DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2022/874

of 1 June 2022

on the terms and conditions of the authorisation of a biocidal product containing N-(trichloromethylthio)phthalimide (Folpet) referred by the Netherlands in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2022) 3465)

(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 29 September 2016, the company TROY CHEMICAL BV ('the applicant') submitted an application to the competent authorities of a number of Member States, including Germany for mutual recognition in parallel of a biocidal product for preservation of fibrous or polymerised materials (product-type 9 in accordance with Annex V to Regulation (EU) No 528/2012) containing N-(trichloromethylthio)phthalimide (Folpet) as an active substance ('the biocidal product'). The Netherlands 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) Pursuant to Article 35(2) of Regulation (EU) No 528/2012, Germany, referred objections to the coordination group on 1 October 2020, indicating that the biocidal product does not meet the conditions laid down in Article 19(1), point (d), of that Regulation.

(3) Germany considers that the biocidal product does not meet the conditions laid down in Article 19(1), point (d), of Regulation (EU) No 528/2012 as there are no conclusions on the classification of the biocidal product with regard to certain physical hazards and safety characteristics, namely, when considered as flammable solid, self-reactive substance or mixture, self-heating substance or mixture, substance or mixture which in contact with water emit flammable gases and relative self-ignition temperature for solids, which belong to the core data set pursuant to point 4 of Title 1 of Annex III, to Regulation (EU) No 528/2012 and therefore, those data requirements cannot be waived, unless adaptation is possible in accordance with Annex IV to that Regulation.

(4) The Netherlands indicated that the biocidal product is identical to the active substance N-(trichloromethylthio) phthalimide (Folpet). Folpet has currently no harmonised classification with respect to physical hazards established in Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]) on classification, labelling and packaging of substances and mixtures.

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

([2]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(5) As no agreement was reached in the coordination group, on 5 January 2021 the Netherlands referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. The Netherlands hereby 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. A copy of that statement was forwarded to the Member States concerned and the applicant.

(6) Article 19(1), point (d), of Regulation (EU) No 528/2012 lays down as one of the conditions for granting an authorisation that the physical and chemical properties of the biocidal product have been determined and deemed acceptable for the purposes of the appropriate use and transport of the product.

(7) Article 20(1), point (a)(i), of Regulation (EU) No 528/2012 establishes that the applicant for an authorisation of a biocidal product shall submit a dossier or letter of access for the biocidal product satisfying the requirements set out in Annex III to that Regulation.

(8) Article 21 of Regulation (EU) No 528/2012 establishes that the applicant does not need to provide data required under Article 20 of that Regulation where the data are not necessary owing to the exposure associated with the proposed uses, it is not scientifically necessary to supply the data or it is not technically possible to generate the data, and that the applicant may propose to adapt those data requirements in accordance with Annex IV to Regulation (EU) No 528/2012 and that the justification for the proposed adaptations to the data requirements shall be clearly stated in the application with reference to the specific rules in Annex IV to that Regulation.

(9) Pursuant to point 4 of Title 1 of Annex III to Regulation (EU) No 528/2012, data to determine whether a biocidal product is to be considered as explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emit flammable gases, oxidising solid, organic peroxides, corrosive to metals and the relative self-ignition temperature for solids, belong to the core data set, which are to be provided to support the application for the authorisation of biocidal products. Pursuant to point 18(a) of Annex VI to that Regulation, the risk assessment is to determine the hazards due to the physico-chemical properties.

(10) Moreover, pursuant to Article 4(1) of Regulation (EC) No 1272/2008 manufacturers, importers and downstream users are to classify substances or mixtures in accordance with Title II of that Regulation before placing them on the market. Article 8(2) of that Regulation establishes that for the purposes of determining whether a substance or a mixture entails any of the physical hazards referred to in Part 2 of Annex I of that Regulation, the manufacturer, importer or downstream user is to perform the tests required in that Part, unless there is adequate and reliable information already available.

(11) Consequently, self-classification is to entail new testing for those physical hazards where, pursuant to Article 8(2) of Regulation (EC) No 1272/2008, adequate and reliable information is not available. According to the self-classifications provided in the inventory of classification and labelling maintained by the European Chemicals Agency ([3]), currently none of the 2 572 notifiers for Folpet classify the substance for physical hazards and notifiers have provided reasons that for some physical hazards, data are available and sufficient to conclude that the classification criteria are not met, while for other physical hazards, data are lacking.

(12) Despite the obligation under Article 20(1), point (a), of Regulation (EU) No 528/2012 in conjunction with point 4 of Title 1 of Annex III to that Regulation and the obligation under Article 8(2) of Regulation (EC) No 1272/2008, no information on the classification of the biocidal product with regard to physical hazards and safety characteristics were provided.

([3]) Notification Details - C&L Inventory (europa.eu)

(13) On 19 May 2021, the Commission provided the applicant with the opportunity to submit written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The applicant submitted comments on 18 June 2021.

(14) In its comments, the applicant provided justifications for waiving the data requirements established in point 4 of Title 1 of Annex III to Regulation (EU) No 528/2012 for some of the physical hazards (self-reactive substances and mixtures, pyrophoric solids, self-heating substances and mixtures, oxidising solids, organic peroxides, corrosive to metals) by making reference to known experience while for others (explosives, flammable solids, substances and mixtures which in contact with water emit flammable gases and relative self-ignition temperature for solids) the applicant made reference to the assessment report of the active substance.

(15) After having carefully examined the comments provided by the applicant and after having consulted the European Chemicals Agency, the Commission considers that with the exception of corrosive to metals, for which the waiving justification provided by the applicant can be accepted, all the other information provided by the applicant does not allow to conclude on the classification of the product for physical hazards and safety characteristics belonging to the core data set referred to in point 4 of Title 1 of Annex III to Regulation (EU) No 528/2012 and no adequate justification for adaptation of data requirements in accordance with Annex IV to Regulation (EU) No 528/2012 were provided. Therefore, the Commission considers that it is not possible to establish if the biocidal product meets the conditions laid down in Article 19(1), point (d), of Regulation (EU) No 528/2012.

(16) 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

This Decision applies to the biocidal product identified by the case number BC-FS027255-29 in the Register for Biocidal Products.

Article 2

Without the submission of the relevant information in point 4 of Title 1 of Annex III to Regulation (EU) No 528/2012, subject to the general possibilities for the adaptation of data requirements set out in Annex IV to that Regulation, it has not been demonstrated that the biocidal product meets the conditions laid down in Article 19(1), point (d), of Regulation (EU) No 528/2012.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 1 June 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission