COMMISSION IMPLEMENTING DECISION (EU) 2021/2149

of 3 December 2021

on unresolved objections regarding the terms and conditions of the provisional authorisation of a biocidal product containing 5-Chloro-2-methyl-2H-isothiazol-3-one (C(M)IT) referred by France in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2021)8693)

(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 27 July 2018, the company THOR GmbH ('the applicant') submitted an application for mutual recognition in parallel, in accordance with Article 34 of Regulation (EU) No 528/2012, of a provisional authorisation of a biocidal product, as referred to in Article 55(2) of that Regulation, to the competent authorities of a number of Member States, including Germany. The biocidal product concerned is to be used for the preservation of products during storage and contains as an active substance 5-Chloro-2-methyl-2H-isothiazol-3-one (C(M)IT) ('the biocidal product'). 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) Pursuant to Article 35(2) of Regulation (EU) No 528/2012, Germany referred objections to the coordination group on 24 January 2020, indicating that the biocidal product is not expected to meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of that Regulation. On 27 January 2020, the coordination group secretariat invited the other Member States and the applicant to submit written comments on the referral. The referral was discussed in the coordination group on 9 and 23 March 2020.

(3) As no agreement was reached by the coordination group, on 11 January 2021 France 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.

(4) Germany considers that risk-mitigation measures for treated articles can only be included in an authorisation of a biocidal product if they were laid down in the approval decision of the active substance. As C(M)IT is not yet approved as active substance, Germany considers that the risk-mitigation measures for treated articles proposed by France cannot be included in the authorisation of the biocidal product. Consequently, unacceptable risks remain for use 2 (in-can preservation of paints and coatings), use 3 (preservation of additives used in paper production) and use 7 (preservation of polymer dispersions), described in the application for the provisional authorisation.

(5) Article 19(1), points (b)(iii) and (b) (iv), of Regulation (EU) No 528/2012 provides that one of the conditions for granting an authorisation is that a biocidal product has no unacceptable effects itself, or as a result of its residues, on the health of humans and animals, and on the environment.

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

(6) Article 58(2) of Regulation (EU) No 528/2012 provides that a treated article is not to be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2) of that Regulation, for the relevant product-type and use, or in Annex I to that Regulation, and any conditions or restrictions specified therein are met.

(7) Article 55(2) of Regulation (EU) No 528/2012 allows competent authorities to authorise for a period not exceeding 3 years, a biocidal product containing a new active substance provided that dossiers have been evaluated in accordance with Article 8 of that Regulation, the evaluating competent authority has submitted a recommendation for approval of the new active substance, and the competent authorities which received the application for the provisional authorisation consider that the biocidal product is expected to comply with Article 19(1), points (b), (c) and (d), of that Regulation taking into account the factors set out in Article 19(2) of that Regulation.

(8) Although C(M)IT is not yet approved, the French evaluating competent authority submitted to the European Chemicals Agency on 18 September 2019 a recommendation for approval of C(M)IT for product-type 6. The draft opinion and the assessment report of the evaluating competent authority were discussed at the meeting of the Biocidal Products Committee of 16 June 2020, and unacceptable risks were identified for the aquatic and terrestrial compartment from use 2 (in-can preservation of paints and coatings) and use 7 (preservation of polymer dispersions) of the representative biocidal product and it was concluded that, in the absence of further studies, only a restriction on the use of articles treated with biocidal products containing C(M)IT to indoor uses would lead to acceptable risks. For use 3 of the representative biocidal product (preservation of additives used in paper production), a safe use of treated articles was identified for all the environmental compartments.

(9) The Commission considers that the fact that the conditions or restrictions for treated articles can be included only in the approval decision of the active substance should not prevent the possibility to grant a provisional authorisation of a biocidal product pursuant to Article 55(2) of Regulation (EU) No 528/2012, as that derogation is based precisely on the absence of approval of that active substance and is valid until an active substance is approved and as such provisional authorisation may anticipate future conditions or restrictions for treated articles in the approval decision.

(10) Taking into account all those considerations, the Commission considers that it can be expected that the active substance C(M)IT can be approved and that the approval decision will specify the conditions associated with its use in treated articles, namely a restriction on outdoor use of such articles, and that therefore the biocidal product is expected to meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012 provided that, for use 2 (in-can preservation of paints and coatings) and use 7 (preservation of polymer dispersions), the use of articles treated with the biocidal product is allowed only indoors.

(11) On 25 June 2021, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012.

(12) 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-DW041712-25 in the Register for Biocidal Products.

Article 2

The biocidal product referred to in Article 1 of this Decision is expected to meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012, provided that the provisional authorisations granted by Member States stipulate both of the following conditions:

(a) for use 2 (in-can preservation of paints and coatings) and use 7 (preservation of polymer dispersions), as described in the application for the mutual recognition, articles treated with the biocidal product can only be used indoors;

(b) the person responsible for the placing on the market of such treated articles ensure that the label of such treated articles provides the following instruction 'Indoor use only'.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 3 December 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission