II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/2148

of 3 December 2021

on the unresolved objections regarding terms and conditions of the authorisation of the biocidal product family Oxybio in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2021) 8690)

(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 26 July 2018, the company Intergaz et Services ('the applicant') submitted an application to the competent authorities of a number of Member States, including France, for mutual recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product family Oxybio of surface disinfectant products containing the active substance hydrogen peroxide in concentrations between 12 and 49 % weight for weight ('the biocidal product family'). Belgium 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) The biocidal product family comprises products containing hydrogen peroxide in concentrations of 12 %, 30 %, 35 % and 49 %, organised in three sub-families, the technical properties of which are described in three summaries of biocidal product characteristics (meta SPCs), namely meta SPC 1, meta SPC 2 and meta SPC 3. In its assessment report Belgium recommended authorisation only for those products of the biocidal products family which contain hydrogen peroxide in a concentration of 12 %. Those products are covered by meta SPC 1 (Oxybio L12).

(3) Pursuant to Article 35(2) of Regulation (EU) No 528/2012, France referred objections to the coordination group on 29 September 2020, indicating that the contested product family does not meet the conditions laid down in Article 19(1), point (d), of that Regulation.

(4) France considered that the determination of the physical hazards of the products in the biocidal product family made by Belgium with regard to the oxidising liquids property, and indicated in the draft summary of the biocidal product characteristics (SPC) pursuant to Article 22(2), point (i), of Regulation (EU) No 528/2012, was not correct. Belgium indicated that specific concentration limits of hydrogen peroxide, as set out in Table 3 of Part 3 of Annex VI to

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

Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]), had been considered for the determination of oxidising property of the biocidal product family and that the lower limit, namely 50 %, was not met by any of the products of the biocidal product family. Hence, Belgium concluded that the products were not to be classified in relation to this property.

(5) France argued that not classifying the products in relation to the oxidising liquids property is incorrect. France maintained that, as indicated in the Guidance on the Application of the CLP criteria ([3]) of the European Chemicals Agency ('ECHA Guidance'), the experience in the handling and use of substances or mixtures which shows them to be oxidising is an important factor in considering classification in this hazard class. According to France, the application of the UN Model Regulations on the Transport of Dangerous Goods (UN RTDG Model Regulations) represents such experience and the classification according to these Regulations should be included in the draft SPC. Consequently, France concluded that the correct classification of the products of the biocidal product family covered by the meta SPC 1 (Oxybio L12) should be Oxidising liquid, Packing group III, as set out in the UN RTDG Model Regulations.

(6) As no agreement was reached in the coordination group, on 10 December 2020 Belgium referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. Belgium 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.

(7) Article 19(1), point (d), of Regulation (EU) No 528/2012, lays down one of the conditions for granting an authorisation, namely 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.

(8) Point 2.13.2.1 of Annex I to Regulation (EC) No 1272/2008 provides that an oxidising liquid is to be classified in one of the three categories for this class (Category 1, 2 or 3) using test O.2 in Part III, sub-section 34.4.2 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, in accordance with the criteria laid down in Table 2.13.1 of that Annex.

(9) Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 provides in the entry with index number 008-003-00-9 the harmonised classification for hydrogen peroxide solutions in relation to the oxidising liquids property with specific concentration limits, as follows: Oxidising Liquid Category 1 with not less than 70 % hydrogen peroxide and Oxidising Liquid Category 2 with not less than 50 % but no more than 70 % hydrogen peroxide. However, four asterisks '(****)' accompany those limits, indicating that the correct classification is to be confirmed by testing, as laid down in point 1.2.4 of Part 1 of Annex VI to that Regulation.

(10) The applicant did not provide any test data in relation to the oxidising liquids property. The applicant considered that the specific concentration limits indicated in Table 3 of Part 3 of Annex VI, to Regulation (EC) No 1272/2008, in the entry with index number 008-003-00-9, were applicable for the classification in relation to the oxidising liquids property and that their application led to the non-classification of the products of the biocidal product family in relation to this property.

([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).

([3]) ECHA Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 5.0, July 2017 https://echa.europa.eu/documents/10162/23036412/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5

(11) In accordance with the UN RTDG Model Regulations, aqueous solutions with more than 8 % hydrogen peroxide should be classified in division 5.1 (oxidising substances) as follows: Oxidising liquid, Packing group III, with not less than 8 % but not more than 20 % hydrogen peroxide; Oxidising liquid, Packing group II, with not less than 20 % but not more than 60 % hydrogen peroxide; Oxidising liquid, Packing group I, with more than 60 % hydrogen peroxide. The classification in relation to this hazard class is based on the same test as the one required by point 2.13 of Part 2 of Annex I to Regulation (EC) No 1272/2008.

(12) As provided in section 2.13.5 of the ECHA Guidance, Packing group I, II and III as defined under the UN RTDG Model Regulations for Oxidising liquids correspond directly to Category 1, 2 and 3 for Oxidising liquids, respectively, of Regulation (EC) No 1272/2008.

(13) Pursuant to point 2.13.4.3 of Part 2 of Annex I to Regulation (EC) No 1272/2008, in the event of divergence between test results and known experience, judgement based on known experience is to take precedence over test results. Corresponding section 2.13.4.3 of the ECHA guidance also indicates that, apart from testing, also experience in the handling and use of substances or mixtures, which shows them to be oxidising, is an important additional factor in considering classification in this hazard class.

(14) For the carriage of dangerous goods within and between the territories of the Member States, Article 3 of Directive 2008/68/EC of the European Parliament and of the Council ([4]) imposes the application of Annexes A and B of the European Agreement concerning the International Carriage of Dangerous Goods by Road ('ADR'), of the Annexed Regulations to the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways ('ADN'), as well as Articles 3(f), 3(h), 8(1) and 8(3) of the ADN, and of the Annex to the Regulations concerning the International Carriage of Dangerous Goods by Rail ('RID').

(15) The ADR, ADN and RID are following the UN RTDG Model Regulations and contain the classification of aqueous solutions containing hydrogen peroxide as set out by the UN RTDG Model Regulations. For the purposes of transportation, the products of the biocidal product family covered by meta SPC 1 are therefore to be classified as Oxidising liquid, Packing group III in accordance with ADR, ADN and RID.

(16) In the absence of test data provided by the applicant it seems appropriate to apply judgement based on known experience in the handling and use of aqueous solutions containing hydrogen peroxide concerning the classification in relation to the oxidising liquids property. In this context, the legislation on the carriage of dangerous goods provides binding criteria on the classification of substances and mixtures, including in relation to oxidising liquids hazard class, that are relevant for the case at hand.

(17) It is therefore appropriate to indicate in the draft SPC that products containing hydrogen peroxide in a concentration of 12 % are to be classified as Oxidising liquid, Packing group III, in accordance with the UN RTDG Model Regulations, corresponding to Oxidising liquid, Category 3, in accordance with Regulation (EC) No 1272/2008.

(18) On 8 April 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. The applicant provided comments which the Commission, subsequently, took into account.

(19) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

([4]) Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

HAS ADOPTED THIS DECISION:

Article 1

This Decision applies to the products covered by meta SPC 1 (Oxybio L12) of the biocidal product family identified by the case number BC-SK041671-32 in the Register for Biocidal Products.

Article 2

For the purpose of Article 19(1), point (d), of Regulation (EU) No 528/2012, the hazard classification with regard to the oxidising liquids property of the products referred to in Article 1, shall be Oxidising liquid, Packing group III, in accordance with the UN RTDG Model Regulations, corresponding to Oxidising liquid, Category 3, in accordance with Regulation (EC) No 1272/2008.

The products referred to in Article 1 meet the condition laid down in Article 19(1), point (d), of Regulation (EU) No 528/2012 provided that they are classified as Oxidising liquid, Packing group III, in accordance with the UN RTDG Model Regulations, corresponding to Oxidising liquid, Category 3, in accordance with Regulation (EC) No 1272/2008.

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