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/RES-O-0000006907-62-01/F

Agreed

17 September 2020[1]

[1] Minor editorials were done for clarity on 12 Nov 2021.

11 June 2020

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

17 September 2020

RES-O-0000006907-62-01/F

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 supporting document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitter's proposal amended for further information obtained during the 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

Rapporteurs, appointed by SEAC: ***Lars Fock and John Joyce***

(in sequence)

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 **17 September 2020**.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

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

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1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Substance	Conditions of the restriction
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[2]; 3. The restriction shall apply after dd/mm/yyyy[3].

1.1. 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:

Substances	Conditions of the restriction
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[4]. 4. Paragraph 2 shall apply after dd/mm/yyyy[5].

[2] The Dossier Submitter originally proposed to derogate the use of calcium cyanamide as a fertiliser in closed agricultural systems where the use would not result in emissions to the environment from the restriction. However, as no support for such a derogation was received in the consultation on the proposal, and the enforcement of the derogation was considered to be potentially problematic by the Forum, the Dossier Submitter has withdrawn the proposed derogation.

[3] 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 facilitate an orderly substitution.

[4] RAC supports a 24-month transition period for placing calcium cyanamide on the market for use as a fertiliser.

[5] RAC supports a 36-month transition period for the use of calcium cyanamide as a fertiliser. This period 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.

1.2. THE OPINION OF SEAC

The conditions of the restriction proposed by SEAC are:

Substances	Conditions of the restriction
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[6]; 3. The restriction shall apply 36 months after entry into force[7].

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties, the opinion of RAC, as well as other available information as recorded in the Background Document. SEAC concludes that it is uncertain whether the restriction proposed by the Dossier Submitter on **calcium cyanamide** (CAS 156-62-7, EC 205-861-8) is the most appropriate Union wide measure to address the identified risks. There is insufficient information to definitively conclude on the proportionality of the socio-economic benefits to the socio-economic costs as demonstrated in the justification supporting this opinion.

[6] The Dossier Submitter originally proposed to derogate the use of calcium cyanamide as a fertiliser in closed agricultural systems where the use would not result in emissions to the environment. However, as no support for such a derogation was received in the consultation on the proposal, and the enforcement of the derogation was considered to be potentially problematic by the FORUM, the Dossier Submitter has withdrawn the proposed derogation.

[7] The Dossier Submitter proposes a 36-month transition period to utilise existing stocks, and for end-users to acquire information, machinery and knowledge of alternative technologies to be able to replace calcium cyanamide in an orderly way.

2. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

2.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

2.1.1. Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (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).

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 Dossier Submitter (ECHA) concluded 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.

ECHA as 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 Committee found the purpose of the restriction to be 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 considers 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 that could 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). The former 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 concluded that the use of calcium cyanamide as a fertiliser could 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 (RAC, 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[8].

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, fungicidal and fungistatic, molluscicidal and insecticidal, 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 However, RAC notes that 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 which inhibits the enzyme catalase, 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 majority of the effects may be attributed to the effect that calcium cyanamide has on increasing soil pH surrounding the calcium cyanamide granules. 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).

[8] 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

2.1.2. Description of the risk(s) addressed by the proposed restriction

2.1.2.1. Information on hazards

Summary of proposal:

In moist soil calcium cyanamide is transformed into cyanamide and calcium hydroxide (primary transformation substances). Cyanamide is further transformed into secondary transformation products, including urea and cyanoguanidine. Therefore, cyanamide, urea and cyanoguanidine are relevant transformation products and are considered throughout the Dossier Submitter's 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. 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 <u>risk that is not adequately controlled</u> for both surface water adjacent to fertilised fields (the highest Risk Characterisation Ratios (RCRs) calculated were between approximately 2 to 1 504 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)[9] and soil microorganisms (cyanoguanidine)[10]. 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 organisms by the Biocidal Product Committee (BPC) in December 2019[11].

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[9] At typical application rates of calcium cyanamide applied one crop (potatoes), urea was found to pose an uncontrolled risk to aquatic microorganisms.

[10] At various application rates and methods of calcium cyanamide, cyanoguanidine was found to consistently pose an uncontrolled risk to soil microorganisms.

[11] 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.

RAC conclusions:

RAC agrees with the environmental hazard assessment as reported by the Dossier Submitter, with the exception of urea . The Dossier Submitter's hazard assessment was supported by the use of relevant literature sources and the majority of the data had previously also undergone scrutiny under different EU regulatory processes. Additional studies provided were evaluated by the Dossier Submitter and RAC and are described in this opinion. These additional studies were 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.

<u>Hazard assessment was presented in the dossier for the aquatic, sediment and terrestrial environment.</u>

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[12] *Chironomus riparius* Heintze 2001	No data	No data
$PNEC_{soil}$, species & key study	0.15 mg/kg soil *Folsomia candida* Moser & Scheffczyk (2009)	Insufficient data to derive $PNEC_{soil}$	0.25 mg/kg soil Soil microorganisms in OECD guideline 216 Foerster (2014b)

RAC agrees 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 for calcium cyanamide/cyanamide (fish, invertebrates, algae and aquatic plants). 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.

[12] 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.

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 for 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 significant study limitations. RAC considers that the $PNEC_{freshwater}$ value for urea is not sufficiently reliable for hazard assessment. , Additionally, 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 (e.g. Huang, et al, 2014).

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 drinking 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 regulation (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 below.

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.

<u>Hazard to the aquatic compartment (including sediment)</u>

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 were 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* was 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.

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 study 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) it only involved a single dosing event at the start and consequently, the concentration of the test substance was not maintained within ± 20% of the nominal or measured initial concentration throughout the duration of the study 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 agrees 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).

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). Well conducted mesocosm studies can be used in a weight of evidence approach to refine or replace the PNEC derived from laboratory studies.

The observed effects of the test item were assessed 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). This includes four tiers within the acute and chronic effects assessment. Tier 1 and Tier 2 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: 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 three, 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 #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.

The Dossier Submitter reviewed whether the mesocosm study could be used to refine the $PNEC_{freshwater}$ based on EFSA Guidance on tiered risk assessment for edge-of-field surface waters (EFSA, 2013). A NOEC based on an ETO value of 0.032 mg/L was 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 was 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 assessment factors of two and four, 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 interpretation of the mesocosm study data.

RAC notes that some limitations were identified by the Dossier Submitter and EFSA (Aug, 2019) and reported in the Annex XV report. These identified limitations were commented on during the consultation by the study director (comment # 2930). However, some uncertainty remains when interpreting the results of the mesocosm study as:

- The most sensitive insects among those included in the study (Diptera/Chaoborus sp.) presented decreasing abundance during the study also in the control, which is likely linked to seasonality, i.e. a large share emerging before the exposure phase or soon after, indicating that the timing of the study where this group is concerned was not ideal. Hence, most were not likely to be exposed during their most sensitive life stages (early instars).
- In general, when assessing whether a mesocosm study covered vulnerable species, 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. However, other EPT species were not present.
- In relation to the ERO, 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 was performed for a different purpose than regulatory risk assessment. 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 three is appropriate. The observed limitations of the study were:

a) Information on growth medium is not reported;

b) Number of algal cells used is not reported;

c) The duration of the study is non-standard

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 2 500 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 three 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 Registration dossier, 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 $PNEC_{freshwater}$ 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 $PNEC_{freshwater}$ r for cyanoguanidine was 2.5 mg/L.

Hazard to terrestrial compartment (soil dwelling organisms)

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 a 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 to only 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 of 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)[13] 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)[14] cyanamide assessment. This is

[13] 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

[14] 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

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.

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 supplied was not 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 (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 collembolans. 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 reported to account for approximately 90% of the collembola community in the study. While just 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 the NOEC was <3 200 mg/kg soil dw (Adema, D.M.M., 1985) and for the plant *Avena sativa* a NOEC of 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 as 0.8 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 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. RAC notes that as calcium cyanamide is applied as a granulated fertiliser via top dressing 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, 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 for cyanamide reported in ECHA (2018) and for cyanoguanidine in registration dossiers (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 used 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 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.

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)

2.1.2.2. 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[15] of land.

Calcium cyanamide is a slow-release nitrogen fertiliser used for a number of agricultural crops grown in the EU. It is typically applied as a fertiliser in granular form in three different ways, 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.

FOCUS modelling[16] (Boesten et al., 1997) was used by the Dossier Submitter to derive predicted environmental concentrations (PEC) of calcium cyanamide and its transformation products in surface water and sediment. The modelling takes into account the different application methods.

The modelling results for various crops across the range of recommended application rates show the highest $PEC_{freshwater}$ values to be in the range 17.4 – 1 900.4 µg/L, when calcium cyanamide is applied by uniform incorporation or at the soil surface. Soil surface application of calcium cyanamide seems to elevate $PEC_{freshwater}$ values, compared to uniform incorporation. Soil surface application to grassland results in particularly high $PEC_{freshwater}$ values. Conversely, application by deep placement results in $PEC_{freshwater}$ values consistently below 1 µg/L. High

[15] 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).
[16] Further information on the background and operation of FOCUS models is provided on the Commission, JRC's website: https://esdac.jrc.ec.europa.eu/projects/focus-dg-sante.

maximum $PEC_{freshwater}$ values are generally observed with runoff (R) scenarios, rather than drainage (D) scenarios[17], with the exception of calcium cyanamide applied to grassland in which a drainage scenario results in the very high $PEC_{freshwater}$ value. Deep placement of calcium cyanamide up to the recommended application rates of 250 kg/ha calcium cyanamide consistently results in $PEC_{freshwater}$ values for cyanamide of <1 µg/L.

The Dossier Submitter used FOCUSPEARL[18] to model the $PEC_{ground\ water\ (gw)}$ for cyanamide and cyanoguanidine under reasonable worst-case conditions of use (recommended application rates and methods) as well as at application rates above the recommended levels that could feasibly occur in practice. This modelling covered additional crops and a broad range of application rates. At recommended application rates, the Dossier Submitter reported concentrations of cyanoguanidine ranging between 1 377 – 13 802 µg/L. It is worth noting that the Dossier Submitter used a generic conservative DT50 of 1 000 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 used a typical modelling approach for substances intentionally added to soil (Boesten et al. 1997) to estimate predicted environmental concentrations in soil (PEC_{soil})[19]. The model assumes the test substance is applied uniformly down to a particular depth of soil. The results of the modelling 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 concludes that the PEC values obtained by the Dosser Submitter for surface water and sediment are reliable because:

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

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 the main cause of surface water exposure with cyanamide.
- Vegetated buffer strips can significantly reduce the run-off of cyanamide.

Where urea and cyanoguanidine, the secondary transformation products of calcium cyanamide are concerned:

- 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

[17] 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.

[18] A specialised FOCUS model designed for predicting concentrations of a test substance in groundwater. Further details of the PEARL model are provided by the Commission/JRC: https://esdac.jrc.ec.europa.eu/projects/pearl and in: http://www.pearl.pesticidemodels.eu/ .

[19] Commonly used for plant protection products.

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 $PEC_{freshwater}$ values for urea and cyanoguanidine.
- Run off appears to be main cause of surface water exposure with urea
- Run-off and drainage are the main causes of surface water exposure with cyanoguanidine.

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

- The 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.
- The modelling approach included different crop types and cyanoguanidine, a transformation product of calcium cyanamide.

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 as it 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.
- The estimated Predicted Environmental Concentration in soil (PEC_{soil}) for calcium cyanamide, cyanamide, urea and cyanoguanidine in the following scenarios were followed the current FOCUS guidance for different application rates and application methods.
- Low and high molar conversion rates of cyanamide to cyanoguanidine and urea were modelled.
- In addition to cyanamide, the secondary transformation products urea and cyanoguanidine were modelled.

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 in the range of 0.8 – 3.5 mm diameter based on the technical data sheet of the product. In the REACH registration dossier (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 represents the possible transformation routes of calcium cyanamide in the environment as presented in the SCHER (2016).

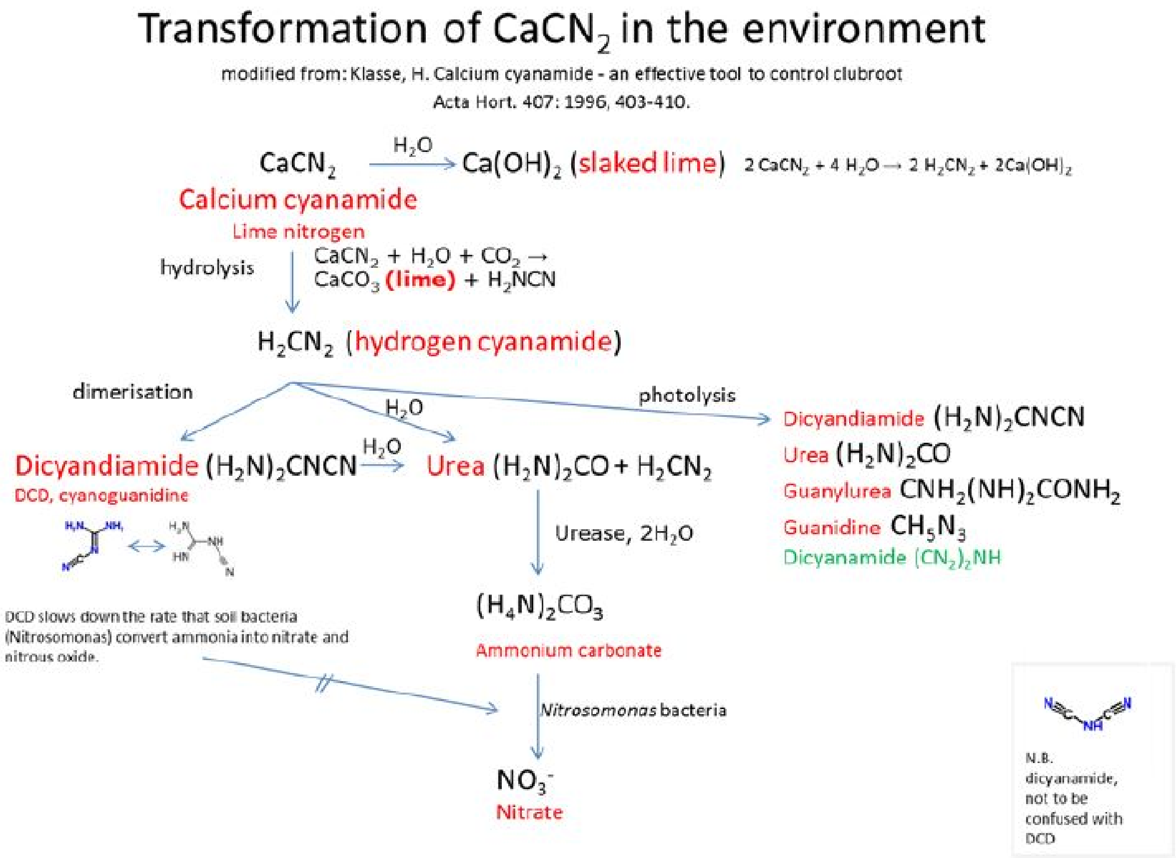

Figure 1 Possible transformation routes of calcium cyanamide in the environment in the SCHER (2016)

Soil water content plays a critical role on the hydrolysis of 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 REACH registration dossier (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 is 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 Registration Dossier (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. 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 Figure 1, 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 then dimerises into cyanoguanidine (6-11%). Cyanoguanidine acts as nitrification inhibitor in soil. RAC notes that the process of dimerisation 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 cyanoguanidine 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 cyanoguanidine (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 dimerisation 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 dimerise 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, 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 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. 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 3.3 days to 27.5 days with increasing concentrations and the average DT50 was calculated to be 13.1 days. (15.1-23 ºC).Thus providing 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=1 000 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 REACH registration for 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 1 000 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 registration 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. Thus, the 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 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 are seasonally waterlogged by water perched over impermeable massive clay substrate. $PEC_{freshwater}$ values for Dossier Submitter ranged almost 0 to a maximum of 8 603 µg/L of cyanamide. Registrant's modelling results 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 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 ranged between 100-500 kg/ha and resulted in $PEC_{freshwater}$ values from almost 0 to a maximum of 15 704 µg/L for **cyanamide** (run off and drainage scenarios). Applications rates of 300 kg/ha resulted $PEC_{freshwater}$ values ranging from almost 0 to 1 948.6 µg/L for **urea** (run off scenarios). Also, $PEC_{freshwater}$ values for **urea** were between from almost 0 to 5 813.3 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 1 480.9 µg/L for **cyanoguanidine** (run off and drainage scenarios). At 700 kg/ha application rate, the $PEC_{freshwater}$ (cyanoguanidine) values range from 4 451.5 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.

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 126-2 115 µg/L, respectively, for **cyanamide** (run off and drainage scenarios). Application rates of 500 kg/ha and uniform application of the fertiliser to a depth of 0 to 10 resulted in $PEC_{freshwater}$ 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 in $PEC_{freshwater}$ 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 2 516.6 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.

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.

<u>Exposure modelling of cyanamide and cyanoguanidine in groundwater</u>

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 1 377 – 13 802 µg/L (see section 3.2.10.3 in the Background document). 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, to derive predicted environmental concentrations (PEC) of cyanamide and its transformation substances in the soil environment.

The Dossier Submitter's results indicated that PEC_{twa} (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. PEC_{twa} (28d) concentrations for all three substances appeared to increase with the 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 reported for cyanamide during the Biocides approval process (2016) and by Dixon (2017) were utilised in the soil exposure modelling. In order to take into account the uncertainty in the molar conversion fraction for urea and cyanoguanidine to scenarios were considered: a low conversion to urea scenario (molar conversion of 0.094 for urea and 0.05 for cyanoguanidine) and a high conversion to urea scenario (molar conversion of 0.957 for urea and 0.0425 for cyanoguanidine) scenarios were considered 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 appreciable difference between the low and high molar conversion approach of soil modelling.

The registrant's soil exposure modelling data were in a similar range to the Dossier's Submitter's. The PEC_{twa} (28d) concentrations for cyanamide were in the range of 1.8 to 11.9 mg/kg soil. The registrant also undertook exposure modelling employing the exposure approach of Dossier Submitter (Boesten et.al., 1997) and using the DT50 values mentioned in its 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.

2.1.2.3. 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)[20] and soil microorganisms (cyanoguanidine)[21].

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 risk 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 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 cyanamide, the primary degradation product of calcium cyanamide. Additionally, risk was not adequately controlled for one of the secondary transformation products of calcium cyanamide, i.e. cyanoguanidine.

As RAC did not support the Dossier Submitter's hazard assessment for urea, the risk characterisation for urea is also not supported. In addition, RAC does not support the Dossier Submitter's risk characterisation for cyanamide in the sediment compartment as there is a discrepancy between the units reported for the PNEC and PEC values. The derived PNEC value was reported in µg/ml while the respective PEC values are reported in µg/Kg of dry weight sediment. This discrepancy prevents a meaningful RCR value to be calculated.

[20] At typical application rates of calcium cyanamide applied one crop (potatoes), urea was found to pose an uncontrolled risk to aquatic microorganisms.

[21] At various application rates and methods of calcium cyanamide, cyanoguanidine was found to consistently pose an uncontrolled risk to soil microorganisms.

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 conclusion of the assessment of the endocrine disrupting properties of cyanamide and agrees that this might have implications in the future for the risk characterisation for environmental endpoints.

Key elements underpinning the RAC conclusions:

Risk characterisation for surface water, as performed by the Dossier Submitter, showed that under different modelling scenarios risks are 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 various crops (winter oilseed rape, potatoes, maize and leafy vegetables) and application rates (100-500 kg/ha). Implementing risk management measures (vegetated buffer zones) resulted in risk reduction (RCR <1) for one of the modelled scenarios (R3,s, winter oilseed rape, 200 kg/ha). Risks from drainage through soil (D2 ditch scenario) were identified for Grassland and Winter Oilseed Rape. RAC notes that the D2 scenario is considered as an extreme worst case drainage scenario, characterised by impermeable clay with field drains, which is seasonally waterlogged by water lying over an impermeable, massive clay substrate. For cyanamide, out of the 271 scenarios modelled by the Dossier Submitter, 62 resulted in RCR >1 and ranged between 1 and 1 504 (Table 4). 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 risks. In the case of the Registrant, out of the 263 scenarios modelled 32 scenarios resulted in RCR >1 and ranged between 1 and 43.

With respect to the secondary transformation products of the calcium cyanamide, risks to surface water were identified only for cyanoguanidine for a single runoff (R3, stream potatoes, 700 kg/ha) and drainage scenario (D5, pond, Apple, 700kg/ha). Of the 45 scenarios modelled by the Dossier Submitter, six resulted in RCR >1 and ranged between 1 and 1.8 (Table 4).

For urea, the risk characterisation proposed by the Dossier Submitter was not considered to be reliable. This is due to uncertainties in relation to the $PNEC_{freshwater}$ derivation. Briefly, RAC did not agree with the Dossier Submitter on the use of the Bringmann & Kuhn (1978) study as point of departure for PNEC freshwater ($PNEC_{freshwater}$=0.47mg/L) because of the study limitations.

Risk characterisation for groundwater was performed based on indirect exposure of humans via the environment (drinking water). No risk was identified by the Dossier Submitter based on a Guideline values (GC) derived following WHO guidelines. 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), risks to human health are identified for cyanamide and cyanoguanidine (Table 4).

Risk to the terrestrial compartment were identified for cyanamide and cyanoguanidine in all of the nine scenarios modelled (three application rates and three application methods). Risk characterisation ratios varied based on the application method and rate but were always greater than one. 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 RCRs were also calculated based on the Registrants exposure modelling results provided during the consultation and were similar to the RCRs reported by the Dossier Submitter.

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

	Cyanamide	**Cyanoguanidine**
Surface water	1-1 504 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 (indirect exposure to humans via the environment)	< 1 for all 56 scenarios modelled	not assessed
Ground water (0.1 µg/L based on Groundwater Directive and EU Drinking Water Quality Directive)	1 - 701 Total modelling scenarios= 56 Scenarios with RCR>1= 56 (100%)	23 151-138 022 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 regard to the risk characterisation.

2.1.2.4. Uncertainties in the risk characterisation

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 reduces this particular 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 reported for cyanamide during the biocide assessment process (BPR, 2016) and by Dixon (2017) have been utilised. In order to take into account 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. However, as noted during the exposure assessment, this source of uncertainty is likely to be insignificant considering the low level of expected dimerisation of 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 $PEC_{freshwater}$ (2.5 mg/L) a conclusion was drawn based on RCRs >1 that risk from 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 $PEC_{freshwater}$ values for cyanoguanidine below the $PNEC_{freshwater}$. The Dossier Submitter notes that application rates well above 500kg/ha are known to be recommended. This indicates 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 surface water might be overestimated.

d) Some minor uncertainty exists on the different DT50 values selected for calcium cyanamide and cyanamide by the Dossier Submitter and the Registrant for surface water, groundwater and soil. RAC notes that in FOCUS modelling the DT50 is not a particularly sensitive input parameter. 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 groundwater modelling where the DT50 have little impact to the groundwater PECs. Similarly, in the terrestrial exposure modelling DT50 differences do not have significant impact on the predicted PECs, which is reflected by the similarity of the PECs reported by both the Dossier Submitter and the Registrant.

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

Summary of proposal:

In its 27 June 2019 registration dossier, the Registrant 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 a conclusion that risks to surface water and soil are not adequately controlled. For soil, the risk characterisation[22] results using a PPP approach are lower than those estimated by following REACH guidance but remain significantly above one.

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, use of calcium cyanamide as a fertiliser poses a clear risk to the terrestrial compartment.

Key elements underpinning the RAC conclusions:

The 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 shows that PNEC values derived either with the PPP approach or REACH guidance show that risk is present when using calcium cyanamide as fertiliser.

Implementing risk management measures (vegetated buffer zones), as modelled, resulted in adequate control of risk (RCR <1) in only one exposure scenario (R3,s, winter oilseed rape, 200 kg/ha).

2.1.4. 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 are detailed in the Background Document.

As a first step, the possibility to address the risks to the environment from the use of calcium

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

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 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 identified that only a restriction on the placing on the market and use of calcium cyanamide as a fertiliser can adequately control the risks in both the aquatic and terrestrial environments.

RAC conclusions:

RAC notes that two restriction options, RO2 (detailed regulation of acceptable agricultural production methods) and RO4 (total ban of calcium cyanamide use) were discussed in the Background Document 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 restriction options appear to be effective in reducing surface water risk, however, in the case of the terrestrial compartment, RO2 does not address 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:

The risk management options examined by the Dossier Submitter, beyond the restriction on placing the fertiliser on the market, were demonstrated to be either difficult to enforce, impractical or difficult to monitor. A restriction on the placing on the market of calcium cyanamide as a fertiliser in powder form (RO1) had little if any risk reduction potential as the powder form of the fertiliser has not been marketed since December 2017 (as reported by the Dossier Submitter). RO2 introduced detailed regulation of acceptable agricultural production methods, which according to the Dossier Submitter showed medium to low potential for risk reduction in surface water but no risk reduction in the terrestrial compartment. 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 proposed the use of existing CAP measures but appeared to not fit to the criteria for effectiveness, practicality and monitorability and/or to not fully remove the risk. 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.

