Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Calcium cyanamide

ECHA/RAC/RES-O-0000006784-64-01/F

ECHA/SEAC/[Opinion N°(same as opinion number)]

Adopted

11 June 2020

11 June 2020

ECHA/RAC/RES-O-0000006784-64-01/F

11 June 2020

[SEAC opinion number]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**Calcium cyanamide**
EC No.:	**205-861-8**
CAS No.:	**156-62-7**

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the public consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/web/guest/restrictions-under-consideration on **25 September 2019**. Interested parties were invited to submit comments and contributions by **25 March 2020**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: ***Kostas Andreou***

Co-rapporteur, appointed by RAC: ***Irina Karadjova***

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **11 June 2020.**

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus.**

ADOPTION OF THE OPINION OF SEAC

Rapporteur (initial), appointed by SEAC: ***Lars Fock***

Rapporteur (replacement), appointed by SEAC: ***John Joyce***

Co-rapporteur, appointed by SEAC: ***Dorota Dominiak***

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **11 June 2020.**

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at http://echa.europa.eu/web/guest/restrictions-under-consideration. Interested parties were invited to submit comments on the draft opinion by **24 August 2020**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]]**[1].

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**]** **[**No comments were received from interested parties during the public consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

[1] Delete the unnecessary part(s)

The opinion of SEAC was adopted **by [consensus**.**][a simple majority]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[6].

Contents

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Column 1	Column 2
Calcium cyanamide EC number: 205-861-8 CAS number: 156-62-7	1. Shall not be placed on the market as a substance on its own or in a mixture for use as a fertiliser; 2. Shall not be used as a substance on its own or in a mixture as a fertiliser; 3. The restriction shall apply after dd/mm/yyyy[2].

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on **calcium cyanamide** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are:

Column 1	Column 2
Calcium cyanamide EC number: 205-861-8 CAS number: 156-62-7	1. Shall not be placed on the market as a substance on its own or in a mixture for use as a fertiliser; 2. Shall not be used as a substance on its own or in a mixture as a fertiliser; 3. Paragraph 1 shall apply after dd/mm/yyyy[3]. 4. Paragraph 2 shall apply after dd/mm/yyyy[4].

THE OPINION OF SEAC

See the opinion of SEAC.

[2] The Dossier submitter proposes a 36-month transition period to utilise products now on the shelves, and for end-users to acquire information, machinery and knowledge of alternative technologies to be able to replace the use of calcium cyanamide as a fertiliser.
[3] RAC supports a 24-month transition period for placing calcium cyanamide on the market for use as a fertiliser.
[4] RAC supports a 36-month transition period for the use of calcium cyanamide as a fertiliser. This periods is intended to allow the use of existing stocks (acquired prior to the expiration of the 24 month transitional period for placing on the market) and for end-users to transition to alternative substances/technologies.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of and justification for targeting (scope)

Summary of proposal:

Calcium cyanamide is used as a (slow-release) nitrogen fertiliser and sold in the EU under the trade name 'PERLKA®'. It is regulated under (EU) 2019/1009 (Fertilising Products Regulation).

The Scientific Committee on Health and Environmental Risks concluded that harmful effects for humans and the environment from the use of calcium cyanamide as a fertiliser could not be excluded (SCHER, 2016). In light of this report, the European Commission requested ECHA to carry out a preliminary assessment of the risks posed by calcium cyanamide to human health and the environment (ECHA, 2018). ECHA (2018) concluded that the use of calcium cyanamide as a fertiliser poses a risk to the environment.

Based on the conclusions of SCHER (2016) and ECHA (2018), the European Commission requested ECHA, in November 2017, to prepare an Annex XV restriction dossier on the use of calcium cyanamide as a fertiliser, limited in scope to possible risks to the environment. The report takes into account available information on the transformation products of calcium cyanamide: cyanamide, urea and cyanoguanidine (DCD). The Dossier Submitter (ECHA) has found that the use of calcium cyanamide as a fertiliser leads to a risk that is not adequately controlled for both surface water adjacent to fertilised fields and to the terrestrial environment.

The Dossier Submitter has identified that a restriction on the placing on the market and use of calcium cyanamide as fertiliser is the only restriction option that can adequately control risks in both the aquatic and terrestrial environments. A transitional period of 36 months is proposed in order that the manufacturer and end users have reasonable time to adjust to the change.

RAC conclusions:

The purpose of the restriction is clear and the target of the proposal to address the environmental risks of calcium cyanamide when used as a fertiliser is appropriate.

RAC notes that a human health risk assessment was not within the Dossier Submitter's mandate from the Commission and that the powder form of calcium cyanamide fertiliser was voluntarily removed from the market by the manufacturer in January 2018 to address potential human health risks posed by this form. From that time onwards, only the granulated form of this fertiliser is placed on the market.

The main transformation products of calcium cyanamide in soil, namely cyanamide, urea and cyanoguanidine are relevant to this assessment and data on these substances are also assessed by the Dossier Submitter. RAC agrees that these are relevant to the assessment.

RAC agrees with the Dosser Submitter that risks are not adequately controlled in the aquatic compartment adjacent to fertilised fields and in agricultural soils to which the fertiliser is applied and, furthermore, that risk management is required at the Union level. RAC notes the transition period of 36 months proposed by the Dossier Submitter and consider this to be reasonable in respect to the use of the fertilising product. However, RAC proposes that a shorter transition period of 24 months should be set for placing calcium cyanamide on the market as a fertiliser to reduce the potential for stockpiling by end users to result in its use as a fertiliser beyond the proposed transitional period for use of 36 months.

Key elements underpinning the RAC conclusions:

The justification for targeting the restriction at the environmental risks is supported by reports from SCHER (2016) and ECHA (2018). SCHER (2016) concluded that harmful effects to the environment from the use of calcium cyanamide cannot be excluded. The conclusion was based on an assessment of the available ecotoxicity data for calcium cyanamide and exposure modelling.

The preliminary assessment by ECHA (2018) also considered the available ecotoxicity data for cyanamide, the main transformation product of calcium cyanamide, and confirmed that the use of calcium cyanamide as a fertiliser might pose a risk to the aquatic, sediment and terrestrial compartments. Calcium cyanamide hydrolyses rapidly to cyanamide and calcium hydroxide. Thus, cyanamide is relevant to also consider for environmental risk assessment purposes. This approach was also supported in the harmonised classification and labelling proposal for cyanamide submitted by Germany (adopted June 2015) were cyanamide was classified as Aquatic Chronic 3, H412 (Harmful to aquatic life with long lasting effects).

The assessment performed by the Dossier Submitter considered the available information on the transformation products of calcium cyanamide: primarily cyanamide, as well as urea and cyanoguanidine. The Dossier Submitter has found that the use of calcium cyanamide as a fertiliser leads to a risk that is not adequately controlled for both surface water adjacent to fertilised fields and to soil. RAC notes that no conclusive monitoring data were available for this assessment.

RAC also notes that the Biocidal Product Committee has recently concluded that cyanamide is an endocrine disruptor for human health and non-target organisms[5].

Another aspect regarding the use of calcium cyanamide is the so called 'beneficial secondary effects' arising from the use of calcium cyanamide as a fertiliser which are reported in the literature. These include herbicidal and phytotoxic effects, fungicidal and fungistatic effects, molluscicidal effects, and insecticidal effects, avoidance effects on wireworms and effects on endo-parasites of grazing animals. These secondary effects are beneficial from an agricultural perspective, as reported by the Registrant, farmers and farmers associations, but efficacy data and official approval for what can be considered as plant protection or medicinal (veterinary) effects are not available.

A specific mode of action is described only in the case of the phytotoxic effect of cyanamide. Cyanamide inhibits the enzyme catalase, which is responsible in plants for the metabolism of hydrogen peroxide (H_2O_2) during photosynthesis (Ma, L., 2015). For the remainder of the secondary effects there is no clear mode of action described in the literature, although the

[5] ECHA (2019) Biocidal Product Committee: Opinion on the application approval of the active Substance Cyanamide. Product Type: 3. ECHA/BPC/230/2019. https://echa.europa.eu/documents/10162/f5e04e73-afe6-4595-abda-864931b167bb
ECHA (2019) Biocidal Product Committee: Opinion on the application approval of the active Substance Cyanamide. Product Type: 18. ECHA/BPC/231/2019. https://echa.europa.eu/documents/10162/0c97e426-a0a0-4030-a2ec-abdd80ef1396

majority of the effects may be attributed to the effect that calcium cyanamide has on soil pH surrounding the calcium cyanamide granules (increasing soil pH). Calcium hydroxide is produced during the rapid hydrolysis of the fertiliser in the soil environment. Increase of the pH of the soil have been shown to promote bacterial activity and suppress fungal activity in soil (Tremblay & Coulombe, 2005 and Webster & Dixon, 1991).

Description of the risks addressed by the proposed restriction

Information on hazards

Summary of proposal:

In moist soil calcium cyanamide is transformed into cyanamide and calcium hydroxide (primary transformation substances). Further on in the terrestrial environment, cyanamide is transformed into secondary transformation products, including urea and cyanoguanidine. Therefore, cyanamide, urea and cyanoguanidine are relevant transformation products and are considered throughout the assessment. These 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 under fertilised fields. Theoretically, calcium cyanamide itself could enter adjacent surface water and then degrade, but most likely the degradation process will have already begun before a run off event, hence cyanamide and its transformation substances will enter adjacent surface water.

The Dossier Submitter has found that the use of calcium cyanamide as a fertiliser (using application rates/methods recommended by the Registrant) leads to a risk that is not adequately controlled for both surface water adjacent to fertilised fields (the highest Risk Characterisation Ratios (RCRs) calculated were between approximately 2 to 1504 under reasonable worst-case assumptions) and to soil (the highest RCRs calculated were between approximately 3 to 135 under reasonable worst-case assumptions). The risk is primarily due to the effects of cyanamide, one of the first transformation products of calcium cyanamide. In some scenarios the secondary transformation products, urea and cyanoguanidine, also pose risks.

The risks are primarily to aquatic and soil macro organisms (cyanamide), algae (urea)[6] and soil microorganisms (cyanoguanidine)[7]. The Dossier Submitter also conducted a semi-quantitative assessment in relation to the risks to human health via groundwater using the WHO approach (WHO Guidelines for Drinking Water Quality) and the DNEL (oral, cyanamide) for the general population. Cyanamide does not exceed the DNEL in the scenarios modelled. However, it should be noted that the limit value is for the general population, whereas some individuals and infants may be more sensitive than adults. On this basis the presence of cyanamide does not appear to pose a concern for drinking water quality. Equally, the assessment does not take into account the endocrine disrupting properties of cyanamide (see below).

Calcium cyanamide is classified as Acute Tox. 4*, STOT SE 3 and Eye Dam 1, whilst cyanamide, is classified as Aquatic Chronic 3, Carc. 2, Repro. 2, Acute Tox. 3, Acute Tox. 3, STOT RE 2, Skin Corr. 1, Skin Sens. 1, Eye Dam. 1.

Cyanamide was identified as an endocrine disruptor for human health and non-target

[6] At typical application rates of calcium cyanamide applied one crop (potatoes), urea was found to pose an uncontrolled risk to aquatic microorganisms.
[7] At various application rates and methods of calcium cyanamide, DCD was found to consistently pose an uncontrolled risk to soil microorganisms.

organisms by the Biocidal Product Committee (BPC) in December 2019[8].

RAC conclusions:

RAC concludes in line with the environmental hazard assessment as reported by the Dossier Submitter with the exception of the hazard assessment for surface water for urea. The hazard assessment was supported by the use of relevant and reliable literature sources and the majority of the data had undergone scrutiny under various previous EU regulatory reviews. RAC agrees with the Dossier Submitter that previously reviewed studies under various EU legislation frameworks should be considered to be reliable for the purpose of this assessment. Additional studies provided to the Dossier Submitter were evaluated by the Dossier Submitter and RAC and their conclusions can be found in the following sections. Data from the new studies was insufficient to justify a revision to the hazard assessment proposed by the Dossier Submitter.

Calcium cyanamide hydrolyses rapidly to cyanamide which is its main transformation product, and therefore RAC agrees with the Dossier Submitter and the Registrant that the ecotoxicological data from the studies using cyanamide as the test substance can be used for the assessment of calcium cyanamide. RAC also notes, that in line with the cyanamide classification, calcium cyanamide was self-classified by the Registrant as Aquatic Chronic 3, (H412) with an M-factor of 1.

Hazard assessment was presented in the dossier for the aquatic, sediment and terrestrial environment.

Table 1: Summary of the derived aquatic, sediment and soil predicted no effect concentrations (PNECs) used for the risk characterisation by the Dossier Submitter.

PNEC	Cyanamide	Urea	cyanoguanidine
$PNEC_{freshwater}$, species & key study	0.01044 mg/L *Daphnia magna* Murrel & Leak 1995	0.47 mg/L *Microcystis aeruginosa* Bringmann & Kuhn 1978	2.5 mg/L *Daphnia magna* Environment Agency Japan 1998b
$PNEC_{sediment}$, species & key study	0.0664 mg/L[9] *Chironomus riparius* Heintze 2001	No data	No data
$PNEC_{soil}$, species & key study	0.15 mg/kg soil *Folsomia candida* Moser & Scheffczyk	Insufficient data to derive $PNEC_{soil}$	0.25 mg/kg soil Soil microorganisms in OECD guideline

[8] On 4-5 June 2019 the Endocrine Disruptor Expert Group (ED EG) reached an agreement that cyanamide should be identified as an endocrine disruptor with regard to human health. On 18-19 September the Biocides Human Health Working Group concluded that cyanamide meets the criteria for endocrine disruption for human health and on 26-27 September 2019 the Biocides Environment Working Group agreed that the current data set is sufficient to conclude on the ED properties of cyanamide for non-target organisms.

[9] This value is based on a NOEC (28d) value of 6.64 mg/L (water column concentration) based upon the development rate of the midges (Heintze 2001). An AF factor 100 was applied as this was the only study available for PNEC derivation.The PNEC was based on the overlying water concentrations, as the test substance was spiked into the overlying water, rather than the sediment.

	(2009)		216 Foerster (2014b)

RAC concludes in line with the Dossier Submitter on the hazard assessment of calcium cyanamide/cyanamide and cyanoguanidine in freshwater and sediment.

Acute and chronic studies from three trophic levels were available (fish, invertebrate, algae and aquatic plants) for calcium cyanamide/cyanamide. The most sensitive organism in freshwater chronic studies was *Daphnia magna* using cyanamide as the test substance. A $PNEC_{freshwater}$ of 0.01044 mg/L of cyanamide was used by the Dossier Submitter. This was based on the 21d NOEC for *Daphnia magna* (NOEC = 0.1044 mg cyanamide/L, Murell et al., 1995) and an Assessment Factor (AF) of 10 since chronic studies are available for three trophic levels. RAC notes that the same study was used as the key study in the previous PPP (2008-10), CLH (2015) and BPR (2016) assessments.

For cyanoguanidine the most sensitive aquatic species was found to be *Daphnia magna* in a 21-day study measuring reproduction in which the NOEC (21d) was found to be 25 mg/L (Environment, Agency Japan 1998b). Based on this data and an assessment factor of 10 the $PNEC_{freshwater}$ for cyanoguanidine is 2.5 mg/L.

For sediment, data were available only for the cyanamide. A chronic study was available, with a resulting NOEC (28d) of 6.64 mg/L for *Chironomus riparius* (Heintze, A., 2001). Based on this study and an assessment factor of 100 the resulting $PNEC_{sediment}$ for cyanamide was 0.0664 mg/L.

For urea the most sensitive species reported in the Registration dossier was *Microcystis aeruginosa* (algae) in a chronic study resulting in a NOEC (8d) of 47 mg/L (Bringmann & Kuhn, 1978). Based on these data and an assessment factor of 100 the Registrant derived a $PNEC_{freshwater}$ for urea of 0.47 mg/L. The Dossier Submitter brought forward this PNEC for its assessment. Other acute studies on fish and invertebrates were also available. For fish (*Gambusia affinis*) the reported NOEC (7d, mortality) was 200 mg/L (Oster, et al. 2011) and for invertebrates (*Daphnia magna*) a reported EC_{50} (24h, mobility) was >1 000 mg/L (Bringmann & Kuhn 1982).

RAC does not support the PNEC for urea derived by the REACH Registrant, as used by the Dossier Submitter, derived from Bringmann & Kuhn (1978) due to obvious study limitations. RAC also notes that, in the literature, it is well documented that *Microcystis aeruginosa* uses urea as a nitrogen and carbon source in concentrations well above the reported NOEC of 47 mg/L (Huang, et al, 2014). As a result, RAC considers that the $PNEC_{freshwater}$ value for urea is not sufficiently reliable for hazard assessment.

RAC agrees with the conclusion of the Dossier Submitter on the hazard assessment for the terrestrial (soil) environment for calcium cyanamide/cyanamide, urea and cyanoguanidine.

Acute and chronic studies from three trophic levels were available (soil microorganisms, earthworms, arthropods and plants) for calcium cyanamide/cyanamide. An EC_{10} (28d) for reproduction of 1.515 mg cyanamide/kg soil dw was determined from a chronic soil collembolan study (ISO 11267) on *Folsomia candida* (Moser and Scheffczyk, 2009). This value was taken forward by the Dossier Submitter for PNEC derivation. Applying an assessment factor of 10 the $PNEC_{soil}$ for cyanamide was determined to be 0.15 mg cyanamide/kg soil dw. RAC notes that this study was also chosen as the key study for the terrestrial compartment in the BPR assessment (BPR, 2016).

$PNEC_{soil}$ values for urea were not reported by the Dossier Submitter as conclusive data were not available. RAC supports the argument presented by the Dossier Submitter that urea is of inherently low toxicity and is rapidly assimilated into the nitrogen cycle by soil microorganisms. However, RAC notes that studies exist indicating potentially toxic effects of urea to soil organisms.

In the case of cyanoguanidine a NOEC (28d) value of 2.5 mg/kg soil dw was determined in a nitrogen transformation study. Because there are studies conducted at three tropic levels (soil microorganisms, earthworms and plants), an assessment factor of 10 was applied and the $PNEC_{soil}$ for cyanoguanidine was determined to be 0.25 mg/kg soil dw.

Hazard to groundwater was also assessed with respect to human exposure to cyanamide through potable water. A Guideline value (GV) of 0.510 mg/l for cyanamide and 19.5 mg/L for cyanoguanidine was calculated for oral route and the general population following WHO methodology. RAC supports the inclusion and the calculations of the Guideline value (GV) of 0.510 mg/l for human health exposure assessment.

Key elements underpinning the RAC conclusions:

The information related to the hazard assessment was retrieved by the Dossier Submitter from REACH registration dossiers (calcium cyanamide [Alzchem], 2019a & 2019b; urea, 2017; cyanoguanidine, 2015), previous EU regulatory reviews (cyanamide-BPR, 2016; cyanamide-CLH, 2015; cyanamide-PPP 2008-10; calcium cyanamide-SCHER, 2016) and other relevant literature sources.

Unpublished study reports were also provided by the calcium cyanamide registrant during the consultation. In general, the Dossier Submitter assumed that if the study was accepted as reliable and relevant in another EU regulatory process then it can be considered to be reliable and relevant within this assessment. Some further studies, reported after the biocidal products (2016) and SCHER (2016) assessments were conducted were assessed on a case-by-case basis by the Dossier Submitter and RAC for their reliability; for which more details are provided in the following paragraphs.

As stated above, calcium cyanamide and cyanamide are classified as Aquatic Chronic 3 (H412). Urea and cyanoguanidine are not classified for environmental hazards due to inconclusive data. RAC agrees with the Dossier Submitter that the results of studies using cyanamide as the test substance can be read across to calcium cyanamide for environmental endpoints.

Hazard to the aquatic compartment (including sediment)

Aquatic toxicity data for three trophic levels were available for calcium cyanamide/**cyanamide**. A total of 16 studies (11 acute or short-term and 5 chronic) in the aquatic compartment were available to the Dossier Submitter, mainly from the Registrant's REACH registration dossier (Alzchem, 2019a). Where necessary, the results of these studies have been checked against previous regulatory reviews. A chronic study for a sediment-dwelling organism was also available.

Aquatic ecotoxicity studies indicated that cyanamide has a low toxicity to fish, a moderate toxicity to algae and a high toxicity to daphnids (NOEC (21d) =0.1044 mg cyanamide/L, Murrel & Leak, 1995). The NOEC values for both the acute and chronic studies ranged between 3.7 and 100.0 mg of cyanamide/L for fish, 0.1 and 6.64 mg of cyanamide/L for algae and aquatic plants and 0.1 and 1.8 mg of cyanamide/L for invertebrates.

In the key study by Murrel & Leak (1995), the growth and reproduction of *D. magna* were assessed in a non-aerated, flow-through 21-day test according to OECD test guideline 202. A NOEC (21d) of 0.1044 mg cyanamide/L for reproduction was calculated based on mean measured concentrations. This value was used as a key endpoint for classification of cyanamide as Aquatic Chronic 3 (CLH, 2015). A $PNEC_{freshwater}$ of 0.01044 mg/L of cyanamide was derived by the Dossier Submitter by applying an assessment Factor (AF) of 10 since chronic studies are available for three trophic levels.

Two additional studies were submitted by the Registrant, a non-standard *D. magna* 21-d reproduction study (Brüggemann, 2019) and an outdoor model ecosystem (mesocosm) study (Hommen, 2019).

The first study, a non-standard *Daphnia magna* 21-d reproduction study intended to simulate exposure in edge of field exposure scenarios (Brüggemann, 2019), had some notable deviations from the OECD 211 guideline and thus the Dossier Submitter concluded that it was not appropriate for PNEC derivation and should not be used instead of the existing chronic 21d *D. magna* study (Murrel & Leak, 1995). Further details of the assessment of this test can be found in the Background Document.

Indeed, the study was included in the most recent update of the registration dossier by the Registrant, but was not considered for hazard assessment purposes, rather it was taken as supporting information on sensitivity of *Daphnia magna*. A clarification on the purpose of the study was provided by the study director. The study was performed as a refined exposure test (Tier 2C) within the context of EFSA (2013) guidance on tiered risk assessment for plant protection products for aquatic organisms in edge of field surface waters. For this reason, RAC considers the some of the limitations reported by the Dossier Submitter are not relevant as they refer to deviations from the standard ecotoxicity guideline (OECD 211), which the study was not designed to be fully compliant with. Nevertheless, RAC agrees with the Dossier Submitter that the study cannot be used as a point of departure for PNEC derivation as (i) because the study only involved a single dosing event at the start of the study, the concentration of the test substance was not maintained within ± 20% of the nominal or measured initial concentration throughout the duration of the as recommended in the OECD test guideline 211 and (ii) no statistically significant concentration-response was observed. However, non-statistically significant reduction of the mobility of juveniles (20%) and adults (30%), relative to the control, was recorded at the 0.026 mg/L and 0.053 mg/L cyanamide test concentrations, respectively.

Therefore, RAC concludes in line with the Dossier Submitter that the non-standard *D. magna* reproduction study (Brüggemann, 2019) does not provide definite data for hazard assessment and shall not be used as a replacement for the chronic 21d *D. magna* study (Murrel & Leak, 1995).

The second study, an outdoor mesocosm study (Hommen, 2019) aimed to investigate the effects of cyanamide on freshwater ecosystems by monitoring zooplankton, macroinvertebrates, phytoplankton, periphyton and macrophytes in lentic outdoor mesocosms. A single application of cyanamide at five concentration levels was performed (0.032; 0.1; 0.32; 1.0; and 3.2 mg cyanamide/L). This study was conducted in accordance with OECD Guidance Document "Freshwater Lentic Field Tests" (2013) and the recommendations from the EFSA PPR Panel (2013) and the Biocide guidance (2017).

Observed effects of the test item are classified according to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA, 2013) and Brock et al. (2015). The PPP tiered approach includes four tiers within the acute and chronic effect assessment. Tier 1 and Tier 2 effects assessments are based on single species laboratory toxicity tests. Tier 3 (population- and community-level experiments and models) and Tier 4 (field studies and landscape-level models) may concern a combination of experimental data and modelling to assess population- and/or community-level responses (e.g. recovery, indirect effects) at relevant spatio-temporal scales.

These effect assessment schemes described in the EFSA guidance (EFSA, 2013) were developed to allow the derivation of Regulatory Acceptable Concentrations on the basis of two options: (1) The ecological threshold option (ETO), accepting negligible population effects only, and (2) the ecological recovery option (ERO), accepting some population-level effects if ecological recovery takes place within an acceptable time period.

The study effects were classified as follows: 1 = No treatment related effects demonstrated, 2 = Slight effect, 3A = Pronounced short term effects (effect period < 8 weeks), followed by recovery, 3B=Pronounced effects longer than 8 weeks but recovery within 8 weeks after last application, 4A = Significant effects in short-term study, 4B=Significant short term effects but minimum detectable difference (MDD) too high in recovery period 5A = Pronounced long term effect followed by recovery, 5B =Pronounced long term effects without recovery.

Based on the Registrant's evaluation of the mesocosm study, an ETO of 0.1 mg/L was derived based on the effect on the zooplankton community structure. An ERO of 0.32 mg/l was derived based on acceptable short-term effects followed by recovery. Based on this ERO value and an assessment factor of 3, the Registrant derived a $PNEC_{freshwater}$ of 0.107 mg cyanamide/L.

A complimentary assessment of the mesocosm study was provided during the consultation from the study director (comment no. 2930; Hommen, 2019). The assessment used assessment factors of 3 and 4 for the ETO and ERO values, respectively resulting in PNEC values of 0.033 mg/L and 0.08 mg/L based on ETO and ERO, respectively, which were lower than those reported in the registration.

Well conducted mesocosm studies can be used in a weight of evidence approach to refine or replace the PNEC derived from laboratory studies. An assessment was performed to derive a $PNEC_{freshwater}$ value based on the Guidance on tiered risk assessment for edge-of-field surface waters (EFSA, 2013). From the study report it can be shown that a NOEC based on an ETO (regulatory acceptable concentration using the ecological threshold option) value of 0.032 mg/L can be derived, based on zooplankton community level analysis (PCR analysis). Also, a NOEAEC-ERO (No Observed Ecologically Adverse Effect Concentration using the ecological recovery option) value of 0.1 mg/L can be derived, based on Diptera/Chaoborus sp. and phytoplankton community level analysis (PCR analysis). The assessment of the study by EFSA (Aug, 2019), as requested by the Dossier Submitter, assigned AF of 2 and 4, respectively, to the ETO and ERO values leading to tentative $PNEC_{freshwater}$ values of 0.016 mg/L based on ETO value and 0.025 mg/L based on the NOEAEC-ERO value. RAC agrees with the Dossier Submitter's assessment.

RAC notes that some limitations were identified by the Dossier Submitter and EFSA (Aug, 2019) and reported in the Annex XV report. These identifed limitations were commented on during the consultation by the study director (comment no. 2930). However, some uncertainty remains when interpreting the results of the mesocosm study as:

- The most sensitive insects among the ones tested (Diptera/Chaoborus sp.) presented decreasing abundance during the study also in the control, which is likely linked to a large share of animals emerging before the exposure phase or soon after, indicating that the timing of the study was not ideal. Hence, most animals were likely not exposed during the most sensitive life stage (early instars).
- In general, when assessing the ability of a mesocosm study to cover vulnerable species, great attention is paid to the presence of so-called EPT (Ephemeroptera, Plecoptera, and Trichoptera). In the present study the mayfly *Cloeon dipterum* (representative of Ephemeroptera) was present and did not show particularly adverse effects up to 1 mg/L level; other EPT species were not present.
- In relation to the ERO option, at the proposed NOEAEC (No Observed Ecologically Adverse Effect Concentration) some differences from the control were seen for Chlorophyceae at the end of the study: while these differences were finally not considered likely to be treatment-related, a degree of uncertainty remains.

In conclusion, RAC considers the mesocosm study to be a well performed and reported study. Therefore, the tentative $PNEC_{freshwater}$ value of 0.016 mg/L based on ETO from the mesocosm study was used for comparison with the $PNEC_{freshwater}$ value of 0.0104 mg/l derived from the chronic endpoint for *Daphnia* (NOEC=0.104 mg/L). The ETO was considered appropriate for deriving $PNEC_{freswater}$ from the mesocosm data (see the BD for further details).

As the $PNEC_{freshwater}$ value derived from the chronic *Daphnia magna* study (Murrel & Leak, 1995) is marginally more conservative, but very close to the $PNEC_{freswater}$ derived from the mesocosm study, it strengthens the conclusion that this value is appropriate for use in risk assessment to the aquatic environment. Usually, it is anticipated that toxicity endpoints derived from higher tier studies (i.e. mesocosm studies) are less conservative that those derived from one species standard ecotoxicity tests.

In respect to the hazard assessment of cyanamide for sediment, one chronic study was available on the sediment dwelling organism *Chironomus riparius* (Heintze, 2001). A NOEC (28d) was estimated to be 6.64 µg/L of cyanamide. An assessment factor of 100 was used since only one chronic study was available, therefore the resulting $PNEC_{sed}$ cyanamide was 0.0664 mg/L. It is worth noting that in the BPR assessment (2016) a PNEC sediment ($PNEC_{sed}$) for cyanamide was derived from the $PNEC_{freshwater}$ using equilibrium partitioning, resulting in $PNEC_{sediment}$ for cyanamide of 0.0916 mg/L. The PNEC value resulting from the experimental data is more conservative and thus preferred for hazard assessment. No hazard assessment was performed for urea and cyanoguanidine in respect to the sediment due to the high hydrophilicity and low Koc values.

For urea a total of 3 studies (2 acute or short-term and 1 chronic) in the aquatic compartment were available to the Dossier Submitter, mainly from the Registrant's REACH registration dossier. The most sensitive species was algae with a NOEC (8d) of 47 mg/L. For fish (*Gambusia affinis*) the reported NOEC (7d, mortality) was 200 mg/L (Oster, et al. 2011) and for invertebrates (*Daphnia magna*) a reported EC_{50} (24h, mobility) was available as >1 000mg/L (Bringmann & Kuhn1982). An assessment factor of 100 was applied by the Registrant since only one chronic endpoint is available to the most stringent endpoint (NOEC(8d) =47 mg/L) to derive the PNEC. The resulting $PNEC_{freshwater}$ as proposed by the Registrant and applied by the Dossier Submitter for urea was 0.47 mg/L.

RAC does not support the use of the Bringmann & Kuhn study (1978) as a point of departure for deriving the PNEC freshwater for urea. This is a non-standard study originating before OECD guidelines and GLP were available and performed for a different purpose. The combination of study limitations and poor reporting, when compared to current OECD and GLP guidelines, render this study unreliable for risk assessment purposes. Based on the Klimisch scale a Klimisch score of 3 is appropriate. The observed limitations of the study were:

a) Information on growth medium is not reported;

b) Number of cells used is not reported;

c) The duration of the study is not reported

d) The results are based on the determination of algal biomass

e) Statistical information on controls and treatments (coefficient of variation of average specific growth rates) is not given or not sufficient.

In the literature it is well documented that *Microcystis aeruginosa* uses urea as a nitrogen and carbon source in concentrations well above the 47 mg/L and up to 2500 mg/L (Huang.W., et al, 2014). *Microcystis* has the ability to metabolise urea and other nitrogen rich substances and it appears that urea is a key nutrient in terms of its ability to shape cell physiology in the natural environment based on the expression patterns of genes in the cyanobacterial metabolic network (Steffen, M. et. al., 2017). RAC did not derive an alternative $PNEC_{freshwater}$ for urea due to insufficient data.

For cyanoguanidine, a total of 3 chronic studies in the aquatic compartment were presented in the proposal by the Dossier Submitter, mainly from the Registrant's REACH registration dossier. However two more studies were available in the RRD, one acute fish study (LC50 > 1 000 mg/l) and one acute study on aquatic invertebrates (NOEC(48h)=1 000 mg/l). These studies do not change the key endpoint selected by the Dossier Submitter and therefore have no impact on the selected $PNEC_{freswater}$ value. The most sensitive species was *Daphnia magna* with a NOEC of 25 mg/L. An assessment factor of 10 was applied since three chronic endpoints were available from species representing three trophic levels. The resulting PNECfreshwater for cyanoguanidine was 2.5 mg/L.

<u>Hazard to terrestrial compartment (soil dwelling organisms)</u>

For the assessment of hazard to the terrestrial compartment from calcium cyanamide/ cyanamide, 17 studies were available to the Dossier Submitter for soil-dwelling organisms (8 short-term and 9 long term studies). The source of the studies was mainly the Registrant's REACH registration dossier (Alzchem, 2019a), but also cross-referenced with BPR 2016, CLH 2015, PPP 2008-10, SCHER 2016. For soil microorganisms the lowest endpoint was NOEC (28d)=27.2 mg/L, for earthworms LC50=111.3 mg/L, for soil macroorganisms EC_{10}=1.5 mg/kg soil dw for the Collembola *Folsomia candida* and for plants EC_{50}=0.58 mg/kg soil dw. The key study used by the Dossier Submitter was the chronic 28 day study with *Folsomia candida* by Moser and Scheffczyk (2009) which resulted an EC10 of 1.5 mg/kg soil dw. Since long-term studies on cyanamide are available for three trophic levels (soil microorganisms, soil macroorganisms and plants) an assessment factor under REACH of 10 is appropriate. Therefore, the resulting $PNEC_{soil}$ cyanamide of 0.15 mg cyanamide/kg soil dw was derived by the Dossier Submitter.

Allium cepa (onion) was shown to be particularly sensitive to cyanamide in short-term studies on seedling emergence (NOEL <0.02 mg a.s./kg soil dw). Other species of plants (*Avena sativa* and *Brassica rapa*) also showed sensitivity to cyanamide in chronic studies (NOEC=50mg/kg soil dw). The Dossier Submitter considered these studies only to be suitable as supporting information for the purpose of risk characterisation. This was argued based on the fact that the Registrant advises against using PERLKA® as a fertiliser at seedling emergence for certain crops, and also because the granulated form of PERLKA® is used, it is unlikely that other plant species will be exposed to PERLKA® outside of the field being fertilised.

However, RAC notes that based on the data gathered from BPR (2016) the NOEL = 0.02 mg a.s./kg soil dw value could not be confirmed. RAC also notes that BPR (2016) provides an EC_{50}=0.58 mg/kg soil dw which is consistent with the assessment done by EFSA (2010)[10] on cyanamide from the Meister, 2001 study. The same study provided an EC_{50}=11.2 mg/kg soil dw for *Lycopersicon esculentum*. The EC_{50} values from the Meister (2001) study were calculated as mg a.s./kg soil dry weight from the initial units of kg a.s./ha, using the parameters of 10 cm soil depth and a bulk density of dry soil with 1 500 kg/m^3. This approach was acceptable within the BPR (2016) and EFSA (2010)[11] cyanamide assessment. This is consistent with the phytotoxicity effect of increased lipid peroxidation and H_2O_2 accumulation by cyanamide and the recommendation from the manufacture the cyanamide has “counteractive effect on freshly germinated weed and rosette plants”. In the study by Meister (2001) the derived EC_{50} was calculated based on the application rate, rather than a direct calculation based upon experimental evidence/sampling in order to elucidate the concentration that the plants were exposed to. Therefore, RAC considers this study as not relevant to be used as a point of departure for PNEC derivation.

Chronic studies with *Abablemma bilineata* (Röhlig, 2006a), a Pardosa species (Röhlig, 2006b) and *Eisenia.fetida* (Scheffczyk, 2016b) estimated NOEC values of 0.4 mg/kg soil dw, 1.2 mg/kg soil dw and ≥1.05 mg/kg soil dw, respectively. These values are lower that the value considered above as the basis for the PNEC derivation, but were not used as a point for departure for risk assessment due to the fact that both studies were deemed not reliable for hazard assessment purpose. In the study by Scheffczyk (2016b) no concentration-effect relationship was observed while in the study by Röhlig (2006) the derived NOEC was calculated by the Dossier Submitter, rather than directly based upon experimental evidence.

Additional studies regarding the terrestrial compartment were supplied to the Dossier Submitter during the assessment process. Two field studies (Ebke, 2018 and Stegger, 2019) were initiated by the Registrant and their reports were made available to the Dossier Submitter and RAC recently.

An interim report from the Ebke (2018) study was available for assessment. A final report for the field study, Ebke (2018) is not expected since the Registrant decided not to continue the monitoring due to obvious limitations of the study design and mainly because the GLP compliant field study by Stegger (2019) on collembolans had already been started in the autumn of 2018. Limitations of the Ebke (2018) study were obvious and hence it could only be used as a supporting evidence. Limitations of the study included: not a GLP study; not a randomised experimental design; only one application rate was investigated, the soil concentration of calcium cyanamide/cyanamide was not measured; the amount of nitrogen

[10] Conclusion on the peer review of the pesticide risk assessment of the active substance cyanamide European Food Safety Authority. EFSA Journal 2010;8(11):1873
[11] Conclusion on the peer review of the pesticide risk assessment of the active substance cyanamide European Food Safety Authority. EFSA Journal 2010;8(11):1873

supplied was not exactly equivalent between the area treated with calcium cyanamide (202 kg N/ha) and the one treated with the conventional fertiliser (173 kg N/ha); collembolans were not presented at the species level in the study and additionally *Folsomia candida* was identified as the most sensitive species based on the ecotoxicity studies; second sampling in October 2018 was hampered by the dry summer; a herbicide treatment was applied to the whole area less than a month before sampling; the depth and volume of soil samples were not specified for earthworms and for collembolans. The study suggested that the use of granulated calcium cyanamide over a period of seven years did not result in any significant effects on the observed populations of terrestrial invertebrates compared to the reference plot. However, such results should be used with great caution due to the abovementioned limitations and their inherent high uncertainty and thus the Dossier Submitter used the study only as supporting information.

The Registrant also initiated a field Study to Evaluate the Effects of granulated calcium cyanamide fertiliser on Collembola in Central Europe (Stegger, 2019). The aim of the study was to investigate the possible effects of calcium cyanamide (as formulated fertiliser Perlka®) on populations of collembolans in the field. Study results were included in a GLP audited final report which was assessed by the Dossier Submitter and RAC.

The Registrant claims that the results of the study suggest that calcium cyanamide does not have a long-term effect on collembolans (≈27 weeks) under realistic field conditions and for realistic application rates (200 and 400 kg/ha). However, the study reports statistically significant lower abundance for total collembolans on day 28 after the first and second application followed by rapid recovery of the population, which indicates effects are occurring after application. RAC notes that recovery of a population in field studies is influenced by the dispersal potential of the organism, plot size, species phenology, and surrounding habitat structure off a plot experiment (Topping J., et al., 2014). The time to recovery, observed in such small plots can be misleading for mobile species that move in and out of plots during the course of a study.

The study evaluates the effect of calcium cyanamide on collembolan species but no other terrestrial species are included in the study. Although *Folsomia candida* was the most sensitive laboratory species RAC notes that this does not preclude that other species might be more sensitive than collembolan species. The likelihood of interspecies differences in sensitivity underpin the use of assessment factors of various size when deriving PNEC values. This study does not address this uncertainty. RAC notes that two recent reviews of the effects of pesticides on soil invertebrates in laboratory studies (Frampton et al., 2006) and field studies (Jänsch et al., 2006) have confirmed that, except for earthworms, in most cases there is insufficient data from field studies to validate risk predictions that are based on laboratory testing.

The order Collembola is one of the most diverse and abundant terrestrial arthropod orders, with 21 families and 20 000 described species. However, just one species (*Lepidocyrtus violaceus*) was accounted for approximately 90% of the collembola community in the study. While just the three species accounted for approximately 98 % of all collembola in the study. In addition, eudaphic and hemiedaphic (in-soil living) collembola, which are less mobile and cannot rely on re-colonisation from external areas are almost absent from the study.

Based on these considerations, RAC supports the conclusions of the Dossier Submitter that the study is not appropriate to replace the *Folsomia candida* chronic endpoint (EC10=1.15 mg/l cyanamide; Moser and Scheffczyk, 2009) as the point of departure to derive the PNEC*soil* value.

No $PNEC_{soil}$ value for urea was estimated due to insufficient data. Urea is of inherently low toxicity and is rapidly assimilated into the nitrogen cycle by soil microorganisms, therefore exposure of non-target organisms is limited.

Four studies are available investigating the toxicity of cyanoguanidine to the terrestrial compartment (1 acute and 3 chronic) from three different trophic levels (soil microorganisms, soil macroorganisms and plants). For earthworms NOEC was < 3 200 mg/kg soil dw (Adema, D.M.M., 1985) and for the plant *Avena sativa* a NOEC=31.6 mg/kg soil dw was recorded (Foerster, B., 2014a). A study on the inhibitory effects of cyanoguanidine to the metabolic performance of soil microorganisms was also conducted (Foerster, B. 2014b). The method followed the OECD test guidelines 216 and 217 (Soil microorganisms: nitrogen transformation test/carbon transformation test). Decrease of metabolic activity was observed in both studies at the highest test concentration, respectively. The NOEC for nitrogen turnover was 2.5 mg/kg soil dw, and the NOEC for carbon transformation was 316 mg/kg soil dw. The Dossier Submitter accepts there are beneficial properties of nitrification inhibition, but for the purposes of the risk assessment under REACH the most sensitive test organism(s) in a chronic study is chosen as the point of departure for the PNEC derivation. On this basis the nitrate formation rate study by Foerster, B. 2014b is considered the key study. The PNECsoil was 0.25 mg/kg soil dw and it was derived from the NOEC value of 2.5 mg/kg soil dw and an assessment factor of 10, as three long term studies were available for species of three trophic levels.

Hazard to terrestrial compartment (non-soil-dwelling organisms)

There are 15 studies available for various non-soil-dwelling terrestrial organisms (12 acute and 3 chronic). The source of the studies was mainly the Registrant's REACH registration dossier (Alzchem, 2019a), but also cross-referenced with BPR 2016, PPP 2008-10, SCHER 2016. This set of studies included a study on rats, which has been used in previous regulatory reviews as a surrogate for small terrestrial mammals (PPP 2008-10). Terrestrial organisms shown to exhibit adverse effects when they were exposed to cyanamide at concentrations. NOEC values were calculated as0.8 mg/kg soil dw for *Aphidius rhopalosiphi* (a parasitic wasp); 13.3 mg/kg body weight (by ingestion) for *Colinus virginianus* (a New World quail); small mammals (rat) 1.3 mg/kg bw/d (by ingestion) and bees at less than 0.0516 µg/bee (by ingestion). However, whether these organisms will be at risk depends upon whether they are actually exposed in practice. Therefore, these studies have not been used for the PNECsoil derivation and are not considered a key driver for the terrestrial risk assessment carried out, but instead are used as supporting information. PPP 2008-10 reviewed the terrestrial effects of cyanamide on non-soil-dwelling organisms and noted the particular sensitivity of bees, certain birds and small mammals to cyanamide. These studies were not taken into consideration for deriving PNEC by the Dossier Submitter, they were considered as supporting information. The Dossier Submitter notes that whether these organisms will be at risk depends upon whether they are actually exposed in practice, but no further exposure assessment was performed. RAC notes that by taking into account that calcium cyanamide is applied as a granulated fertiliser via top dressing application in the terrestrial environment before and after the emergence of plants, exposure to the above-mentioned organisms cannot be excluded.

Hazard to groundwater (Human health)

Even though a human health risk assessment for calcium cyanamide was out of the scope of this proposal, because cyanamide was shown to reach **groundwater** which might be used as potable water, the Dossier Submitter derived limit values for cyanamide and cyanoguanidine in drinking water and thereby considered the potential risk to human health by indirect exposure. The Dossier Submitter used the DNEL values as they were derived in the case of cyanamide in the ECHA (2018) assessment and in the case for cyanoguanidine in in the respective RJRD (2015). The DNEL for cyanamide and cyanoguanidine for oral route (general population) were 0.017 mg/kg bw/d and 6.5 mg/kg bw/d respectively. RAC agrees with the DNEL values as proposed by the Dossier Submitter.

The methodology described followed that underlying the WHO Guidelines for Drinking Water Quality. The method is based upon typical daily consumption, for a person of an average body weight and incorporates the DNEL (oral route) for the test substances. A Guideline value (GC) value of 0.510 mg/l for cyanamide and 19.5 mg/L for cyanoguanidine was calculated. RAC supports the inclusion and the calculations for this exposure assessment.

Additional information on hazard

RAC notes that the Biocidal Products Committee (BPC) on 9-13 December 2019 concluded that cyanamide is an endocrine disruptor for human health and non-target organisms. This further strengthens the case that the use of calcium cyanamide as a fertiliser leads to a risk that is not adequately controlled.

Cyanamide has been approved for use in biocidal products (BPR 2016) as a disinfectant against the bacterium *Brachyspira hyodysenteriae*, a pathogen in pigs, birds, dogs, and humans; and as an insecticide against fly larvae (*Musca domestica*) in liquid manure in animal housings (pig stables). The reported efficacy of cyanamide as a biocide supports the observation of ecotoxic effects in other (non-target) terrestrial organisms.

Table 2: Summary of the derived aquatic, sediment and soil predicted no effect concentrations (PNECs) supported by RAC.

PNEC	Cyanamide	Urea	cyanoguanidine
$PNEC_{freshwater}$, species & key study	0.01044 mg/L *Daphnia magna* Murrel & Leak 1995 (In line with Dossier Submitter's proposal)	Proposed $PNEC_{freshwater}$ was not supported	2.5 mg/L *Daphnia magna* Environment Agency Japan 1998b (In line with Dossier Submitter's proposal)
$PNEC_{sediment}$, species & key study	0.0664 mg/L *Chironomus riparius* Heintze 2001 (In line with Dossier Submitter's proposal)	No $PNEC_{sediment}$ was evaluated	No $PNEC_{sediment}$ was evaluated
$PNEC_{soil}$, species & key study	0.15 mg/kg soil *Folsomia candida* Moser & Scheffczyk (2009) (In line with Dossier Submitter's proposal)	No $PNEC_{soil}$ was evaluated	0.25 mg/kg soil Soil microorganisms in OECD guideline 216 Foerster (2014b) (In line with Dossier Submitter's proposal)

Information on emissions and exposures

Summary of proposal:

Approximately 130 000 tonnes of calcium cyanamide are manufactured annually in the EU of which about 53 000 tonnes are for use as a fertiliser and the rest largely for industrial uses. The fertiliser is supplied mainly to professional farmers and is estimated to be used for fertilising about 230 000 hectares[12] of land.

The use rate recommended by the Registrant is around 300kg per hectare dependent on the crop in question and the total amount of calcium cyanamide sold as a fertiliser is about 70 000 tonnes per year (using the concentration of PERLKA®).

Calcium cyanamide is a slow-release nitrogen fertiliser used for a number of EU agricultural crops. Calcium cyanamide is applied as a fertiliser in granular form mainly in three different ways by farmers, depending upon the crop: (1) surface application –onto a (bare) soil surface (usually broadcasted i.e. spread evenly) or top dressing (applied onto growing crops); 2) uniform incorporation i.e. incorporated from the soil surface down to a specific depth, e.g. 10 cm; (3) deep placement - via a tube at a particular soil depth, e.g. 10 cm. From the fields, calcium cyanamide is released into the aquatic and terrestrial environments affecting surface water, soil and potentially groundwater.

FOCUS modelling has been used by the Dossier Submitter to derive predicted environmental concentrations (PEC) of calcium cyanamide and its transformation products in surface water and sediment. The exposure modelling done by the Dossier Submitter takes into account the different application methods.

The modelling results for various crops across the range of recommended application rates show the highest PECfreshwater values to be in the range 17.4 – 1900.4 µg/L, when calcium cyanamide is applied by uniform incorporation or at the soil surface. Soil surface application of calcium cyanamide seems to elevate PECfreshwater values, compared to uniform incorporation. Soil surface application to grassland results in particularly high PECfreshwater values. Conversely, application by deep placement results in PECfreshwater values consistently below 1 µg/L. High maximum PECfreshwater values are generally observed with runoff (R) scenarios, rather than drainage (D) scenarios[13], with the exception of calcium cyanamide applied to grassland in which a drainage scenario results in the very high PECfreshwater value. In the simulations reported by the Dosser Submitter the run-off (R) scenarios appear to result in the majority of the highest PECfreshwater values for cyanamide and drainage (D) scenarios and almost always result in PECfreshwater values for cyanamide well below the $PNEC_{aqua}$. The exception to this is when calcium cyanamide is used to fertilise grassland where surface water is at risk from drainage through soil. Deep placement of calcium cyanamide up to the recommended application rates of 250 kg/ha calcium cyanamide consistently results in PECfreshwater values for cyanamide of <1 µg/L.

The Dossier Submitter used FOCUSPEARL to model the $PEC_{ground\ water\ (gw)}$ for the transformation products of calcium cyanamide under reasonable worst-case conditions of use (recommended application rates and methods) as well as at application rates above the recommended levels.

[12] Assuming 300kg/ha use rate per hectare and taking the total amount of calcium cyanamide sold as a fertiliser (70 000 tonnes using the concentration of PERLKA).

[13] FOCUS has ten pre-set scenarios which are considered to be representative of geoclimatic conditions across the EU. There are six which simulate drainage of the test substance through soil to nearby surface water (D1 – D6) and four are surface runoff (R1 – R4) scenarios. Lower case 's' denotes stream variant and lower case 'd' denotes ditch variant.

This modelling covered additional crops, a broader range of application rates and also included cyanoguanidine, one of the transformation products of cyanamide. At recommended application rates, in its modelling the Dossier Submitter found concentrations of cyanoguanidine ranging between 1.377 – 13.802 µg/L. It's worth noting that the Dossier submitter used a generic conservative DT50 of 1000 days for this purpose.

The Dossier Submitter also carried out soil modelling to predict the soil concentrations of cyanamide, urea and cyanoguanidine. The Dossier Submitter has used a commonly used modelling approach for substances intentionally added to soil (Boesten et al. 1997) to estimate predicted environmental concentrations in soil (PEC_{soil}) values (mg/kg)[14]. The model assumes the test substance is applied uniformly down to a particular depth of soil. The results of the modelling from the Dossier Submitter indicate $PEC_{soil,twa}$ (cyanamide) concentrations are in the range of 2.2 to 20.3 mg/kg soil. The predicted concentrations of cyanamide decrease depending on application method, declining from soil surface application to application at progressively deeper depths and generally with decreasing application rates of calcium cyanamide. For urea and cyanoguanidine, the predicted soil concentrations appear to follow a similar pattern to that of cyanamide i.e. decrease with increasing application depths and decreasing application rates.

RAC conclusions:

RAC notes that the use of calcium cyanamide (as a substance on its own or in a mixture) as a fertiliser is clearly identified and described in the restriction report which provides a good basis for an exposure/emission assessment.

RAC concludes that the PEC values obtained by the Dosser Submitter for surface water and sediment are reliable because:

- Higher tiers 3 and 4 of FOCUS modelling based on reasonable and realistic worst-case scenarios, which collectively represent agricultural use in the EU was employed.
- Different ways of fertiliser application have been taken account and modelled
- Different applications and rates depending on the crop concerned were modelled.
- Beyond cyanamide, secondary transformation products of calcium cyanamide were modelled (urea, cyanoguanidine)

The method of application of calcium cyanamide as a fertiliser is an important factor in determining the concentrations of cyanamide occurring in surface water.

- Run off appears to be main cause of surface water exposure with cyanamide
- Vegetated buffer strips can significantly reduce the run-off of cyanamide, although in most cases the concentration in surface water remains above the $PNEC_{freshwater}$ value for, indicating a risk.

For urea and cyanoguanidine, secondary transformation products of calcium cyanamide:

- The method of application of calcium cyanamide as a fertiliser is an important factor in determining the concentrations of secondary transformation substances e.g. urea and cyanoguanidine occurring in adjacent surface water
- The $PEC_{freshwater}$ urea and cyanoguanidine are sometimes high when calcium cyanamide is applied to the soil surface to various crops at or above application rates recommended by the Registrant
- Uniform incorporation of calcium cyanamide as a fertiliser into the soil results in very low

[14] Commonly used for plant protection products.

$PEC_{freshwater}$ values for urea and cyanoguanidine.

- Run off appears to be main cause of surface water exposure with urea
- Run off and drainage appear to be main cause of surface water exposure with cyanoguanidine.

RAC also concludes that the PEC values obtained by the Dosser Submitter for groundwater are reliable because:

- FOCUSPEARL model was employed for reasonable worst-case scenarios (based upon recommended application rates and methods) as well as at application rates above the recommended levels.
- Modelling approach different crops and also included the secondary transformation product of calcium cyanamide the cyanoguanidine.

RAC also concludes that the PEC values obtained by the Dosser Submitter for the terrestrial environment are reliable because:

- The approach used as outlined in Boesten et al. (1997) is appropriate and assumes first order degradation kinetics following application of the parent substance to soil, and concentrations in soil are averaged over certain time periods following application.
- Estimate Predicted Environmental Concentration in soil (PECsoil) for calcium cyanamide, cyanamide, urea and dicyandiamide (DCD) in the following scenarios were according to current FOCUS guidance for different application rates and application methods.
- Low and high molar conversion of cyanamide to cyanogunidine and urea were modelled.
- Beyond cyanamide a secondary transformation product of calcium cyanamide was also modelled (cyanoguanidine).

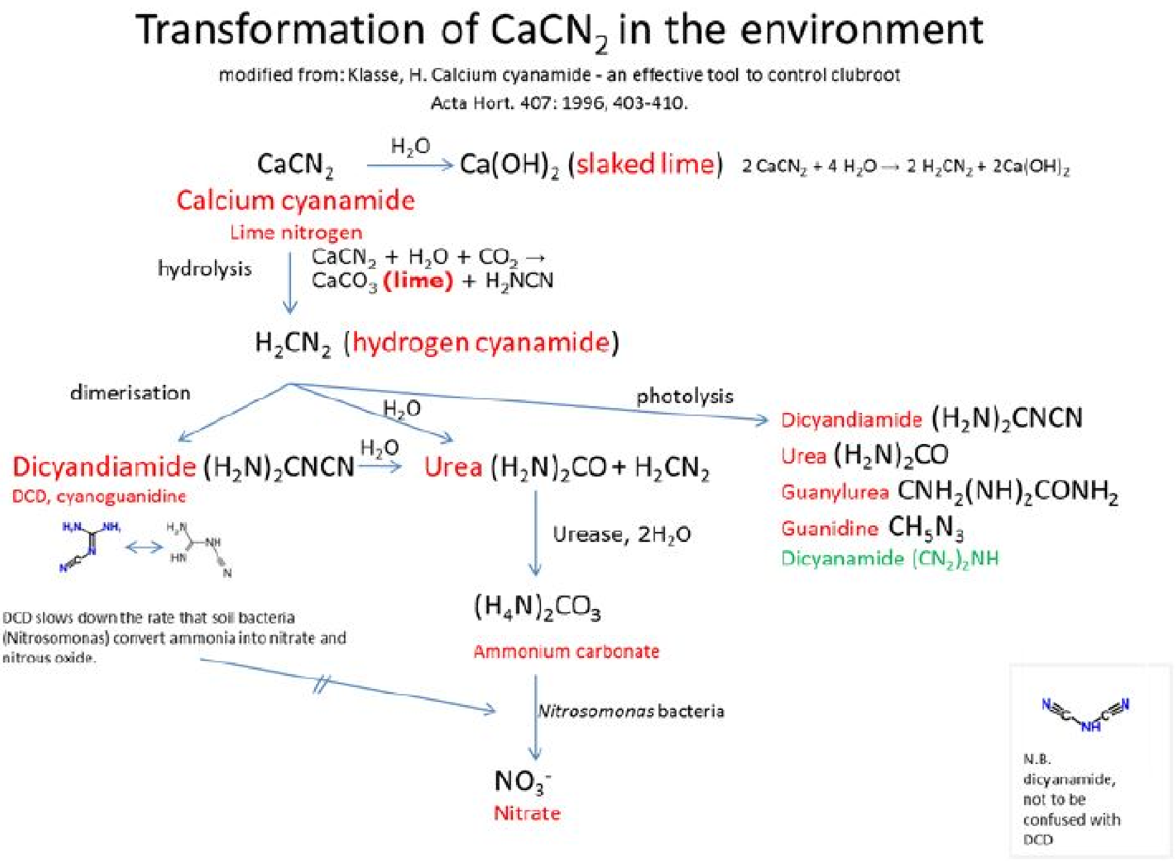
Key elements underpinning the RAC conclusions:

Due to the rapid hydrolysis of calcium cyanamide to cyanamide, predicted environmental concentrations (PECs) of cyanamide were derived from the exposure modelling. Exposure modelling was performed by the Dossier Submitter for surface water and sediment in respect to cyanamide, urea and cyanoguanidine, for ground water in respect to cyanamide and cyanoguanidine and finally for soil in respect to cyanamide, urea and cyanoguanidine. Valid and reliable monitoring data for either calcium cyanamide or cyanamide were not available.

<u>Fate and behaviour of the calcium cyanamide as commercial product (granular form) in the environment.</u>

The restriction proposal applies to calcium cyanamide as a fertiliser. Currently, a commercial formulation is marketed for this use. The fertiliser contains calcium cyanamide > 40% w/v, calcium dihydroxide of 13-15% w/v, graphite ≥11% w/v, Calcium nitrate tetrahydrate ≥10% w/v and calcium sulphate <3% w/v (AlzChem, 2019). The granular size is comprised in the range 0.8 – 3.5 mm diameter based on the technical data sheet of the product. In the RRD (2019) for calcium cyanamide (commercial product) mass median diameter was reported to be 2.142 mm.

Cyanamide, urea and cyanoguanidine are environmentally-relevant transformation products of calcium cyanamide and are considered throughout the proposal. The scheme below is representing the possible transformation routes of calcium cyanamide in the environment as presented in the SCHER (2016).



Soil water content plays a critical role on the hydrolysis of the calcium cyanamide to cyanamide. Soil moisture content close to the water holding capacity of the soil is preferred in order to achieve faster hydrolysis of the calcium cyanamide.

A half-life (DT_{50}) value in water for the fertiliser (calcium cyanamide, commercial product) was determined to be 1 day at 12ºC based on the release of cyanamide after continuous wash of the fertiliser granules with tap water (Becher & Winkler, 2018). The Dossier Submitter and the Registrant accepted the DT50 surface water value of 1d and have used it in their surface water exposure modelling.

For aerobic soil, the DT_{50} value was calculated to be 1.45 days at 12ºC by Güthner (2018). In the study the maximum amount of cyanamide was released after nearly 48 hours with 10% soil moisture and the resulting pH was strongly alkaline. The Dossier Submitter accepted the DT_{50} of 1.45 d for aerobic soil and has used it in its exposure modelling (Güthner, 2018). Additional, data were provided by the Registrant providing a range of DT50 values between 0.60 and 2.51 days for four soils, soil water content of 10% (50% of the Water Holding Capacity) and 5% (25% of the Water Holding Capacity), and 12ºC and 20ºC temperatures (Weinfurtner, 2019). The Registrant accepted a DT_{50} value for aerobic soil of 0.721d as provided in the RRD (2019) by Klein (2019), which was the geometric mean of all the normalised (temperature and moisture) half-lives as provided by Güthner (2018) and Weinfurtner (2019) study. This value was used in the exposure modelling for surface water and groundwater as the DT_{50} value for calcium cyanamide (commercial product) in aerobic soil by the Registrant. RAC acknowledge that the DT_{50} value used by the Registrant is based on the geometric mean of all the normalised (temperature and moisture) and thus provides a more robust DT50 estimation in comparison with the Dossier submitter selection.

Nevertheless, during the exposure modelling for the terrestrial environment the Registrant used a different DT_{50} than the one above (DT_{50}=0.721d) to describe degradation in aerobic soil. However, it's not clear if the DT_{50} value for aerobic soil used in the exposure modelling (ESCAPE 2.0) was 1.1 days by Klein, M. and Klein, J (2019) as mentioned in the latest update of the CSR or DT_{50}=0.74 days as reported in the latest update of the RRD (2020). Nevertheless, this discrepancy has no impact on risk characterisation as PEC_{soil} values reported by the Registrant (the outcome of the exposure modelling) are in close agreement with the ones reported by the Dossier Submitter ultimately leading to unacceptable risk to the terrestrial environment. This is also indicating that DT_{50} values are not particularly sensitive input parameters for FOCUS exposure modelling used by the Dossier submitter and the ESCAPE 2.0 soil exposure model used by the Registrant.

As noted in the diagram above calcium cyanamide hydrolyses in aqueous solution into cyanamide and calcium hydroxide. Hydrolysis data illustrated that at pH 1.2 and 5 cyanamide is quantitatively released from calcium cyanamide within a few minutes. Subsequent hydrolysis of cyanamide releases urea which is further transformed in soil, via ammonium carbonate, to nitrates which are used by crops as a nitrogen source (fertiliser effect). Also, as reported in Dixon (2017) cyanamide is then dimerises into cyanoguanidine (6-11%). Cyanoguanidine acts as nitrification inhibitor in soil. RAC notes that the process of dimerization of cyanamide released after the hydrolysis of calcium cyanamide to cyanoguanidine in not fully characterised and reported in the literature. In a study provided by the registrant, significant quantities of urea and DCD were present following the transformation of calcium cyanamide (commercial product) in soil (pH=5.3) in which up to 20% of recovered nitrogen was in the form of DCD (Weinfurtner, 2019).

RAC notes that as described above, some uncertainty exists on the formation of cyanoguanidine in the soil as a result of the calcium cyanamide hydrolysis to cyanamide and it respective dimerisation. Even though the process is not well characterised and reported in the literature it seems that the pH change caused by the calcium dihydroxide contained in calcium cyanamide commercial product and the calcium hydroxide produced during the hydrolysis in the pore water in vicinity of the calcium cyanamide granule could play an important role the dimerization of cyanamide to cyanoguanidine in soils.

In comparing the fate of cyanamide originating from the hydrolysis of calcium cyanamide in soils versus the fate of the pure cyanamide RAC evaluated the following evidence. Cyanamide tested as pure substance is relatively hydrolytically stable at 25 °C and pH values of 5, 7, and 9. At very low pH values cyanamide is hydrolysed to urea and eventually to carbon dioxide and ammonia (DT50=310 – 320 min at pH 0 and 25 °C, or DT50~77 min at pH ~1.5 and 85 °C (Höhne, 2019). In alkaline solution (pH 12.2-12.4), pure cyanamide was shown to dimerises to cyanoguanidine with an estimated half-live of 11.5 d at temperatures of 18-24 °C (Wildenauer, 2019; Höhne, 2019). RAC also notes that the concentration of cyanoguanidine formed was below 1 % of applied nitrogen in a study provided by the Registrant (Weinfurtner, 2019) by applying cyanamide in one soil (pH 5.3). During the cyanamide biocides assessment process under the Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, cyanoguanidine was detected at 14.5% of the applied active ingredient after 71 days in liquid manure (pH range for liquid manure is pH=8-12).

Transformation of cyanamide, urea and cyanoguanidine in the aquatic compartment

Cyanamide is considered to be a rapidly biodegradable substance in the aquatic compartment (RAC, 2015) and the same studies were used for this assessment. From a water sedimentation study a DT_{50} of 4.3 days at ~20ºC for cyanamide in freshwater was derived and was accepted by the Dossier submitter (Völkl, 2000) for surface water exposure modelling. The Registrant used a value of 3.5 days at 20ºC (EFSA, 2010) for surface water exposure modelling. The RAC also acknowledges that a reported DT_{50} from mesocosm studies cannot be used for risk assessment purposes, but notes that during the aquatic mesocosm study by Hommen (2019) the DT50 value of cyanamide ranged from 3.3d to 27.5d with increasing concentrations and the average DT50 was calculated to be 13.1 d. (15.1-23 ºC).Thus providing some supporting evidence of the half-life of cyanamide in the environment. For the sediment both the Dossier submitter and the Registrant used the default DT50 value as provided in FOCUS model, DT50=1000 days.

The estimated DT_{50} values (12°C) of **urea** were 14.2 days in the water phase and 15.2 days in the total pond system as well as 5.1 days in the water phase and 5.5 days in the total river system in BPR 2016. During the Cyanamide PPP assessment (2008-10) a mean DT50 value was derived for urea (river & pond) of 4.8 days at 20oC (Völkl, 2000). This DT_{50} urea (4.8 days at 20ºC) was chosen for exposure modelling by the Dossier Submitter. The DT_{50} derived with in the BPR (2016) and the PPP (2008-10) were similar. The Registrant did not consider urea as relevant for surface water exposure modelling.

Cyanoguanidine is formed when cyanamide is transformed in soil moisture (Güthner, 2018). Data presented in the Joint REACH registration for cyanoguanidine (RJRD cyanoguanidine, 2015) showed that in surface water/sediment systems cyanoguanidine is likely to be reasonably persistent and a DT_{50} value has been derived by the Dossier Submitter of >**28 days** at 22ºC. For the purpose of exposure modelling Dossier Submitter used the DT50 default conservative value from the FOCUS surface water modelling of 1000 days. The Registrant did not consider cyanoguanidine as relevant for surface water exposure modelling.

The transformation of cyanamide, urea and cyanoguanidine in aerobic soil

Half-life DT_{50} (aerobic soil) values for **cyanamide** were calculated to be in the range of 0.7 – 4.6 days, with a mean value of 2.65 days at 20ºC from laboratory soil simulation studies (Schmidt 1990 & 1991). Similar DT50 values, with a mean value of **2.9 days** at 12ºC were reported by a later study (Güthner, 2018) were cyanamide was firstly released from the fertiliser and then was subsequently degraded. In this study a standard soil for FOCUS scenario R2 was used. This value was used by the Dossier Submitter for exposure modelling. The Dossier Submitter accepted these results and noted that they were consistent with those accepted by BPR, 2016 and PPP 2008-10. RAC notes that this study by Güthner (2018) was considered as supporting information (Reliable with restrictions) by the Registrant as this was a non-guideline, not GLP study.

Results from another study by Weinfurtner (2019) provide DT_{50} values from four different soil types and two soil water content levels (25 and 50% of the Soil Water Holding Capacity). The study was not a GLP study and it was performed based on the OECD Guideline 307 (Aerobic and Anaerobic Transformation in Soil) with some deviations. (Microbial biomass of each soil was not determined, no soil pre-incubation was performed). Values of DT_{50} ranged from 0.42 to 1.21 days (20ºC). The experiments were performed with the fertiliser and after the release of the calcium cyanamide in the soil water, cyanamide was subsequently degraded. Part of this results are reported in the proposal with the reference to the Fraunhofer 2018a study. Additionally, the Registrant provided in the RRD for Calcium cyanamide the geometric mean of all experimental data (Güthner, 2018 and Weinfurtner, 2019) after normalisation to 20°C but without soil moisture normalisation. The estimation predicted slightly shorter half-lives for cyanamide of DT_{50} 0.78 at 20ºC and this value was used by the Registrant for exposure modelling (Klein, 2019).

The DT_{50} value of **urea** in aerobic soil of 5-10 days (at ~11 - 22ºC) is based on a study by Vilsmeier and Amberger (1978). The Dossier Submitter accepted these study results and a DT50 urea used by the Dossier Submitter was the mean value of **7.5 days** at ~16ºC. The Registrant did not consider urea as relevant for soil exposure modelling.

Complete degradation of **cyanoguanidine** was reported in the REACH registration dossier for cyanoguanidine (RJRD cyanoguanidine, 2017) to take between 3 days and 34 weeks depending upon temperature, soil moisture and soil type. A study performed a regression analysis on 16 measurements from four studies and resulted a half mean DT50 value of **72 days** at <10ºC +/- 14 days with 95% confidence limits of 43–102 d. (Kelliher et al, 2008). The Dossier Submitter has used this DT50 value in its risk assessment. The Registrant did not consider cyanoguanidine as relevant for soil exposure modelling.

Monitoring data

There are no conclusive environmental monitoring data available in the literature for calcium cyanamide or cyanamide. And thus, exposure assessment relies on modelling.

Exposure modelling of cyanamide, urea and cyanoguanidine in surface water and sediment

FOCUS Steps 3 and 4 modelling was used by both the Registrant and the Dossier Submitter to derive predicted environmental concentrations (PEC) of cyanamide and its transformation substances in surface water and sediment. FOCUS modelling is the recommended modelling approach in the EU to assess whether active substances in plant protection products (PPPs), directly applied to crops, meet the requirements of the PPP legislation.

The exposure modelling was considered to be as a reasonable worst case scenario:

• Reasonable because the modelling was carried out at application rates and application methods recommended by the Registrant and because FOCUS modelling has been configured to be representative of 10 (surface water modelling) geoclimatic conditions across the EU

• Worst case because: 1) the summary results shown are the highest predicted environmental concentrations in surface water ($PEC_{freshwater}$) observed for particular crop type/application rate combinations; and 2) the FOCUS model is configured so that for each of the 10 conditions, the worst case geoclimatic condition is applied to ensure the environment is protected e.g. each scenario assumes there is 10 mm of rainfall within 10 days of application to simulate run off before significant degradation/uptake of the applied substance occurs.

A comparison of the Dossier Submitter’s FOCUS modelling results with those of the Registrant indicated they are of similar magnitude. In the Dossier Submitter's simulations the run-off (R) scenarios (R1, R2, R3 and R4) appeared to result in the majority of the highest $PEC_{freshwater}$ cyanamide values. For the drainage (D) scenarios, high PEC values where recorded on in the case of the D2 scenario which is considered to be an extreme worst case drainage scenario characterised by impermeable clay with field drains which is seasonally waterlogged by water perched over impermeable massive clay substrate. $PEC_{freshwater}$ values for Dossier submitter ranged almost 0 to a maximum of 8603 µg/L of cyanamide. Registrants modelling results also identified also identified run-off (R) scenarios (R1, R2, R3 and R4) as the scenarios with the highest $PEC_{freshwater}$ and similarly the D2 drainage scenario also resulted in high $PEC_{freshwater}$ values. Additionally, the registrants modelling identified drainage D1 scenario as a contributed with high $PEC_{freshwater}$ value when the granular calcium cyanamide was applied to grassland without incorporation. $PEC_{freshwater}$ values for Registrant ranged between 0 to 401.4 µg/L of cyanamide.

Soil surface application of the fertiliser with application rates were ranging between 100-500 kg/ha and resulted in $PEC_{freshwater}$ values from almost 0 to a maximum of 15704 µg/L for **cyanamide** (run off and drainage scenarios). Applications rates of 300 kg/ha resulted $PEC_{freshwater}$ values ranging from almost 0 to 1948.6 µg/L for **urea** (run off scenarios). Also, $PEC_{freshwater}$ values for **urea** were between from almost 0 to 5813.3 µg/L and occurred always in the run off (R) scenarios when application as performed at the soil surface of calcium cyanamide at worst case application rates (700 kg/ha). Applications rates of 300 kg/ha resulted $PEC_{freshwater}$ values ranging from almost 0 to 1480.9 µg/L for **cyanoguanidine** (run off and drainage scenarios). At 700 kg/ha application rate, the $PEC_{freshwater}$ (cyanoguanidine) values range from 4451.5 µg/L also for soil surface application. The effect of the buffer strip was reduction of the $PEC_{freshwater}$ value ranging from 0% for the drainage scenarios and 66% for the runoff scenarios. It is noted that even with the 66% reduction of the $PEC_{freshwater}$ value this was exciting the respective $PNEC_{freshwater}$ value.

Uniform application of the fertiliser to a depth of 0 to 10 and 0 to 15 cm with application rates ranging 100-500 kg/ha resulted $PEC_{freshwater}$r maximum values of 126-2115 µg/L respectively for **cyanamide** (run off and drainage scenarios). Applications rates of 500 kg/ha and uniform application of the fertiliser to a depth of 0 to 10 resulted $PEC_{freshwater}$ values of almost 0 to 161.3 µg/L for **urea** (run off scenarios).

Applications rates of 500 kg/ha and uniform application of the fertiliser to a depth of 0 to 10 resulted $PEC_{freshwater}$ values of almost 0 to and 182.7 µg/L for **cyanoguanidine** (one run off scenario). At 700 kg/ha application rate, the $PEC_{freshwater}$ values range from almost 0 to 2516.6 µg/L for **cyanoguanidine**. The effect of the buffer strip was reduction of the $PEC_{freshwater}$ value ranging from 0% for the drainage scenarios and 66% for the runoff scenarios. It is noted that the 66% reduction of the $PEC_{freshwater}$ value resulted in a value below the respective $PEC_{freshwater}$ value.

Deep placement of the fertiliser to a depth 15 cm with application rates ranging 100-250 kg/ha resulted $PEC_{freshwater}$ values lower than 1 µg/L for cyanamide (run off and drainage scenarios).

PEC sediment (PEC_{sed}) values for **cyanamide** appeared to range from <1.0 to 31.5 µg/L. However, when the fertiliser was applied to grassland (soil surface) the predicted cyanamide levels in sediment increased to 375.5 µg/L. Deep placement resulted in very low PEC_{sed}

(cyanamide) values.

Exposure modelling of cyanamide and cyanoguanidine in groundwater

FOCUS PEARL modelling was used by both the Registrant and the Dossier Submitter to derive predicted environmental concentrations (PEC) of cyanamide and its transformation substances in groundwater. The maximum $PEC_{groundwater}$ values for **cyanamide** were in the range of 1-70 µg/L. Using a different crop resulted in significantly different values. Values lower than <0.1 µg/L were estimated for Potatoes and maize while values in the range of 1-70 µg/L were estimated for apples and vegetable beans. The method of application is an important factor in determining the concentrations of cyanamide occurring in groundwater. At recommended application rates (300-500 kg/ha), concentrations of **cyanoguanidine** ranged between 1377 – 13802 µg/L. The concentrations increased when using application rates above the recommended levels. The results are as expected from a substance such as cyanoguanidine which is considered to be reasonably mobile in soil and is persistent.

Exposure modelling of cyanamide and cyanoguanidine in the terrestrial compartment

The modelling approach by Boesten et. al., 1997 and the modelling tool ESCAPE v.2 was used by the Dossier Submitter and the Registrant respectively derive predicted environmental concentrations (PEC) of cyanamide and its transformation substances in the soil environment.

Dossier submitter's results of the soil exposure modelling indicated that PECtwa (28d) concentrations for cyanamide were in the range of 2.2 to 20.3 mg/kg soil, for urea in the range of 11.4 to 92 mg/kg soil and for cyanoguanidine in the range of 0.81 to 6.26 mg/kg soil. PECtwa (28d) concentrations for all three substances appeared to be increasing with depth of the fertiliser application (surface application uniform incorporation 7.5 cm and uniform incorporation to 15 cm). The application rates used for the soil exposure modelling were 150, 300 and 500 kg/ha of the fertilising product. The conversion rates as reported for cyanamide during the Biocides approval process (2016) and by Dixon (2017) have been utilised in the soil exposure modelling. In order to take into account of the uncertainty in the molar conversion fraction for urea and cyanoguanidine both a low conversion to urea (molar conversion of 0.094 for urea and 0.05 for cyanoguanidine) and a high conversion to urea (molar conversion of 0.957 for urea and 0.0425 for cyanoguanidine) were considered in the calculations by the Dossier Submitter. The Dossier Submitter also included degradation, leaching and volatilisation of cyanamide during the exposure modelling. RAC notes that the data showed no difference between the low and high molar conversion approach of soil modelling.

Registrant's results of the soil exposure modelling were in a similar range with the Dossier's submitter's results. The PECtwa (28d) concentrations for cyanamide were in the range of 1.8 to 11.9 mg/kg soil. Registrant also provided exposure modelling results by employing the exposure approach of Dossier submitter (Boesten et.al., 1997) and by employing the DT50 values as mentioned in it's own modelling approach. The data were provided during the consultation and the PECtwa (28d) concentrations for cyanamide were in the range of 1.5 to 9.9 mg/kg soil.

Characterisation of risks

Summary of proposal:

The use of calcium cyanamide as a fertiliser (using application rates/methods recommended by the Registrant) leads to a risk that is not adequately controlled for both surface water adjacent to fertilised fields (the highest Risk Characterisation Ratios (RCRs) calculated were between approximately 2 to 494 under reasonable worst-case assumptions) and to soil (the highest RCRs calculated were between approximately 3 to 135 under reasonable worst-case assumptions) (as calculated by the Dossier Submitter). The risk is primarily due to the effects of cyanamide, one of the first transformation products of calcium cyanamide, but also in some scenarios and to a lesser degree, the secondary transformation products of calcium cyanamide, namely urea and cyanoguanidine. The risks are primarily to aquatic and soil macro organisms (cyanamide), aquatic microorganisms (urea)[15] and soil microorganisms (cyanoguanidine)[16].

Cyanamide and cyanoguanidine pose a risk to groundwater that is not adequately controlled when calcium cyanamide is used to fertilise apple crops (if the results are compared to the threshold value of 0.1 µg/L, which is the concentration limit set for individual active substances in pesticides, including their relevant metabolites, degradation and reaction products in the EU Groundwater Directive and in the EU Drinking Water Quality Directive).

However, because calcium cyanamide is not being used as a pesticide in this context, using the WHO approach and the DNEL (oral, cyanamide) for the general population (the calculated drinking water limit value for the general population is 510 µg/L), cyanamide does not exceed this limit value in the scenarios modelled. On this basis the presence of cyanamide does not appear to pose a concern for drinking water quality. Nevertheless, the recent conclusion by the Biocidal Product Committee (BPC) in December 2019 that cyanamide is an endocrine disruptor for human health and non-target organisms has implications for the migration of cyanamide to groundwater i.e. contamination of groundwater and potentially leading to contamination of drinking water and therefore may also have implications on the risk to aquatic and terrestrial organisms.

RAC conclusions:

RAC agrees in line with the Dossier Submitter that the use of calcium cyanamide as a fertiliser leads to a risk that is not adequately controlled for both surface water adjacent to fertilised fields and to soil (Table 3). The application rate and application method appear to be important determinants for the risk. RAC notes that risk is associated with primary degradation product of the calcium cyanamide, cyanamide for aquatic organisms and soil macro organisms. Additionally, risk was not adequately controlled for one of the secondary transformation products, cyanoguanidine for aquatic organisms and soil microorganisms. RAC does not support the hazard assessment as performed by the Dossier submitter in respect to urea, a secondary transformation product of calcium cyanamide. The proposed $PNEC_{freshwater}$ value for urea was considered not reliable for risk assessment purposes. Thus, the risk characterisation as proposed by the Dossier Submitter for urea is not supported. Additionally, RAC does not support the risk characterisation for cyanamide in the sediment compartment due the discrepancy between the relevant PNEC and PEC values in

[15] At typical application rates of calcium cyanamide applied one crop (potatoes), urea was found to pose an uncontrolled risk to aquatic microorganisms.
[16] At various application rates and methods of calcium cyanamide, cyanoguanidine was found to consistently pose an uncontrolled risk to soil microorganisms.

respect to their units. The derived PNEC value was reported in µg/ml while the respective PEC values are reported in µg/Kg of dry weight sediment.

Table 3: Risk characterisation summary as supported by RAC.

Environmental compartment	Cyanamide	Urea	Cyanoguanidine
Surface water	Risk is not adequately controlled	**-not supported by RAC**	Risk is not adequately controlled
Sediment	**-not supported by RAC**	not assessed	not assessed
Ground water	Risk is adequately controlled	not assessed	Risk is adequately controlled
Soil	Risk is not adequately controlled	not assessed	Risk is not adequately controlled

RAC notes the recent evaluation of the EDC potential of cyanamide in respect to the human health and environmental properties and agrees that this might have implications on the risk to aquatic and terrestrial organisms. However, human health endpoints are not in the scope of this proposal.

Key elements underpinning the RAC conclusions:

Risk characterisation ratios for the surface water as performed by the Dossier submitter showed that under different modelling scenarios risk is not adequately controlled. Surface water adjacent to fields fertilised with calcium cyanamide were at most risk from cyanamide through run off. This was the case for the runoff stream scenarios (R1, R2, R3 and R4) for different crops (Winter oilseed rape, Potatoes, Maize and Leafy vegetables) and application rates (100-500 kg/ha). Implementing RMM's (vegetated buffer zones) resulted risk reduction (RCR<1) for one occasion (R3,s, Winter oilseed rape, 200 kg/ha). Risk from drainage through soil (D2 ditch scenario) was identified for Grassland and Winter Oilseed Rape fertilised fields. RAC notes that D2 scenario is a scenario which is considered extreme worst case drainage scenario characterised by impermeable clay with field drains which is seasonally waterlogged by water perched over impermeable massive clay substrate. For cyanamide, out of the 271 scenarios modelled by the Dossier submitter 62 scenarios resulted in RCR> 1 and ranged between 1 and 1504 (Table 3). Similarly, runoff stream scenarios (R1, R2, R3 and R4) and drainage ditch scenarios for different crops (Winter oilseed rape, Potatoes, Maize, Vegetables and grasslands) and application rates (60-500 kg/ha) showed unacceptable risk. In the case of the Registrant out of the 263 scenarios modelled 32 scenarios resulted in RCR> 1 and ranged between 1 and 43.

In respect to the secondary transformation products of the calcium cyanamide risk to the surface water was identified only for Cyanoguanidine for a runoff (R3, stream Potatoes, 700kg/ha) and a drainage scenario (D5, pond, Apple, 700kg/ha). Out of the 45 scenarios modelled by the Dossier submitter 6 scenarios resulted in RCR> 1 and ranged between 1 and 1,8 (Table 3). For urea risk characterisation as proposed by the Dossier submitter was considered to be not reliable by RAC. This is due to uncertainties in relation to the $PNEC_{freshwater}$ derivation as described above. Briefly, RAC did not agree with the Dossier submitter on the use of the Bringmann, G. & Kuhn, R. study (1978) as point of departure for PNEC freshwater for Urea ($PNEC_{freshwater}$=0.47mg/L) as it is well documented in the literature that *Microcystis aeruginosa* use urea as nitrogen and carbon source in concentrations well above the 47 mg/L (Huang.W., et al, 2014). Risk characterisation for sediment showed that risk was not adequately controlled only when the D2 scenario was employed for cyanamide.

Risk characterisation for groundwater was performed on the basis of human health risk assessment even though this was outside the scope of this restriction proposal. No risk was identified for human health via the groundwater exposure (drinking) by applying the Dossier submitter approach based on the WHO methodology on derivation of Guideline values (GC). Results of the exposure modelling were well below the Guideline value derived. When $PEC_{groundwater}$ values were compared with the 0.1 µg/L value, which is the concentration limit set for individual active substances in pesticides, including their relevant metabolites, degradation and reaction products in the EU Groundwater Directive and in the EU Drinking Water Quality Directive), risk to human health is identified for cyanamide and Cyanoguanidine (Table 3).

Risk was identified to the terrestrial compartment for Cyanamide and Cyanoguanidine for all the 9 scenarios modelled (3 application rates and 3 application methods). Risk characterisation ratios varied based on the application method and rate but were always greater than 1. For cyanamide the RCR ranged from 14.7 (Uniform incorporation to 15 cm, 150 kg/ha) to 135.3 (Surface application, 500 kg/ha) and for Cyanoguanidine from 3.2 (Uniform incorporation to 15 cm, 150 kg/ha) to 25.4 (Surface application, 500 kg/ha) (Table 4). RAC notes that RCR's were also calculated based on the Registrants exposure modelling results provided during the consultation were identical to the RCR's reported by the Dossier submitter.

Table 4: Summary of Risk Characterisation Ratios (derived by the DS) as supported by RAC.

	Cyanamide	Cyanoguanidine
Surface water	1-1504 Total modelling scenarios= 271 Scenarios with RCR>1= 62 (23%)	1-1.8 Total modelling scenarios (worst case, Soil surface application at 700Kg/ha) = 45 Scenarios with RCR>1= 6 (13%)
Ground water (WHO methodology)	< 1 for all 56 scenarios modelled	not assessed
Ground water (0.1µg/L based on Groundwater Directive and EU Drinking Water Quality Directive)	1 - 701 Total modelling scenarios= 56 Scenarios with RCR>1= 56 (100%)	23151-138022 Total modelling scenarios= 56 Scenarios with RCR>1= 18 (32%)
Soil	14.7-135.3 Total modelling scenarios= 9 Scenarios with RCR>1= 9 (100%)	3.2-25.4 Total modelling scenarios= 9 Scenarios with RCR>1= 9 (100%)

RAC notes that the Dossier Submitter also performed a sensitivity analysis exploring the significance of the size of the assessment factor used to derive the relevant PNEC value in order to assess the uncertainty in respect to the applicable regulatory framework for this substance. Assessments under the PPP legislation typically use smaller assessment factors when deriving a PNEC than those outlined in the REACH Guidance (see Annex B.10.4. of the BD) for surface water and soil. For surface water the PPP risk characterisation results are identical to those derived from an assessment under REACH due to the use of an identical assessment factor. For soil, the risk characterisation values calculated using a typical PPP assessment factor were lower than those calculated using the REACH assessment factor, but remained significantly above the threshold value of 1. Either approach lead to the same outcome in regards to the risk characterisation.

<u>Uncertainties in the risk characterisation</u>

Uncertainties were identified in assessing the environmental risk of calcium cyanamide and they are described below:

a) There is very little monitoring data available for calcium cyanamide or its transformation products in the environment. As a result, the Dossier Submitter's risk assessment is based upon exposure modelling. This approach has also been used by the Registrant and in previous regulatory assessments e.g. for cyanamide; Exposure modelling has intrinsic uncertainty due to the need for parameterisation of the model environment and the uncertainty that input data have. RAC notes that uncertainty in exposure modelling cannot be avoided but the use of appropriate models and input parameters in this proposal minimises the uncertainty.

b) In the soil exposure modelling there is some uncertainty about the molar conversion rate of calcium cyanamide to urea and cyanoguanidine. The conversion rates according as reported for cyanamide during the biocide assessment process proves (2016) and by Dixon (2017) have been utilised. In order to take into account of the uncertainty in the molar conversion fraction for urea and DCD both a low conversion to urea (molar conversion of 0.094 for urea and 0.05 for DCD) and a high conversion to urea (molar conversion of 0.957 for urea and 0.0425 for DCD) are considered in the calculations. However as noted during the exposure assessment this source of uncertainty is likely to be insignificant considering the low level of expected dimerization of the cyanamide to cyanoguanidine in soils and also the fact that little is known about the processes that underlies such dimerisation in soils.

c) During the surface water exposure modelling for cyanoguanidine a worst case scenario with an application rate of 700 kg/ha was modelled and based on the predicted $PEC_{freshwater}$ a conclusion was drawn based on RCR's > 1 that risk from the presence of cyanoguanidine is not adequately controlled. The other two scenarios included application rates of 500 kg/ha (reasonable worst case scenario) and 300 kg/ha (recommended application rate). These two scenarios calculated PECfreshwater values for cyanoguanidine below the respective $PNEC_{freshwater}$ value (2.5 mg/L). Dossier submitter notes that during the preparation of the preliminary report leading to the restriction proposal Dossier submitter received a report of application rates recommended locally well above 500kg/ha. This is indicating a probable source of uncertainty in relation to the application rates used in agriculture versus the recommended application rates by the Registrant. If the worst case scenario with an application rate of 700 kg/ha is an extreme scenario (based in the current use patterns of the fertiliser) then the risk of cyanoguanidine to the surface water might be overestimated.

d) Some minor uncertainty exists on the different DT50 values selection for calcium cyanamide and cyanamide by the Dossier submitter and the Registrant for surface water, groundwater and soil. RAC notes that for DT5O parameters in FOCUS modelling are not particularly sensitive input parameters. This is the case particularly for the ditch and stream water bodies during the surface water exposure modelling, which are also the water bodies identified as most vulnerable in this assessment based on both the Dossier Submitter and Registrants modelling. Also, this is reflected during the ground water modelling were the DT50 as process parameters and not system parameters have little impact to the groundwater PEC's. Similarly, in the terrestrial exposure modelling DT50 differences do not have significant impact on the predicted PEC's and is reflected by the similarity of the PEC's reported by the Dossier submitter and the Registrant.

Evidence if the risk management measures and operational conditions implemented and recommended by the manufacturer and/or importers are not sufficient to control the risk

Summary of proposal:

In its 27 June 2019 registration dossier, the Registrant has indicated in an annex of the CSR whether the risk is adequately controlled. The results of an additional sensitivity analysis show that using the PPP approach to PNEC derivation still leads to the conclusion that risks to surface water and soil are not adequately controlled. For soil the risk characterisation[17] results are lower than those under REACH, but remain significantly above the threshold value of 1.

RAC conclusions:

RAC agrees that the risk posed to the environment is sufficiently described for the purpose of the restriction proposal. RAC notes that risk management measures (RMMs) modelled and presented in the proposal (vegetated buffer strips) were mostly insufficient to reduce the risk to adjacent surface water. Similarly, if calcium cyanamide is continued to be used it will pose a clear risk to beneficial soil macro organisms.

Key elements underpinning the RAC conclusions:

Dossier Submitter's risk assessment is based on exposure modelling since no monitoring data are available either for calcium cyanamide or its transformation products.

Sensitivity analysis performed by the Dossier Submitter show that PNEC values derived either with the PPP approach or the REACH guidance show that risk is present when using calcium cyanamide as fertiliser.

Implementing risk management measures (vegetated buffer zones) as modelled in this proposal, resulted risk reduction (RCR<1) for only one occasion (R3,s, Winter oilseed rape, 200 kg/ha) out of the 12 scenarios that showed RCR's > 1 without the implementation of the vegetated buffer zones.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

An analysis of different risk management options (RMOs) to identify the most appropriate option to address this risk, and to define its scope and conditions was examined in the Background Document.

As a first step, the possibility to address the risks to environment from the use of calcium cyanamide as a fertiliser under other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined. However, these were assessed to be inappropriate to address all potential risks. Therefore, the possibility to impose a restriction under REACH was investigated further.

Several potential restriction options (RO) that could be used to manage the risk to the environment were considered. They could be used alone or in a combination. The potential measures varied according to their endpoint, efficacy and cost efficiency, and therefore this directly affected the suitability and acceptability of the potential restriction.

The RO options have been assessed against the main criteria for restriction: effectiveness, practicality and monitorability. As a result of this assessment, a total ban on the placing on the market and use of calcium cyanamide as a fertiliser (as a substance on its own or in a mixture) was proposed and the other RO were rejected. The risk reduction capacity (effectiveness) of other RO was found to be limited i.e. they would not address or remove the

[17] For surface water the input data are the same as in the Dossier Submitter's RCR, hence the results are identical.

risk that was not adequately controlled or their application would be too complex and challenging to design, implement and enforce in practice.

The Dossier Submitter has identified that only a restriction on the placing on the market and use of calcium cyanamide as a fertilizer can adequately control the risks in both the aquatic and terrestrial environments. Other restriction options considered would not adequately control risks in both the aquatic and terrestrial compartments.

RAC conclusions:

RAC notes that two restriction options, RO2 (Detailed regulation of acceptable agricultural production methods) and RO4 (Total ban of CaCN2 use) were discussed in the dossier as the other two available options (RO1- Ban of powder form and RO3- Utilisation of existing CAP measures) would not address the risk that was not adequately controlled. RAC considers that both of those ROs appear to be effective in reducing surface water risk, however, in case of soil organisms the RO2 cannot fully remove the risk. As a result, RAC agrees with the Dosser Submitter that only a restriction on placing on the market and use of calcium cyanamide (RO4) as a fertiliser (as a substance on its own or in a mixture) can fully address the identified risk. The proposed restriction appears to be effective, practical and monitorable.

Key elements underpinning the RAC conclusions:

Risk management options examined in the proposal beyond the restriction of placing the fertiliser in the market showed to be either difficult to enforce, not practical and difficult to monitor. Restriction on placing on the market of the calcium cyanamide as a fertiliser in powder form (RO1) had little if any risk reduction potential as the powder form of the fertiliser is not marketed since December 2017 as reported by the Dossier submitter. RO2 was introducing detailed regulation of acceptable agricultural production methods which based on the Dossier submitter showed medium to low potential of risk reduction on some waterways but no risk reduction on terrestrial/soil risk. RAC notes that some risk reduction could be attained in the terrestrial/soil environment by employing good agricultural practices. RO2 would require different measures per crop, field and location and this might be particularly complex and challenging in respect to the implementation and enforcement of the proposed restriction. RO3 was proposing the utilisation of existing CAP measures but appeared either not fit to the criteria of effectiveness, practicality and monitorability and/or do not fully remove the risk. Lastly, RO4 considered the total ban of calcium cyanamide use which result in a pronounced risk reduction for both the surface water and the terrestrial environment.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter has concluded that action is required on a Union-wide level due to several reasons. First, Calcium cyanamide (PERLKA®) benefits from free circulation in the EU Single Market and is sold in several EU Member States. Secondly, decisions and regulation concerning fertilisers made in one country may well affect the environment in other Member States. Furthermore, as the EU agricultural sector is largely managed through the Common Agricultural Policy (CAP), the legislation affecting the ways and means of production needs to take this into account. Based on this, the Dossier Submitter emphasises that separate, national policies could result in a distortion of the internal market and potentially unfair market competition, and therefore any legislation to regulate fertiliser use for the protection of the environment needs to be assessed at the Union level.

SEAC and RAC conclusions:

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with use of Calcium cyanamide as a fertiliser should be implemented in all MS.

Key elements underpinning the SEAC and RAC conclusions:

As mentioned above calcium cyanamide is a fertiliser benefiting from free movement in internal market as described in the EU Fertilizing Products Regulation (2019). Furthermore, its uses and the risks associated are largely uniform across the agricultural sector within the EU.

JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

Scope

Justification for the opinion of RAC

Summary of proposal:

The proposed scope of the restriction aims at preventing the placing on the market and use of calcium cyanamide as a fertiliser (as a substance on its own or in a mixture).

Based on the Dossier Submitter analysis, the proposed restriction is the only EU-wide measure that would fully remove the identified risk associated with the use of calcium cyanamide as a fertiliser. An alternative restriction option RO4 proposed (ban on placing on the market and use) consisting of specific limitations on agricultural production methods and techniques was discarded by the Dossier Submitter as it would only address a part of the risk and it would be challenging to set in practise.

RAC conclusions:

RAC agrees that both RO2 and RO4 have their merits – RO2 causes complex regulation and expensive implementation, whereas RO4 is simpler, easier to implement and fully controls the identified risk. RAC concludes in line with the Dossier submitter that the restriction on placing on the market and the restriction if the use of the calcium cyanamide as fertiliser is the most appropriate measure for risk reduction within the scope of the proposal.

Key elements underpinning the RAC conclusions:

Based on the Dossier submitter's proposal, the restriction on placing on the market and use of Calcium cyanamide as a fertilizer (as a substance on its own or in a mixture) is able to fully eliminate the risk that the parent molecule and its transformation products pose to the environment, namely to surface water and soil environment.

Justification for the opinion of SEAC

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter estimates that a total emissions reduction of calcium cyanamide to aquatic and terrestrial compartments could be obtained through this Annex XV restriction. The proposed restriction will address environmental risks to surface water and to soil.

The restriction, although designed to address risks for the environment, has co-benefits for human health as potential impacts on humans via the environment and professional workers are also reduced.

RAC conclusions:

RAC agrees that the proposed restriction will be highly effective in reducing the risks posed to the environment, namely surface water and soil. Total ban of the fertilising product from the market and thus eliminating its use will ultimately eliminate the risk that the substance poses as identified in the proposal.

Key elements underpinning the RAC conclusions:

Removing the product from the market is the most effective way to eliminate risk associated with the calcium cyanamide. A cessation of a usage of calcium cyanamide as fertiliser, should result in practically immediate risk elimination.

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Benefits

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Other impacts

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Overall proportionality

Summary of proposal:

The following sections demonstrate that the proposed restriction may in principle be a sound regulatory action by assessing its affordability and cost-effectiveness. However, the result in practice remains unclear. On the cost side the analysis is mainly concerned with the productivity losses incurred by the end users (farmers) as those appear to be the largest cost element.

Based on the assessment presented above, the proportionality appears to be difficult to demonstrate quantitatively in practice as farmer's response is not known and the environmental net impacts of the proposed restriction are not easily quantifiable. This is because the use of any (combination of) alternatives imply their own environmental impacts. Looking only on the costs involved, the productivity losses per hectare induced by the restriction appear to be relatively high. The recent finding, that calcium cyanamide may be an endocrine disruptor would, if agreed, increase the expected benefits. This makes the proportionality assessment more robust and improves the proportionality of the proposed restriction.

RAC and SEAC conclusions:

RAC proposed a transition period of 36 months for the use of the fertilising product and a transition period of 24 months for placing on the market. RAC considers this arrangement adequate in order to allow farmers and practitioners to move to new fertilising products, application methods and crops if appropriate but reduce the likelihood that stocks of calcium cyanamide will be used beyond the transitional period for use of 36 months.

Key elements underpinning the RAC and SEAC conclusions:

The restriction as described in the proposal targets environmental endpoints and can be enforced thought the EU in a consistent way reducing risk to the environment. The availability of alternatives in terms of fertilising products, knowledge, technology and machinery supports the proportionality of this restriction.

Uncertainties in the proportionality section

The main uncertainty regarding the proportionality of this restriction arises from the assessment of the available alternative fertilising products in comparison with the calcium cyanamide as a fertiliser and additionally as a fertiliser that has some secondary effects (herbicidal and phytotoxic effects, fungicidal and fungistatic effects, molluscicidal effects, and insecticidal effects, avoidance effects on wireworms and effects on endo-parasites of grazing animals). Even though these secondary effects are deemed significant from a farmer's point of view, the mode of action for each one of these effects is not known and to a large extent these secondary effects can be associated with the presence of the calcium and calcium dihydroxide as part of the commercial product. Therefore, even though some degree of uncertainty exists in respect to the calcium cyanamide alternative this is likely to be insignificant within the proportionality context.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter maintains that the proposed restriction is implementable and enforceable. It will directly affect one manufacturer (and its supply chain) and indirectly a large number of farmers. However, because the restriction addresses the placing on the market and use, and there are no monitorability or enforcement concerns at the end-user level, the enforcement is considered to be reasonably straight forward.

RAC and SEAC conclusions:

RAC agrees with the Dossier Submitter that the restriction is implementable and enforceable. RAC notes implementation and enforceability of the restriction might be challenged were there are instances of use of stock calcium cyanamide by farmers beyond the transition period. Therefore, RAC proposes a shorter transitional period for placing on the market to increase the likelihood that all stocks will be consumed 36 months after entry into force.

Key elements underpinning the RAC and SEAC conclusions:

As noted by the Dossier Submitter the restriction addresses the placing on the market and use, and there are no monitorability or enforcement concerns at the end-user level, the enforcement is considered to be reasonably straight forward. This reflected clearly in the Forum's advice.

Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

It is expected that the monitoring and enforcement of placing on the market will be carried out by REACH inspections in the usual manner.

RAC and SEAC conclusions:

RAC agrees that the restriction can be monitored. However, RAC notes that there might instances of use of stock calcium cyanamide by farmers beyond the transition period and this can only be identified through MS comprehensive enforcement and monitorability.

Key elements underpinning the RAC and SEAC conclusions:

Forum also notes that there is no necessity of specific sampling and preparation methods and therefore there is no need for special consideration regarding the feasibility of market inspections and inspector training. Additionally, the restriction eliminates the need for analytical method for detecting calcium cyanamide.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

The main uncertainties in the dossier are listed below:

a) There is very little monitoring data available for calcium cyanamide or its transformation products in the environment, or in human biomonitoring.
b) There is uncertainty related to the possible exposure of birds, small mammals and bees to cyanamide when calcium cyanamide is used as a fertiliser.
c) In the soil exposure modelling there is some uncertainty about the molar conversion rate of calcium cyanamide to urea and cyanoguinidine.

RAC conclusions:

RAC agrees that uncertainties exist in the restriction proposal especially in respect to the exposure assessment but considers them to have no significant impact on the risk assessment of the use of calcium cyanamide as a fertiliser as descripted in the Dossier Submitter proposal and evaluated here.

Key elements underpinning the RAC conclusions:

They main areas where uncertainty lies within the proposal would be the absence of monitoring data and the subsequent use of exposure modelling. However, their significance in the restriction outcome is sought to be small. The main evaluation uncertainties as identified during this process were:

a) The degradation pathway of cyanamide, the first transformation product of the calcium cyanamide is yet to be elucidated. Dimerisation of cyanamide to cyanoguanidine in soils, even though was reported in the literature, still exact conditions and degradation rates are unknown.

b) Absence of relevant scientific literature and testing on the fertilisers secondary effects as supported by the Registrant introduced some uncertainty evaluation of alternatives within the context of this proposal.

c) There is very little monitoring data available for calcium cyanamide or its transformation products in the environment, or in human biomonitoring. As fertiliser that is in use for a long time such data would have been crucial in addressing risk from the its use, fate and behaviour in the environment. RAC notes that this uncertainty does not affect the proposed restriction as the exposure modelling was performed with relevant and validated modelling tools.

d) There is some uncertainty related to the possible exposure of birds, small mammals and bees to cyanamide when calcium cyanamide is used as a fertiliser. RAC notes that this uncertainty does not affect the proposed restriction.

e) The uncertainty regarding the proportionality of this restriction arises from the assessment of the available alternative fertilising products in comparison with the calcium cyanamide as a fertiliser and additionally as a fertiliser that has some alleged secondary effects.

f) The conversion rates as reported for cyanamide during the Biocides approval (2016) and by Dixon (2017) have been utilised in the soil exposure modelling. In order to take into account of the uncertainty in the molar conversion fraction for urea and cyanoguanidine both a low conversion to urea (molar conversion of 0.094 for urea and 0.05 for cyanoguanidine) and a high conversion to urea (molar conversion of 0.957 for urea and 0.0425 for cyanoguanidine) were considered in the calculations by the Dossier submitter. The Dossier submitter also included degradation, leaching and volatilisation of cyanamide during the exposure modelling. RAC noted that data showed no difference between the low and high molar conversion approach of soil modelling. As noted during the exposure assessment this source of uncertainty is likely to be insignificant considering the low level of expected dimerization of the cyanamide to cyanoguanidine in soils and also the fact that little I known about the processes that underlies such dimerisation in soils. RAC also notes that this uncertainty does not affect the proposed restriction as the restriction is based primarily on the uncontrolled risk associated with cyanamide to surface water and soil environment.

g) If the worst case scenario with an application rate of 700 kg/ha is an extreme scenario (based on the current use patterns of the fertiliser) then the risk of cyanoguanidine to the surface water might be overestimated. RAC notes that this uncertainty does not affect the proposed restriction as the restriction is based primarily on the uncontrolled risk associated with cyanamide to surface water and soil environment.

h) A small degree of uncertainty exists on the different DT_{50} values selection for calcium cyanamide and cyanamide by the Dossier submitter and the Registrant for surface water, groundwater and soil. However, this uncertainty has insignificant impact on PEC calculation and thus on risk characterisation.

SEAC

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

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GLOSSARY

a.s.	Active substance
BPR	Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.
BPC	ECHA's Biocidal Products Committee
bw	Body weight
$CaCN_2$	Calcium cyanamide
CAS	Chemical Abstract Services
CAP	Common Agricultural Policy, EU
Cyanoguanidine	dicyandiamide
d	Day
dw	Dry weight
ECHA	European Chemicals Agency
EU	European Union
FOCUS	Forum for the coordination of pesticide models and their use
GLP	Good Laboratory Practice
h	Hour
ha	Hectare
EC10 or EC50	The concentration at which 10% (or 50%) effect was observed or derived statistically when compared to the control group.
ETO-RAC	Ecological Threshold Option - Regulatory Acceptable Concentrations
ERO-RAC	Ecological Recovery Option- Regulatory Acceptable Concentrations
NOEC	No Observed Effect Concentration
NOEAEC	No Observed Ecologically Adverse Effect Concentration
PEC	Predicted Environmental Concentration
PEC_{twa}	Time Weighted Average Predicted Environmental Concentration
PNEC	Predicted No Effect Concentrations
PPP	Plant Protection Product
PPP Regulation	Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market
RAC	ECHA's Committee for Risk Assessment
RCR	Risk Characterisation Ratio
REACH Regulation	Regulation (EC) No 1907/2006 on registration, evaluation and authorisation of chemicals
RRD	REACH registration dossier
RJRD	REACH joint registration dossier
SCHER	Scientific Committee on Health and Environmental Risks
SRF	Slow release fertiliser
ww	Wet weight