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

(notified under document C(2022) 4226)

(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 19 March 2013 the biocidal product Black Pearl Pasta and on 27 August 2013 the biocidal product Le Foudrayant Souris Pate Rouge were authorised in France and Sweden in accordance with Directive 98/8/EC of the European Parliament and of the Council ([2]). On 9 October 2013, the biocidal product Black Pearl Pasta was mutually recognised in sequence by Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council. On 21 October 2019 and 5 March 2018, the biocidal product family Alphachloralose Pasta, which includes the product Black Pearl Pasta and the product Le Foudroyant Souris Pate Rouge, was authorised by France and Sweden respectively ('the biocidal product family'). The biocidal product family includes biocidal products that are rodenticides, falling under product-type 14 in accordance with Annex V to Regulation (EU) No 528/2012. The biocidal products are placed on the market in refillable covered bait boxes by trained professionals and in pre-filled tamper-resistant bait boxes by non-professionals. The biocidal products contain the approved active substance alphachloralose. The authorisation holder of the biocidal products is LODI S. A.S.

(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 were 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, between 2017 and 2018.

(3) In 2019, Sweden received information from veterinary clinics indicating that rodenticides containing alphachloralose had caused secondary poisoning in cats. The Swedish University of Agricultural Sciences, Small Animal Hospital stated that, there had, in recent years, been an increased number of reports of suspected alphachloralose poisoning in cats.

(4) On 30 October and 17 December 2019, France and Sweden respectively amended the authorisations of the biocidal product family Alphachloralose Pasta 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.

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

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

([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).

(6) Based on the information supplied to the Swedish Chemicals Agency, Sweden amended the authorisation of the product to restrict the use to trained professionals and added the conditions that the biocidal product was not to be used in environments where cats are expected to be present and that dead mice must be collected after the use of the biocidal product. The authorisation holder appealed the amendment made by Sweden and the Swedish Land and Environment Court concluded that the Swedish Chemicals Agency's decision to amend the authorisation of products containing alphachloralose and to issue a restriction in respect of those products were well-founded, and the appeal was rejected.

(7) Pursuant to Article 48(3) of Regulation (EU) No 528/2012, on 15 April 2020, Germany and Denmark referred to the coordination group objections to the amendments of the authorisation of the biocidal product family, made by France and Sweden.

(8) The objection from Germany related to the measures introduced by France, which were in their opinion not sufficient. Germany considered that, in order to address secondary poisoning incidents, the use of the biocidal product family should be restricted to trained professionals.

(9) The objection from Denmark relates to the restriction of the use of the biocidal product family to 'trained professionals' by Sweden. According to Denmark, the restriction of use to trained professionals was not justified in their territory. Denmark informed that they were not aware of secondary poisonings happening in Denmark and that there was no definition of 'trained professionals' in relation to chemical control of mice in their national legislation.

(10) 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.

(11) As no agreement was reached in the coordination group, France on 21 October 2020 and Sweden on 7 August 2020 referred the unresolved objections to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012 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.

(12) After the referrals pursuant to Article 36(1) of Regulation (EU) No 528/2012 by France and Sweden, in May 2021 the Finnish Safety and Chemical Agency (Tukes) requested an opinion from the Finnish Food Authority and the Finnish Veterinary Association on the effects of alphachloralose products on pets and the need to restrict the use of alphachloralose 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, that the number of pet poisonings reported to Tukes and the Finnish Food Authority is significant and that derogations to the authorisations made in accordance with Article 37(1)(a) and (c) of Regulation (EU) No 528/2012 in 2019 consisting of restricting the marketing and use of the biocidal products for non-professionals only to prefilled bait boxes, which Finland had already introduced, had not sufficiently reduced the number of cases. Therefore, the Finnish Food Authority recommended that the use and availability of products containing alphachloralose should be restricted to trained professionals. On 8 December 2021, Finland modified the authorisations of rodenticides containing alphachloralose to restrict the products to professional use in accordance with Article 48(1) of Regulation (EU) No 528/2012.

(13) 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 the poisoned animals.

(14) 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 animals, directly or through drinking water, food, feed, air, or through other indirect effects.

(15) 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. Article 19(5), second subparagraph, furthermore 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 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 of the first subparagraph is met.

(16) Having carefully examined the information submitted by the Member States and the authorisation holder of the biocidal product family, the Commission considers that the biocidal product family does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, taking 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, in which it was indicated that the biocidal product family has unacceptable effects on animal health and confirmed, by analytical tests conducted on the poisoned animals, that a significant number of poisoning incidents with alphachloralose involving cats had occurred.

(17) Therefore, in accordance with Article 19(5) of Regulation (EU) No 528/2012, the biocidal product family 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.

(18) 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 animals and the environment to that biocidal product is minimised.

(19) The active substance alphachloralose was included in Annex I to Directive 98/8/EC 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 that Directive.

(20) On 24 December 2019, pursuant to Article 13(1) of Regulation (EU) No 528/2012, an application for renewal of the active substance alphachloralose was submitted to the 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.

(21) As a result, for reasons beyond the control of the applicant, the approval of alphachloralose for use in biocidal products of product-type 14 was to expire on 30 June 2021, before a decision would have been taken on its renewal. Therefore, the expiry date of approval of alphachloralose was postponed to 31 December 2023, to enable the examination of the application, by Commission Implementing Decision (EU) 2021/333 ([3]).

(22) The risk of secondary poisoning of animals due to the use of biocidal products containing alphachloralose and the necessary risk mitigation measures to be applied in order to reduce that risk to an acceptable level should be 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.

([3]) 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) Having regard to the foregoing considerations, the Commission considers that risk mitigation measures to address the risk of primary and secondary poisoning incidents from the use of products containing alphachloralose should, exceptionally, pending the conclusion of the evaluation of alphachloralose, depend on the particular circumstances and available evidence of the occurrence of secondary poisoning incidents in the individual Member States. Some Member States might, for example, consider it necessary to restrict use to trained professionals while others might consider that additional labelling requirements suffice.

(24) On 14 February 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 the Commission, subsequently, took into account.

(25) 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 family identified by the asset number in the Register for Biocidal Products FR-0018427-0000 does not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

The biocidal product family identified by the asset number in the Register for Biocidal Products FR-0018427-0000 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.

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 in each Member State shall be adopted based on the particular circumstances and available evidence of the occurrence of secondary poisoning incidents in that Member State.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 24 June 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission