000, ES-0014035-0000, FR-0012648-0000, IE-0014481-0000, IT-0014977-0000, LU-0012652-0000, LT-0018189-0000, NL-0016288-0000, NO-0015333-0000, PT-0020295-0000 in the Register for Biocidal Products ('the biocidal product') does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

The biocidal product may only be authorised in accordance with Article 19(5) of Regulation (EU) No 528/2012 in Member States who consider that not authorising it would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The use of the biocidal product shall be subject to appropriate risk mitigation measures, as referred to in Article 19(5) of Regulation (EU) No 528/2012, which shall be adopted in each Member State based on the particular circumstances and available evidence of the occurrence of primary and secondary poisoning incidents in that Member State.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 9 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission