COMMISSION IMPLEMENTING DECISION (EU) 2023/1084

of 1 June 2023

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

(notified under document C(2023) 3447)

(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 15 June 2021, the company Menno Chemie-Vertrieb GMBH ('the applicant') submitted an application to the competent authority of the Netherlands for the mutual recognition in sequence, in accordance with Article 33 of Regulation (EU) No 528/2012, of the national authorisation of the biocidal product A-Quasan ('the biocidal product') already granted in Germany. The biocidal product, containing benzoic acid as active substance, has been authorised as a disinfectant of product-type 3, veterinary hygiene, to be used for disinfection in the veterinary healthcare area, including veterinary clinics and operating rooms, surfaces, equipment, and objects for companion animals.

(2) On 24 October 2021, the Netherlands referred objections to the coordination group indicating that the biocidal product does not meet the condition laid down in Article 19(1), point (a), of Regulation (EU) No 528/2012 for the use in operating rooms in the veterinary healthcare area, as such use corresponds to product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, and benzoic acid is not approved for that product-type. To support their position, the Netherlands referred to the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) ('the efficacy guidance') of the European Chemicals Agency, version of April 2018 ([2]), which indicates in its chapter 5.4.3.1 that biocidal products applied for general disinfection of surfaces in the medical area (medical practices, hospitals) as well as of surfaces in veterinary practices associated with examination and operation/treatment of the animals are assigned to product-type 2, whereas products for specific veterinary hygiene purposes (e.g. products with specific claims against a target organism only relevant in the veterinary area) are considered to be in product-type 3. The efficacy guidance follows the note for guidance CA-May15-Doc8.3 ([3]) ('the CA document') presented by the Commission services and agreed by the competent authorities of the Member States for the implementation of Regulation (EU) No 528/2012.

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

([2]) European Chemicals Agency, Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B +C), Version 3.0, April 2018 https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468

([3]) European Commission, Health and Food Safety Directorate General, Safety of the food chain, Pesticides and Biocides - Note for Guidance, Assignment of products used for general disinfection in veterinary practices or hospitals to product type 2 or 3 under the BPR, May 2015
https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/0015a899-662d-4b86-ab1d-d73b42bf1888/details

(3) Germany is of the opinion that the agreement presented in the CA document does not make it mandatory to assign biocidal products used for the disinfection of surfaces in the veterinary health care area exclusively to product-type 2. In their opinion, the CA document provides the possibility to assign, to product-type 2, biocidal products for general surface disinfection in veterinary health care area when the products are used both in human and veterinary clinics, while the biocidal product is not intended to be used in the human medical area. Germany is of the opinion that it is not the purpose of the efficacy guidance and the CA document to establish a description of the product-type, as such a description is established in Annex V to Regulation (EU) No 528/2012. For those reasons, Germany considers the use in veterinary healthcare as appropriate for product-type 3 for the biocidal product.

(4) As no agreement was reached in the coordination group, on 24 August 2022 Germany referred the unresolved objection to the Commission, pursuant to Article 36(1) of Regulation (EU) No 528/2012. It thereby 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 to the applicant.

(5) Article 2(1) of Regulation (EU) No 528/2012 states that a list of the types of biocidal products covered by that Regulation and their descriptions is set out in Annex V to that Regulation.

(6) Article 19(1), point (a), of Regulation (EU) No 528/2012 provides that one of the conditions for granting an authorisation is that the active substances contained in the biocidal product are included in Annex I to that Regulation or approved for the relevant product-type and any conditions specified for those active substances are met.

(7) Annex V to Regulation (EU) No 528/2012 provides that product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, includes products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs; usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities; products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil; products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials; products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties. Annex V to Regulation (EU) No 528/2012 provides that product-type 3, veterinary hygiene, includes products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function; products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

(8) After having carefully examined all the available information, the Commission concurs with the views of Germany that the use of the biocidal product should be assigned to product-type 3 as described in Annex V to Regulation (EU) No 528/2012, as the product is to be used for disinfection in the veterinary health care area, including veterinary clinics and operating rooms, surfaces, equipment and objects for companion animals. Product-type 3 includes products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function, products used to disinfect the materials and surfaces associated with the housing or transportation of animals. Therefore, as the biocidal product is intended to be used for disinfection in the veterinary health care area, it should be considered as a disinfectant used for veterinary hygiene purposes.

(9) The CA document reflects the agreement reached by the Commission services and competent authorities for the implementation of Regulation (EU) No 528/2012 to harmonise practices on the allocation of the product-types for disinfectants used in the medical area and in veterinary health care. The CA document indicates that it is feasible to assign to product-type 2 biocidal products for disinfection of surfaces in veterinary practices or hospitals associated with examination and operation/treatment of the animals, whereas products for specific veterinary hygiene purposes (e.g., products with specific claims against a target organism only relevant in the veterinary area) should be assigned to product-type 3. The CA document thus provides for flexibility on the allocation of such products to either product-type 2 or product-type 3 and does not preclude the allocation of the biocidal product to product-type 3.

(10) The wording of the efficacy guidance, chapter 5.4.3.1, has been updated by the European Chemicals Agency ([4]) to accurately reflect the agreement reached by the Commission services and competent authorities for the implementation of Regulation (EU) No 528/2012, contained in the CA document.

(11) Taking into account those arguments and the fact that benzoic acid has been approved for use in biocidal products of product-type 3 by Commission Implementing Regulation (EU) No 1035/2013 ([5]), the Commission considers that the biocidal product meets the condition laid down in Article 19(1), point (a), of Regulation (EU) No 528/2012, for the disinfection of surfaces in the veterinary health care area, including operating rooms.

(12) On 4 October 2022, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The applicant did not provide comments.

(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 biocidal product identified by the case number BC-FG047486-40 in the Register for Biocidal Products meets the condition laid down in Article 19(1), point (a), of Regulation (EU) No 528/2012 for the disinfection of surfaces in the veterinary health care area, including operating rooms.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 1 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

([4]) European Chemicals Agency, Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B +C), Version 5.0, November 2022 https://echa.europa.eu/documents/10162/2324906/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/ae2e9a18-82ee-2340-9354-d82913543fb9?t=1667389376408

([5]) Commission Implementing Regulation (EU) No 1035/2013 of 24 October 2013 approving benzoic acid as an existing active substance for use in biocidal products for product-types 3 and 4 (OJ L 283, 25.10.2013, p. 31).