EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2022/1833
(POOL/E4/2022/1833/1833-EN.docx)
[…](2022) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving cyanamide as an existing active substance for use in biocidal products of product-types 3 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

not approving cyanamide as an existing active substance for use in biocidal products of product-types 3 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014[2] establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes cyanamide (EC No: 206-992-3; CAS No: 420-04-2).

(2) Cyanamide has been evaluated for use in biocidal products of product-type 3, veterinary hygiene biocidal products, and product-type 18, insecticides, acaricides and products to control other arthropods, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council[3], which correspond respectively to product-types 3 and 18 as described in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 30 July 2013. After the submission of the assessment report, discussions took place in technical meetings organised by the European Chemicals Agency ('the Agency').

(4) It follows from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC.

(5) In accordance with Article 75(1), point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee is responsible for preparing the opinion of the Agency regarding applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee

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

[2] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

[3] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

adopted the opinions of the Agency on 16 June 2016 ("the opinions of 16 June 2016")[4], having regard to the conclusions of the evaluating competent authority.

(6) According to the opinions of 16 June 2016, cyanamide met the criteria to be classified as carcinogen category 2 and toxic for reproduction category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[5], and was therefore considered as also having endocrine-disrupting properties in accordance with Article 5(3) of Regulation (EU) No 528/2012, pending the adoption of delegated acts specifying the scientific criteria for the determination of endocrine-disrupting properties. The opinions of 16 June 2016 also considered that the risks to human health and the environment of using the representative biocidal products presented in the application for approval of cyanamide for product-types 3 and 18 were acceptable subject to appropriate risk mitigation measures. However, the risk assessment presented in those opinions did not take into account the risks resulting from the endocrine-disrupting properties of cyanamide.

(7) Commission Delegated Regulation (EU) 2017/2100[6] setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 entered into force on 7 December 2017 and came into effect on 7 June 2018.

(8) In anticipation of the application of the new scientific criteria set out in Delegated Regulation (EU) 2017/2100, and to provide clarity as regards the hazard properties and the risks resulting from the use of cyanamide, on 26 April 2018, pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency[7] to revise its opinions of 16 June 2016 and to clarify whether cyanamide has also endocrine-disrupting properties on the basis of the scientific criteria laid down in that Delegated Regulation. The Agency was requested to update only that part of the opinions relating to the assessment of the endocrine-disrupting properties, unless the conclusion of that assessment affected the results of the risk assessment already performed or the recommendations for approval. In the latter case, such assessment and recommendations were also to be updated. For the preparation of the revised opinions of the Agency, the evaluating competent authority of Germany invited the applicant to submit additional information as regards the assessment of the endocrine-disrupting properties of cyanamide in accordance with the criteria laid down in Delegated Regulation (EU) 2017/2100.

(9) The Biocidal Products Committee adopted the revised opinions of the Agency on 10 December 2019 ("the opinions of 10 December 2019")[8], having regard to the conclusions of the evaluating competent authority.

---

4 Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 3, ECHA/BPC/116/2016, adopted on 16 June 2016; Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 18, ECHA/BPC/117/2016, adopted on 16 June 2016.

5 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).

6 Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

7 Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR - "Evaluation of the Endocrine disrupting properties of certain biocidal actives substances according to the new scientific criteria"

8 Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 3, ECHA/BPC/230/2019, adopted on 10 December 2019; Biocidal Products

(10) According to the opinions of 10 December 2019, cyanamide has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms) on the basis of the criteria laid down in Delegated Regulation (EU) 2017/2100. The opinions remarked that there is no agreed methodology for undertaking a risk assessment of endocrine-disrupting properties and that, given the exposure of cyanamide to humans and the environment, a risk related to endocrine-disrupting properties cannot be excluded.

(11) The opinions of 10 December 2019 did not contain any information as to whether a safe threshold can be derived in relation to endocrine-disrupting properties of cyanamide, and, if so, whether the risks of using the representative biocidal products presented in the application for approval of cyanamide for product-types 3 and 18 could be considered acceptable or not, in relation to the endocrine-disrupting properties of cyanamide.

(12) On 2 September 2020, pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency[9] to revise its opinions of 10 December 2019 and to clarify whether a safe threshold may be derived in relation to the endocrine-disrupting properties of cyanamide, and to conclude whether the risks for human health and for the environment could be considered acceptable or not.

(13) The Biocidal Products Committee adopted the new revised opinions of the Agency on 30 November 2021 ("the opinions of 30 November 2021")[10], having regard to the conclusions of the evaluating competent authority. According to those opinions, since it was not possible to derive a safe threshold with respect to the endocrine-disrupting properties of cyanamide, it is not possible to conclude whether risks for both human health for the general public and the environment for the representative biocidal product used for product-type 3 (for the disinfection by professional users against *Brachyspira hyodysenteriae* of the liquid manure stored underneath the slatted floor in pig stables in order to protect fattening pigs against the pig disease dysenteria) and product-type 18 (for the control by professional users of *Musca domestica* in liquid manure in pig stables) are acceptable or not. Therefore, no conclusion could be drawn whether cyanamide fulfils the approval conditions.

(14) Therefore, given that the opinions of 30 November 2021 of the Agency do not provide either a positive or a negative conclusion on whether cyanamide fulfils the approval conditions, the Commission considers that it has ultimately not been demonstrated based on the data available in the application submitted for the approval that the representative biocidal product containing cyanamide for product-types 3 and 18 may be expected to not have unacceptable effects itself, or as a result of its residues, on human health and on the environment.

(15) Taking into account the opinions of 30 November 2021, it has not been demonstrated that biocidal products of product-types 3 and 18 containing cyanamide meet the criteria laid down in Article 5(1), points (b) (iii) and (iv), read in conjunction with

---

Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 18, ECHA/BPC/231/2019, adopted on 10 December 2019.

9 Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR - "Evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18".

10 Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 3, ECHA/BPC/116/2016, adopted on 30 November 2021; Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 18, ECHA/BPC/302/2021, adopted on 30 November 2021.

Article 10(1) of Directive 98/8/EC. It is therefore appropriate not to approve cyanamide for use in biocidal products of product-types 3 and 18.

(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

Cyanamide (EC No: 206-992-3; CAS No: 420-04-2) is not approved as an active substance for use in biocidal products of product-types 3 and 18.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN