EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards calcium cyanamide used as a fertiliser

(Text with EEA relevance)

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amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards calcium cyanamide used as a fertiliser

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (ECHA), amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 68(1) thereof,

Whereas:

(1) Calcium cyanamide is used, *inter alia*, as a slow-release nitrogen fertiliser. The fertiliser is supplied in the EU in granular form, mainly to professional farmers, in one registrant's commercial formulation called PERLKA®'. It is typically applied as a fertiliser in three different ways depending upon the crop: surface application onto a soil surface, uniform incorporation from the soil surface down to a specific depth or deep placement via a tube. In moist soils, calcium cyanamide is transformed into cyanamide and calcium hydroxide. Cyanamide is further transformed into urea and cyanoguanidine. Cyanamide, urea and cyanoguanidine ('transformation substances') are transported to the aquatic compartment via run-off from the surface of fertilised fields adjacent to surface waters or via drainage through soil. Cyanamide is classified as Aquatic Chronic 3 (H412: Harmful to aquatic life with long lasting effects) in Part 3 of Annex VI to Regulation (EC) No 1272/2008[2]. The single registrant for calcium cyanamide under REACH ('the registrant'), self-classifies calcium cyanamide in the same hazard class. Urea and cyanoguanidine are also hazardous to aquatic or soil organisms.

(2) On 22 March 2016, the Scientific Committee on Health and Environmental Risks (SCHER) concluded that harmful effects for humans and the environment could not be excluded when calcium cyanamide is used as a fertiliser[3]. The Commission, therefore,

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1 OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

3 Scientific Committee on Health and Environmental Risks (SCHER): Potential risks to human health and the environment from the use of calcium cyanamide as fertiliser.

requested[4] the European Chemicals Agency ('the Agency') to carry out a preliminary assessment of the risks posed by calcium cyanamide used as a fertiliser to human health and the environment. In January 2018[5], the Agency concluded that SCHER's assessment may have underestimated the risk that calcium cyanamide used as a fertiliser poses to the environment. The Agency's concern was that a risk to aquatic organisms may be present in a greater number of aquatic exposure scenarios than previously identified; there were also uncertainties associated with the possible risk of calcium cyanamide to a wide range of terrestrial organisms. Based on an advance copy of these findings indicating the presence of a risk to the environment, on 24 November 2017 the Commission requested[6] the Agency to prepare a dossier, pursuant to Article 69(1) of Regulation (EC) No 1907/2006 ('Annex XV dossier'), with a view to a possible restriction of calcium cyanamide as a fertiliser.

(3) On 19 July 2019, the Agency submitted the Annex XV dossier on the use of calcium cyanamide as a fertiliser[7]. The Agency found that the use of calcium cyanamide as a fertiliser (using application rates and methods as recommended by the registrant) leads to a risk of toxicity to aquatic and soil organisms that is not adequately controlled both for surface waters adjacent to fertilised fields and for soil. The risk is mainly due to the toxicity of cyanamide to aquatic and soil macroorganisms. In some scenarios, and to a lesser degree, the risk is also due to the toxicity of urea to algae and to the toxicity of cyanoguanidine to soil microorganisms. The Agency proposed a restriction on the placing on the market of calcium cyanamide for use as a fertiliser with a transitional period of 36 months.

(4) On 11 June 2020, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion[8] concluding that the proposed restriction on the use and placing on the market of calcium cyanamide as a fertiliser is the most appropriate Union wide measure to address the identified risk in terms of its effectiveness in reducing the risk, its practicality and its monitorability. RAC noted that the powder form of calcium cyanamide fertiliser was voluntarily removed from the market by the registrant in January 2018. Since then, only the granular form has been placed on the market. RAC proposed a shorter transitional period of 24 months for a restriction on the placing of

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https://health.ec.europa.eu/publications/potential-risks-human-health-and-environment-use-calcium-cyanamide-fertiliser_en

4 Request from the Commission to the European Chemicals Agency to perform a preliminary review of the risks of calcium cyanamide as a fertiliser (24 February 2017). https://echa.europa.eu/documents/10162/13641/calcium_cyanamide_request_to_echa.pdf/6ccd9451-52fd-abab-f9cd-04030ae2b19d

5 ECHA (2018). A preliminary assessment if the use of calcium cyanamide as a fertiliser poses an unacceptable risk to human health or the environment. https://echa.europa.eu/documents/10162/13641/calcium_cyanamide_review_report_en.pdf/e0b43a34-1a52-b6a9-8d96-bd8183c7beb4

6 Request from the Commission to the European Chemicals Agency to prepare a restriction proposal for the use of calcium cyanamide as a fertiliser, conforming to the requirements of Annex XV to REACH (24 November 2017) https://echa.europa.eu/documents/10162/13641/calcium_cyanamide_cion_reqst_axvdossier_en.pdf/d31415b4-4162-826b-034f-2d9e6c137b5d

7 ECHA (2019). Annex XV restriction report on calcium cyanamide. https://echa.europa.eu/documents/10162/13641/rest_calcium_cyanamide_axvreport_en.pdf/78b546d1-e496-a930-a3d8-50b67bb904e6

8 Committee for Risk Assessment (RAC) (11 June 2020): Opinion on an Annex XV dossier proposing restrictions on calcium cyanamide. https://echa.europa.eu/documents/10162/2342f774-8154-e502-de01-1a2f4e1ceb28

calcium cyanamide on the market as a fertiliser, to reduce the potential for stockpiling by end users that could result in its use as a fertiliser beyond the proposed transitional period of 36 months for use.

(5) RAC agreed with the Agency and the registrant that the ecotoxicological data from the studies using cyanamide as the test substance can be used in a read-across approach for the environmental assessment of calcium cyanamide. RAC agreed with the Agency on the environmental hazard assessment and the Predicted No-Effect Concentration ('PNEC') values of calcium cyanamide (based on read-across from cyanamide) and of cyanoguanidine in freshwater and sediment. However, RAC disagreed with the Agency on the PNEC value of urea in freshwater, which was considered not to be sufficiently reliable for hazard assessment. RAC concurred with the conclusion of the Agency on the hazard assessment for the terrestrial (soil) environment for calcium cyanamide (based on read-across from cyanamide), as well as for urea and cyanaguanidine. However, PNEC values for urea in soil were not reported by the Agency, as conclusive data was not available, and RAC supported the argument that urea is of inherently low toxicity.

(6) The exposure assessment relied on modelling, as there was no conclusive environmental monitoring data available. RAC considered the predicted environmental concentration ('PEC') values of calcium cyanamide and its transformation substances obtained by the Agency for surface water and sediment applying FOCUS[9] exposure modelling, taking into account the different application methods. RAC also considered the PEC values for the terrestrial environment applying the typical modelling approach for substances intentionally added to soil[10] that are commonly used as plant protection products. RAC concluded that both values were reliable. FOCUS PEARL[11] modelling was used by both the Agency and the registrant, in order to predict PEC values of calcium cyanamide and its transformation substances in groundwater, which was also considered to be reliable by RAC.

(7) RAC agreed with the Agency that the use of calcium cyanamide as a fertiliser (using application rates and methods recommended by the registrant) leads to a risk that is not adequately controlled, both for surface water adjacent to fertilised fields and for soil, since the relevant risk characterisation ratio values were greater than one. The risk is primarily due to the effects of cyanamide but also, in some scenarios, to those of cyanoguanidine and urea.

(8) The Agency assessed four restriction options to address the identified risks against the criteria of effectiveness, practicality and monitorability. The Agency found that two of those restriction options, a prohibition of the powder form of calcium cyanamide and a requirement to follow the rules of existing Common Agricultural Policy measures of cross-compliance, would not address the identified risks. RAC noted that, of the other two restriction options examined in the Annex XV dossier, the restriction option of using mandatory vegetated buffer strips was insufficient to reduce the risk to adjacent surface water and the risk to the terrestrial compartment from the use of calcium

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9 Joint Research Centre. The FOrum for Co-ordination of pesticide fate models and their Use (FOCUS). Surface water. https://esdac.jrc.ec.europa.eu/projects/surface-water

10 FOrum for the Co-ordination of pesticide fate models and their Use (FOCUS), Soil Modelling Work group (1997). Soil persistence models and EU Registration. https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_guide_fate_soil-persistance-1997.pdf

11 A specialised FOCUS model designed for predicting concentrations of a test substance in groundwater.

cyanamide as a fertiliser would not be addressed. As a result, RAC agreed with the Agency that only the option of a restriction on placing on the market and use of calcium cyanamide as a fertiliser, as a substance on its own or in a mixture, can fully address the identified risk and also be effective in reducing that risk, both from a practical and monitoring perspective.

(9) On 17 September 2020, the Agency's Committee for Socio-economic Analysis ('SEAC') adopted its opinion. SEAC noted that the Agency highlighted that, in addition to its function as slow-release fertiliser, calcium cyanamide has secondary effects such as herbicidal, fungicidal, molluscicidal effects as well as other effects that aid plant growth, which were recognised to be potentially useful for farmers. SEAC also noted that calcium cyanamide is not approved as an active substance for use in plant protection products under Regulation (EC) No 1107/2009 of the European Parliament and of the Council[12].

(10) The Agency concluded that regulatory action is required on a Union-wide level in light of the fact that the commercial formulation of calcium cyanamide is sold in several Member States and decisions and regulations concerning fertilisers made in one Member State may well affect the environment in another, as many Member States have common waterways within the Union. RAC and SEAC supported the view that any necessary action to address risks associated with the use of calcium cyanamide as a fertiliser should be implemented in all Member States.

(11) In its opinion, SEAC concluded that the proposed restriction will entail profit losses for farmers and for the sole manufacturer of PERLKA® in the order of tens of millions of euros per year. SEAC also recognised that job losses at the manufacturer's site are likely to occur in the short to medium term. However, SEAC concluded that the overall economic activity in the Union is unlikely to be affected since European producers of alternatives are likely to gain market share thereby compensating for some of the socio-economic losses. SEAC also concluded that crop volumes in the Union are unlikely to change as calcium cyanamide represents a small share of the total nitrogen fertilisers. SEAC emphasised that the cost analysis by the Agency is partial as it does not take into account farmers' reaction to substitute the secondary effects of calcium cyanamide, which could result in an increased use of authorised plant protection products or alternative farming measures. SEAC acknowledged the conclusion by the Agency and RAC that the risk from the use of calcium cyanamide as a fertiliser is not adequately controlled. SEAC also concurred with the Agency that the net environmental benefits of the proposed restriction are uncertain due to a lack of assessment of net changes in environmental risks resulting from the likely use of alternative fertilisers and of authorised plant protection products or other farming measures. SEAC also noted, as a potential benefit of the proposed restriction, the possible reduction of risks associated with the endocrine disrupting properties of cyanamide for human health and non-target organisms, which were concluded by the Biocidal Product Committee in 2019 and confirmed in 2021[13] but not assessed by the

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12 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj).

13 ECHA (2021) Biocidal Product Committee: Opinion on the application for approval of the active Substance Cyanamide. Product Type: 3. ECHA/BPC/301/2021. https://echa.europa.eu/documents/10162/f5e04e73-afe6-4595-abda-864931b167bb

Agency for the proposed restriction. In particular, SEAC opinion reflects that the discussion on cyanamide as a potential endocrine disruptor may affect the socioeconomic assessment.

(12) SEAC concluded that the proposed restriction on the use and placing on the market of calcium cyanamide as a fertiliser is the most appropriate Union-wide measure to address the identified risks among the four risk management options assessed by the Agency. However, SEAC concluded that it is uncertain whether it is the most appropriate Union-wide measure to address the identified risks in terms of its socioeconomic benefits and its socioeconomic costs, given the uncertainties regarding the net environmental risk reduction of the proposed restriction.

(13) In order to provide sufficient time to farmers and to the registrant to comply with to the new restriction requirements, SEAC recommended deferring the application of the restriction for 36 months.

(14) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1)(f) of Regulation No 1907/2006, was consulted during the restriction process and its advice has been taken into account.

(15) On 15 April 2021, the Agency submitted the opinions of RAC and SEAC[14] to the Commission.

(16) Taking into account the Annex XV dossier and the opinions of RAC and SEAC, the Commission considers that an unacceptable risk to the environment arises from the use of calcium cyanamide as a fertiliser. The Commission considers that the proposed restriction will be highly effective in reducing the risks to the environment, and that it will be practical and monitorable.

(17) The Commission, taking into account the Annex XV dossier and the opinion of SEAC, considers that alternative fertilisers and alternative farming techniques are available in the Union. The Commission also notes that, according to the Agency and SEAC, farmers may decide to use authorised plant protection products or alternative farming measures to substitute the secondary effects of PERLKA®.

(18) The Commission agrees with SEAC that the impacts on the overall economic activity and on the crop volumes in the Union are expected to be limited, while recognising that profit losses for the registrant and some farmers will occur. The Commission notes SEAC's conclusion on the uncertainty of the net environmental benefits of the restriction due to the possible substitution with alternative fertilisers and authorised plant protection products. Nevertheless, the use of authorised plant protection products, for which the environmental impact is confirmed acceptable during the authorisation process, is preferable to the use of products having "secondary" plant protection effects but which never underwent such process and have an unknown environmental impact. At the same time, the Commission notes that farmers may decide to switch to alternative farming techniques that do not involve the use of plant protection products. Furthermore, although SEAC expects the potential use of certain

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ECHA (2021) Biocidal Product Committee: Opinion on the application for approval of the active Substance Cyanamide. Product Type: 18. ECHA/BPC/302/2021. https://echa.europa.eu/documents/10162/0c97e426-a0a0-4030-a2ec-abdd80ef1396

[14] Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC) (17 September 2020): Opinion on an Annex XV dossier proposing restrictions on calcium cyanamide. https://echa.europa.eu/documents/10162/b2b4d2e8-836e-c073-155f-5ad5455e2164

alternatives to calcium cyanamide to cause environmental costs, leading to uncertainties about the net benefits, this should not prevent taking measures to address the risk posed by the use of this substance in fertilisers, as identified and assessed by RAC. Moreover, the Commission agrees with SEAC that the reduction of risks associated with potential endocrine disrupting properties for human health and non-target organisms constitutes an additional benefit of the restriction.

(19) The Commission considers that the proposed restriction, as amended by RAC, and taking into account its socio-economic impact and the availability of alternatives, as well as the potential endocrine disruption properties of cyanamide for human health and the environment, is an appropriate Union-wide measure to address the identified risk.

(20) The Commission takes note of RAC support for deferring the application of the prohibition on placing on the market of calcium cyanamide as fertiliser by 2 years from the entry into force of this Regulation, also of RAC support for deferring the prohibition to use calcium cyanamide as fertiliser by 3 years, as well as SEAC support for deferring the prohibition of both placing on the market and use of calcium cyanamide as fertiliser by 3 years. However, the Commission notes that the geopolitical and economic situation has changed significantly between the adoption of the final opinions of RAC and SEAC and the adoption of this Regulation. In particular, the recent geopolitical and economic conjunctures have highlighted the importance of ensuring supply chain resilience. Against this background, the Commission considers the decision to defer the application of the restrictions for longer periods than those proposed by RAC and SEAC in order to provide operators with more time to adapt to the restrictions is justified. In particular, the prohibition to place calcium cyanamide on the market as fertiliser should start applying 5 years after the entry into force of this Regulation, while the prohibition to use it as fertiliser should apply one year later, to allow for existing stocks to be used up.

(21) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(22) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen