Official Journal
of the European Union

EN
L series

2024/2712

28.10.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/2712

of 23 October 2024

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Phenogen in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2024) 7275)

(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 23 April 2019, the company Synthèse élevage SARL ('the applicant') submitted an application for the mutual recognition in parallel, in accordance with Article 34 of Regulation (EU) No 528/2012, of the biocidal product Phenogen identified by the case numbers BC-DV051147-24, BC-WW051333-08, BC-VN051246-22, BC-DN051247-38, BC-DG051329-48 ('the product'). The product is a disinfectant of product-type 3 to be used by professionals for disinfection of livestock housings, equipment, and transportation vehicles, and contains as active substances chlorocresol and L(+) lactic acid. France is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.

(2) On 26 November 2021, Germany referred objections to the coordination group pursuant to Article 35(2) of Regulation (EU) No 528/2012, indicating that the conditions of the authorisation set by France do not ensure that the product meets the conditions laid down in Article 19(1), point (b)(iii) and point (e), of that Regulation.

(3) Germany considers that the dietary risk assessment for consumers performed by France does not ensure that the condition laid down in Article 19(1), point (b)(iii) of Regulation (EU) No 528/2012 is met, since the experimental data from chlorocresol residue studies in pigs and poultry ('the experimental data') used for the refinement of livestock exposure assessment were not suitable, as metabolites of chlorocresol were not measured, and as only one of the three studies presented in the application for product authorisation covers the application rate of the product. Germany considers that when experimental data are not used for the refinement of the risk assessment, it cannot be excluded that the residues of chlorocresol in edible tissues will exceed the maximum residue level (MRL) of 0,01 mg/kg established for chlorocresol in accordance with Article 18(1), point (b), of Regulation (EC) No 396/2005 of the European Parliament and of the Council ([2]). France considers it unlikely that metabolites will be produced during the use of the product due to the properties of chlorocresol. France pointed out that the experimental data were used for the assessment of the application for approval of the active substance to conclude that no residues were expected in livestock edible tissues after use of chlorocresol at a rate of 2 000 mg/m^2, whereas the application rate for the product is lower than the one assessed for the approval of chlorocresol, namely maximum of 1 200 mg/m^2. France confirmed that, when the experimental data are not considered, the estimation of residues of chlorocresol in edible tissues when using the European Food Safety Authority (EFSA) Pesticide Residue Intake Model (PRIMo model) ([3]) exceeds the MRL of 0,01 mg/kg established for chlorocresol in accordance with Article 18(1), point (b), of Regulation (EC) No 396/2005. To ensure that the MRL for chlorocresol in edible tissues is not exceeded by the use of the product, Germany proposed as a risk mitigation measure the rinsing of surfaces with water after the application of the product and proposed that, in the absence of experimental studies regarding efficacy of rinsing, a default factor

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/396/oj).
([3]) https://www.efsa.europa.eu/en/applications/pesticides/tools.

of 90 % be used for efficacy of rinsing for water soluble compounds including chlorocresol. France disagreed as it considers that the efficacy of rinsing was not supported by experimental data; moreover, in the instruction for use provided in the application for authorisation of the product, the applicant included the following instruction: 'the surfaces must not be rinsed after application'.

(4) The second point of disagreement raised by Germany concerns the dermal absorption value used by France for the assessment of exposure of livestock. Germany considers that the default dermal absorption value for water-based dilutions of 50 % established in the EFSA guidance on dermal absorption ([4]) only applies to human skin and is not applicable by analogy to animals. As there is no data on livestock dermal absorption, France believes that the dermal absorption value of 50 % should be used for livestock as it represents the worst case scenario, and points out that the dermal absorption value of 50 % was used for the evaluation of the application for approval of chlorocresol. To refine the assessment on exposure of livestock, Germany proposed the application of a default transfer coefficient for dislodgeable residues transferred from treated surfaces as established in the European Chemicals Agency (ECHA) Human Health Exposure Methodology ([5]), and the application of empirical transfer factors from a study by Leeman et al. (2007), as established in the European Medicines Agency guideline on risk characterisation and assessment of maximum residue limits for biocides ([6]) to estimate the maximum transfer of an external oral dose to livestock edible tissues. France considers that even considering those two refinement factors, the estimation of residues in edible tissues exceeds the MRL of 0,01 mg/kg established for chlorocresol in accordance with Article 18(1), point (b), of Regulation (EC) No 396/2005.

(5) As the coordination group did not reach an agreement, on 17 May 2022, France 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 agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and the applicant.

(6) On 21 November 2022, the Commission requested ECHA to determine whether the experimental data submitted in the application for approval of chlorocresol can be used for the refinement of livestock exposure assessment to the product, and to assess the risks for consumers and whether the use of the product would lead to an exceedance of the MRL of 0,01 mg/kg established in accordance with Article 18(1), point (b), of Regulation (EC) No 396/2005. ECHA was also requested to determine the dermal absorption value to be used for the livestock exposure assessment of the product and to assess the risks for consumers using that value and whether the use of the product considering that value would lead to an exceedance of the MRL of 0,01 mg/kg.

(7) The Commission also requested ECHA to determine the consequences of the refinements proposed by Germany as regards the residue levels in edible tissues and the potential risks for consumers.

(8) On 2 March 2023, the Biocidal Products Committee of ECHA adopted its opinion ([7]).

([4]) EFSA Guidance on dermal absorption of 24 May 2017 https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4873.
([5]) ECHA Guidance for Human Health Risk Assessment, Volume III Human Health, Part B Risk Assessment, Draft Version 2.0, May 2015. https://echa.europa.eu/documents/10162/23047722/bpr_vol_iii_partb_draft_chapter3_ca_en.pdf/04f7ba38-c55e-48a7-a1f3-e9ef0024cc23.
([6]) EMA/CVMP/90250/2010.
([7]) BPC opinion on unresolved objections during a mutual recognition procedure for a PT 3 biocidal product intended for disinfection of livestock animals' housings and equipment, and animal transportation vehicles.

(9) ECHA considers that the experimental data can be used for the refinement of livestock exposure assessment to the product, and those data lead to the conclusion that there would be no exceedance of the MRL of 0,01 mg/kg , even if the rate of application of the product is covered by only one of the studies, provided that rinsing of the surfaces on which the product is applied before letting the animals enter the facilities is required in the instructions for use. ECHA is of the opinion that although there is no study measuring the efficacy of rinsing to reduce the levels of chlorocresol on the treated surface, it is reasonable to assume a 90 % reduction. ECHA confirmed that the experimental data used for the assessment of the application for approval of chlorocresol lead to the conclusion that no residues were expected in livestock edible tissues after use of chlorocresol at a rate of 2 000 mg/m^2. However, two of the studies were performed using an application rate 10 times lower than the one intended for the product while in the third study, the application rate was 1,5 times higher than the one intended for the product. Furthermore, the assessment report for the approval of chlorocresol ([8]) indicates that an updated assessment of the risk in food and feed areas may be required at product authorisation stage.

(10) ECHA suggested that a protection factor for furs and feathers of 50 % can be used, whereas the livestock dermal absorption value should be 100 %. According to ECHA, when considering the experimental data, the 50 % systemic availability and residues transfer coefficient of chlorocresol and the 100 % dermal absorption value for livestock, the MRL of 0,01 mg/kg would not be exceeded.

(11) ECHA pointed out that, even without considering the experimental data, the consumer exposure does not exceed the acceptable daily intake of chlorocresol established in the active substance assessment report of 0,3 mg/kg of body weight.

(12) Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 establishes as a condition for authorisation that a 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, while Article 19(1), point (e), of that Regulation provides that biocidal products are to be authorised provided that, where appropriate, MRLs for food and feed or specific migration limits or limits for the residual content in food contact materials have been established in accordance with relevant Union legislation.

(13) Article 18(1), point (b), of Regulation (EC) No 396/2005 sets a default MRL of 0,01 mg/kg for pesticide residues in food of animal origin for which no specific MRLs are set. According to Article 3(2), point (c), of that Regulation, pesticide residues are residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant protection products as defined in Article 2, point 1, of Council Directive 91/414/EEC ([9]), which are present in or on the products covered by Annex I to Regulation (EC) No 396/2005, including in particular those which may arise as a result of use in plant protection, in veterinary medicine and as a biocide. After analysis, it appears that chlorocresol was never used as an active substance in plant protection products under Directive 91/414/EEC or Regulation (EC) No 1107/2009 of the European Parliament and of the Council ([10]). As there is no evidence that chlorocresol is currently or was formerly used in plant protection products, the Commission concludes that chlorocresol does not fall within the scope of Regulation (EC) No 396/2005 and that the default value of 0.01 mg/kg set out in Article 18(1), point (b), of that Regulation does not apply to the biocidal active substance chlorocresol.

(14) The active substance chlorocresol is used as a biocide in animal husbandry, and is classified as a substance for which no MRL is required pursuant to Commission Regulation (EU) No 37/2010 ([11]). Chlorocresol has indeed been evaluated by the Committee for Veterinary Medicinal Products which has concluded ([12]) that there is no need to establish a MRL for chlorocresol in all food-producing species as chlorocresol is considered to have low toxicity, is rapidly metabolised and excreted, with no potential to accumulate in tissues and has been safely used in human medicine for many years.

([8]) https://echa.europa.eu/documents/10162/1045ae08-2fd5-067a-ad43-cae52527bccf.

([9]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1, ELI: http://data.europa.eu/eli/dir/1991/414/oj).

([10]) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj).

([11]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1, ELI: http://data.europa.eu/eli/reg/2010/37(1)/oj).

([12]) EMEA/MRL/074/96-FINAL.

(15) Taking into account the arguments raised by France, Germany and the ECHA opinion, the Commission considers that the product meets the condition laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, as there is no dietary risk for the consumer arising from the use of the product considering that the consumer exposure does not exceed the acceptable daily intake of chlorocresol. For the same reason, the Commission also considers that it is not necessary that the instruction to rinse surfaces in which the product has been applied before letting the animals enter the facilities, is included in the summary of product characteristics.

(16) The Commission considers that the product also meets the condition set in Article 19(1), point (e), of Regulation (EU) No 528/2012 as chlorocresol is classified as a substance for which no MRL is required pursuant to Regulation (EU) No 37/2010 and is not within the scope of Regulation (EC) No 396/2005.

(17) 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 Phenogen identified by the case numbers BC-DV051147-24, BC-WW051333-08, BC-VN051246-22, BC-DN051247-38, BC-DG051329-48 in the Register for Biocidal Products meets the condition for authorisation laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

Article 2

The biocidal product Phenogen identified by the case numbers BC-DV051147-24, BC-WW051333-08, BC-VN051246-22, BC-DN051247-38, BC-DG051329-48 in the Register for Biocidal Products meets the condition for authorisation laid down in Article 19(1), point (e), of Regulation (EU) No 528/2012.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 23 October 2024.

For the Commission
Stella KYRIAKIDES
Member of the Commission