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ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

- ★ **Decision No 3/2021 of the ACP-EU Committee of Ambassadors of 26 November 2021 to amend Decision No 3/2019 of the ACP-EU Committee of Ambassadors to adopt transitional measures pursuant to Article 95(4) of the ACP-EU Partnership Agreement [2021/2175]** 3

⁽¹⁾ Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/2174

of 3 December 2021

on unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Konservan P40 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) 8686)***(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 24 April 2016, the company THOR GmbH ('the applicant') submitted to the competent authorities of several Member States an application for the mutual recognition in parallel of an authorisation for a biocidal product in accordance with Article 34 of Regulation (EU) No 528/2012. The biocidal product concerned, containing permethrin as an active substance, is intended to be used as an insecticide for textiles in the manufacturing of clothing and for non-washable wool used in the manufacturing of carpets ('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) On 1 August 2019, pursuant to Article 35(2) of Regulation (EU) No 528/2012, Belgium referred objections to the coordination group set up pursuant to Article 35(1) of that Regulation, indicating that the biocidal product does not meet the conditions laid down in Article 19(1), point (b)(iii), of that Regulation. On 5 August 2019, 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 16 and 26 September 2019.
- (3) Belgium considered that the migration rate for permethrin used by France in the human health exposure assessment was not adequate. According to Belgium, the migration rate should have been 1 % as agreed in the assessment report established in the context of the approval of permethrin ⁽²⁾ instead of 0,1 % used by France. Following the discussions that took place in the coordination group, France proposed to use the dermal absorption value of 3 % as agreed in the assessment report established in the context of the approval of permethrin while Belgium considered that the value was not adequate and that the 75 % default value specified in the European Food Safety Authority (EFSA) Guidance should be used instead.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ <https://echa.europa.eu/documents/10162/49872cf9-4c65-ce75-2230-d7d8befef7ab>

- (4) As no agreement was reached in the coordination group, on 28 October 2019 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 the applicant.
- (5) On 4 March 2021, the Commission requested an opinion on that matter from the European Chemicals Agency ('ECHA') in accordance with Article 36(1) and Article 38 of Regulation (EU) No 528/2012. ECHA was requested to indicate which migration rate and dermal absorption value should be used in the human health exposure assessment for the different uses envisaged of the articles treated with the biocidal product, and whether using those values allows to conclude that the biocidal product has no unacceptable effects on the health of humans.
- (6) On 17 June 2021, the Biocidal Products Committee of the Agency adopted its opinion ⁽³⁾.
- (7) According to ECHA, the appropriate migration rate for clothes treated with permethrin is 1 %, while for wool carpets treated with permethrin it is 0,5 %. For the dermal absorption of permethrin, the adequate value is the default value of 50 % recommended by EFSA for water-based products ⁽⁴⁾.
- (8) According to ECHA, the conditions of Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 are met for the use of the biocidal product in wool carpets, while for use in clothing, those conditions are met if the biocidal product is not used for manufacturing of clothing intended for the general public.
- (9) Therefore, in light of the opinion of ECHA, the Commission considers that the biocidal product meets the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 if the biocidal product is not used for manufacturing of clothing intended for the general public.
- (10) 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 case number BC-SH023802-41 in the Register for Biocidal Products meets the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, provided that the authorisations granted by Member States stipulate the condition that the biocidal product shall not be used for manufacturing of clothing intended for use by the general public.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 3 December 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

⁽³⁾ <https://echa.europa.eu/bpc-opinions-on-article-38>

⁽⁴⁾ Guidance on dermal absorption (wiley.com).

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 3/2021 OF THE ACP-EU COMMITTEE OF AMBASSADORS of 26 November 2021

to amend Decision No 3/2019 of the ACP-EU Committee of Ambassadors to adopt transitional measures pursuant to Article 95(4) of the ACP-EU Partnership Agreement [2021/2175]

THE ACP-EU COMMITTEE OF AMBASSADORS,

Having regard to the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States, of the other part ⁽¹⁾, and in particular Article 15(4) and Article 16(2) in conjunction with Article 95(4) thereof,

Whereas:

- (1) The Partnership Agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States, of the other part (the 'ACP-EU Partnership Agreement') was signed in Cotonou on 23 June 2000 and entered into force on 1 April 2003. In accordance with Decision No 3/2019 of the ACP-EU Committee of Ambassadors ⁽²⁾ (the 'decision on transitional measures'), it is to be applied until 30 November 2021.
- (2) Pursuant to Article 95(4), first subparagraph, of the ACP-EU Partnership Agreement, negotiations towards a new ACP-EU Partnership Agreement (the 'new Agreement') were launched in September 2018. The new Agreement will not be ready to be applied by 30 November 2021, the expiry date of the current legal framework. It is therefore necessary to amend the decision on transitional measures to further extend the application of the provisions of the ACP-EU Partnership Agreement.
- (3) Article 95(4), second subparagraph, of the ACP-EU Partnership Agreement provides for the ACP-EU Council of Ministers to adopt any transitional measures that may be required until the new Agreement comes into force.
- (4) Pursuant to Article 15(4) of the ACP-EU Partnership Agreement, on 23 May 2019, the ACP-EU Council of Ministers delegated the powers to adopt the transitional measures to the ACP-EU Committee of Ambassadors ⁽³⁾.
- (5) It is therefore appropriate that the ACP-EU Committee of Ambassadors adopt a decision, pursuant to Article 95(4) of the ACP-EU Partnership Agreement, to amend the decision on transitional measures in order to extend the application of the provisions of the ACP-EU Partnership Agreement until 30 June 2022, or until the entry into force of the new Agreement or the provisional application between the Union and the ACP States of the new Agreement, whichever comes first.
- (6) The provisions of the ACP-EU Partnership Agreement will continue to be applied with the aim of maintaining continuity in relations between the Union and its Member States, on the one hand, and the ACP States, on the other. Accordingly, the amended transitional measures are not intended as amendments to the ACP-EU Partnership Agreement as provided for in Article 95(3) thereof,

⁽¹⁾ OJ L 317, 15.12.2000, p. 3. The ACP-EU Partnership Agreement was amended by the Agreement signed in Luxembourg on 25 June 2005 (OJ L 209, 11.8.2005, p. 27) and by the Agreement signed in Ouagadougou on 22 June 2010 (OJ L 287, 4.11.2010, p. 3).

⁽²⁾ Decision No 3/2019 of the ACP-EU Committee of Ambassadors of 17 December 2019 to adopt transitional measures pursuant to Article 95(4) of the ACP-EU Partnership Agreement (OJ L 1, 3.1.2020, p. 3).

⁽³⁾ Decision No 1/2019 of the ACP-EU Council of Ministers of 23 May 2019 on the delegation of powers to the ACP-EU Committee of Ambassadors on the decision to adopt transitional measures pursuant to Article 95(4) of the ACP-EU Partnership Agreement (OJ L 146, 5.6.2019, p. 114).

HAS ADOPTED THIS DECISION:

Article 1

In Article 1 of Decision No 3/2019 of the ACP-EU Committee of Ambassadors, the date '30 November 2021' shall be replaced by that of '30 June 2022'.

Article 2

This Decision shall enter into force on 1 December 2021.

Done at Brussels, 26 November 2021.

*For the ACP-EU Council of Ministers
By the ACP-EU Committee of Ambassadors
The President
Iztok JARC*

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