2.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter 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 Member State 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 Member States.

Key elements underpinning the SEAC and RAC conclusions:

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

SEAC: The Dossier Submitter has identified that the use of calcium cyanamide as a fertiliser on arable land poses a risk for the environment wherever it is used in the EU. Calcium cyanamide fertiliser is used in a number of EU Member States. Since separate national policies will not ensure an equivalent control of risk for the environment and in order to ensure a level playing field, SEAC agrees that EU-wide action would be justified.

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

2.3.1. Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

The proposed scope of the restriction (RO4) 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 (RO2) 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:

Calcium cyanamide is a slow release nitrogen fertiliser used for a number of EU agricultural crops. The manufacturer claims that calcium cyanamide has several secondary effects that are useful for farmers, including herbicidal, fungicidal, molluscicidal and, plant protection properties (e.g. managing wireworm in potatoes). However, calcium cyanamide is not approved as an active substance for use in Plant Protection Products (PPPs), and the manufacturer has not applied for such an authorisation for PERLKA®.

The manufacturer, until December 2017, placed a powdered form of calcium cyanamide fertiliser on the market. However, due to risks for human health, the powdered form is now identified as a use advised against in the REACH registration.

The Dossier Submitter assessed four restriction options: RO1 - Ban of powder form; RO2 - Detailed regulation of acceptable agricultural production methods; RO3 - Utilisation of existing CAP measures; RO4 - Total ban of calcium cyanamide use (as a fertiliser).

After assessing the options against the main criteria for restriction – effectiveness, practicality and monitorability - the Dossier Submitter proposed the RO4. Furthermore, the Dossier Submitter considered the originally proposed derogation for the use of granulated fertilisers in a closed system to be justified as by definition there is no release to the environment from closed systems. However, the derogation was withdrawn as no support was received in the consultation on the Annex XV report and its enforcement was thought to be challenging by the Forum.

SEAC conclusions:

SEAC agrees that, when comparing the scope of the four restriction options assessed by the Dossier Submitter, the proposed restriction option (RO4 – ban on the placing on the market and use) is the most appropriate to address the identified risks out of the four ROs proposed.

Key elements underpinning the SEAC conclusions:

The Dossier Submitter assessed four different restriction options, of which three (RO2, RO3 and RO4 (the proposed option)) can be considered to address, to a greater or lesser extent, the identified risks for the environment.

RO1 (ban on the placing on the market of calcium cyanamide in powder form), according to RAC, does not address the identified risk to the environment. Furthermore, the manufacturer informed the Dossier Submitter that it ceased sales of the powder form of calcium cyanamide in 2017, and thus its use has not been supported by the manufacturer since 2017. Therefore, this option would rather act as a precautionary measure to account for a scenario where the product was re-introduced to the market. SEAC concurs with this assessment.

RO2 requires specific mandatory guidelines for the use of calcium cyanamide fertiliser e.g. specifying maximum application rates (kg/ha); the mandatory adoption of vegetative buffer strips; limiting or banning of broadcasting on bare soil; the mandatory incorporation of fertiliser into soil after application. SEAC acknowledges that such measures could contribute to reducing the identified risks, especially concerning those to surface water. However, RAC confirmed that, RO2 cannot adequately address the identified risk to soil organisms[23]. Furthermore, SEAC agrees with the Dossier Submitter that RO2 would not be practical as it would require complex sector-specific regulation, and the effectiveness of such measures can be variable and are site specific. In addition, it would be difficult to enforce within the REACH framework.

RO3 requires that calcium cyanamide can only be used if (already existing) agri-environmental measures are followed e.g. cross-compliance measures. Cross-compliance requires that farmers receive payments from the European Common Agricultural Policy (CAP) system if they agree to implement certain good agricultural practices. Although partial risk reduction could be achieved by this restriction option it is not considered to be sufficiently effective, practical and monitorable according to RAC. SEAC concurs with RAC.

Other RMOs described by the Dossier Submitter were also deemed ineffective.

[23] In addition, SEAC notes the ongoing discussions with respect to the endocrine disrupting properties of cyanamide (the transformation product of calcium cyanamide), which were not considered by the Dossier Submitter and may not be addressed by RO2. In the consultation on the SEAC draft opinion a respondent noted (#596) that the ongoing discussions on endocrine disrupting properties concerns cyanamide.

A voluntary agreement requiring the use of special agricultural techniques or conditions (similar to RO2 e.g. deep placement and vegetative buffer strips, except that the measures would be voluntary for the user). The effectiveness of these measures and the degree of uptake of these measures is uncertain. In addition, it would be administratively complex to implement. The large number of potential users would make it difficult to ensure that the agreement was implemented by a sufficient number of actors, which thus raises issues regarding compliance and also compliance costs. SEAC concurs with this. Furthermore, even if the voluntary actions are promoted by providing incentives e.g. through the CAP, these actions may derive limited environmental benefits as they, according to RAC, will not always provide sufficient risk reduction.

The Fertilising Products Regulation (FPR) Regulation (EC) 2019/1009 was also considered[24]. However, this regulates impact of fertilisers on the environment in case they are placed on the market as CE marked fertilisers. Hence, this Regulation does not address all fertilisers used in the EU. Furthermore, SEAC notes that besides functioning as a nitrogen fertiliser, calcium cyanamide would appear to provide plant protection functions, which would exclude calcium cyanamide from the scope of the Fertilising Products Regulation (as described in Recital 23 of that regulation)[25].

Within the REACH Regulation, the authorisation process cannot be used as the risk management measure for calcium cyanamide because it is not identified as an SVHC. SEAC notes that in case calcium cyanamide would be identified as SVHC on the basis of its endocrine disrupting properties, the authorisation process could be considered.

Therefore, out of the RMOs considered a restriction, and more specifically the scope of the proposed restriction RO4 (a general ban on placing on the market and use) is considered the most appropriate. SEAC concurs with RAC and the Dossier Submitter, that the other restriction options discussed by the Dossier Submitter (RO1-RO3) would not be effective in addressing the range of risks and/or would not be administratively practical.

SEAC takes into account that 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. Considering the proposed scope of the restriction option RO4, this appears to be the most effective in reducing risks, practical and monitorable out of the four ROs assessed.

SEAC agrees with the Dossier Submitter that a derogation for use in closed systems (as proposed in the original dossier) is not needed, since such a use has not been identified or requested in the consultation on the Annex XV report or on the draft SEAC opinion.

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[24] Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1).

[25] SEAC notes that according to Recital 23 of the FPR, *products with one or more functions, one of which is covered by the scope of Regulation (EC) No 1107/2009, are plant protection products falling within the scope of that Regulation. Those products should remain under the control developed for such products and provided for by that Regulation. Where such products also have the function of a fertilising product, it would be misleading to provide for their CE marking under this Regulation, since the making available on the market of a plant protection product is contingent on a product authorisation valid in the Member State concerned. Therefore, such products should be excluded from the scope of this Regulation.* Based on the available information (including consultation comments), calcium cyanamide would appear to have PPP properties that would be consistent with the concept of dual function stated in the FPR.

2.3.2. 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.

2.3.3. Socio-economic impact

Justification for the opinion of SEAC

2.3.3.1. Costs

Summary of proposal:

According to the RAC opinion the proposed restriction is effective in addressing the identified risk. The Dossier Submitter noted that only a small proportion of farmers in the EU use calcium cyanamide as a fertiliser and that the use does not correspond to any specific set of conditions and/or crops (i.e. other farmers use different fertilisers for the same crops/conditions). This implies that suitable alternatives are available and in use in the EU. Nevertheless, the Dossier Submitter's calculated that the proposed restriction would result in impacts for affected farmers due to decreased quantity and quality of yields of € 35-50 million per year. The Dossier Submitter's analysis highlights that the proposed restriction would impact the manufacturer and farmers through reduced profits. The Dossier Submitter did not quantify potential direct costs to other parties besides farmers. The Dossier Submitter refers to costs to the manufacturers supply chain and costs to society (e.g. possible job losses).

The Dossier Submitter highlights that the proposed restriction is expected to have a sizable impact on the manufacturer, especially on the subsidiary located in Trostberg, as it is expected to cause a major reduction in the manufacturing of PERLKA® with potential job losses. However, European producers of alternative fertilisers can be expected to gain a large portion of the current market share of calcium cyanamide and thus compensate for some of the socio-economic losses. It is presumed that the inputs used in the production of calcium cyanamide find use in other production processes and are not left idle. Farmers using calcium cyanamide will have other affordable fertilisers available. It is noted that a large part of the claimed added value of using calcium cyanamide is the secondary effects.

SEAC conclusions:

1. SEAC concurs with the Dossier Submitter that some farmers will incur productivity losses in the short to medium term. A summary of this analysis is presented in *Table* 5. SEAC estimates farm level costs to be €10-16 million per year, which is lower than the Dossier Submitter's estimates of €35-50 million[26] per year. However, SEAC notes that the Dossier Submitter did not quantitatively or monetarily account for possible costs that farmers may incur as they transition to use of authorised PPPs, or alternative farm production inputs or farm production methods to substitute for the secondary effects of calcium cyanamide. In the consultation on the SEAC draft opinion[27] additional numerical estimates for the cost to farmers as a result of the restriction was provided (#634), which suggests that farmers are likely to incur costs (e.g. via productivity losses) 4-5 times greater than those estimated by the Dossier Submitter (and thus also greater than the costs estimated by SEAC). A comment (#547) provides information based on an example of one farm with cost estimates about 2-2.5 times greater than those provided by the Dossier Submitter. However, whilst SEAC acknowledges the information it notes that insufficient supporting evidence was presented to allow the claims to be substantiated. Therefore, SEAC considers that this information tends to support the Dossier Submitter's cost estimates but underlines the uncertainty of these estimates. In addition, several comments emphasised impacts on vegetable growers (#547; #556; #559; #573; #574; #587; #598; #607; #615; #617; #634; #636), grain (rice) growers (#562; #604) and fruit growers (#562; #571; #595). SEAC considers that this information provides further clarification on the type of farm production that will be impacted by the restriction.

2. SEAC concurs with the Dossier Submitter that the manufacturer will incur direct costs due to profit losses; only one manufacturer is directly affected. However, the Dossier Submitter's cost analysis did not quantitatively or monetarily account for possible actions taken by the manufacturer to reduce their losses, such as possible redeployment of financial or human capital. In the consultation on the SEAC draft opinion additional information on cost to the manufacturer of PERKLA was provided (#634) in terms of profit losses as a result of the restriction (stating a minimum cost of €10m per year). SEAC considers that this type of information could contribute to an evidence base from which to assess profit losses that the manufacturer may incur as a result of the restriction. SEAC considers that including the profit losses of the manufacturer over a long period does not consider the possibility of actions that could reduce the economic impacts (e.g. human and financial capital being redeployed by the manufacturer) and may therefore overstate any long-term impacts. This type of data needs to be considered in a societal context in order to evaluate the net impacts to society of the proposed restriction, not just to certain actors. Although acknowledging the manufacturer's possible losses, SEAC concurs with the Dossier Submitter that economic activity in the EU (societal level) is unlikely to change, as manufacturers of other nitrogen fertilisers and/or PPPs in the EU are likely to gain market share.

3. SEAC concurs with the Dossier Submitter that society will incur some job losses at the manufacturers' site, which might not be replaced by job increases in other nitrogen

[26] A range for "Average productivity loss range in a realistic case" given "Public information" in Table 30 in *4.5.1 Economic impacts on end users* in the Background Document.

[27] SEAC considers that comments received provide useful information and takes it into account in its assessment, however, mostly the information is non-scientific data and SEAC is not in a position to assess the robustness of the information provided.

fertiliser manufacturers in the short term. SEAC considers that job losses over a long period do not consider the possibility of workers obtaining new jobs or being redeployed by the manufacturer. In the consultation on the SEAC draft opinion additional data estimating direct job losses in manufacturing and in agriculture were provided. A comment (#634) used a range of scenarios (optimistic case, realistic case and worst case) and estimated the impacts regarding workers employed by the registrant to be between the range of €25m to €134m[28]. Additional information was also provided suggesting categories of workers that are likely to be affected (i.e. full-time workers, contract workers and seasonal workers). SEAC considers that these data could contribute to an evidence base from which to assess job losses at the manufacturer's site and in agriculture, and as such it contributes mainly to an understanding of possible local/regional unemployment effects and possible categories of workers affected. However, SEAC considers it a partial analysis as it does not account for adjustments in the economy (e.g. impacts on producers of alternatives or impacts of the use of alternatives on jobs in agriculture) and as such it does not describe net effects to society.

4. SEAC concurs with the Dossier Submitter that the supply of the different crops on the **EU-market** is not likely to change significantly, as other farmers may modify their production.

Table 5: Cost Categories, Estimates, Uncertainties and Assumptions

Cost Categories	Cost Estimates	Uncertainties/assumptions
Profit losses for farmers	Estimated monetarily for farmers the change in profits due substituting calcium cyanamide fertiliser with another nitrogen fertiliser – (change in fertiliser costs and change in product returns).	Possible other costs related to substitution (i.e. additional use of authorised PPPs, or alternative methods (farm production measures) not quantified, therefore leading to a possible underestimation of the costs to farmers. In the consultation on SEAC draft opinion several comments (#589; #595; #631) reflected on the costs and effectiveness of alternative measures. SEAC considers that this information contributes to the evidence base to assess the costs and effectiveness of alternative measures. SEAC notes that the data provided comes from a limited number of data points.
Manufacturer losses	Monetary costs estimate on profit losses (claimed confidential by the manufacturer, however known to SEAC). There will be financial consequences directly on the manufacturer.	Data has not been provided on the manufacturer's ability to redeploy financial and human resources to other productive activities, leading to a possible overestimation of manufacturer's losses.
EU-economic manufacturing activity	No quantified or monetised cost estimates provided.	Qualitatively described that on the societal level (EU economic activity). There are gains to other (competing) EU manufacturers which may gain market share.

[28] It is not obvious, whether this is a one-time cost or an annual figure. The comment explains that the unemployment impact is calculated according to guidelines given for estimating unemployment impacts for authorisation, which generally provides a one-time cost estimate. However, in the comment, the cost is expressed as an annual cost.

Cost Categories	Cost Estimates	Uncertainties/assumptions
EU-agricultural production	No quantified or monetised cost estimates provided.	Qualitatively described that crop volumes at the EU will remain largely unchanged as the share of calcium cyanamide of the total nitrogen fertilisers is small. From the consultation, one comment (#634) assumed that a certain percentage of farmers would shift to producing cereals. SEAC notes that estimates provided here relied on an assumption about farmers reacting in a certain way and the data provided comes from a limited number of data points.
Supply chain	No quantified or monetised cost estimates provided.	Qualitatively described that risks to supply chain are expected to be low.
Unemployment	Job losses claimed confidential by the manufacturer, however, known to SEAC.	According to a comment (#634), unemployment at the manufacturer's site are likely to occur, and potential employment effects on agricultural labour was also cited. Some information describing local/regional unemployment effects was provided. The unemployment estimates did not account for the possibility of human resources been redeployed to other uses. The unemployment estimates did not account for the net (EU) societal impact in terms of jobs.

Key elements underpinning the SEAC conclusions:

1. Productivity losses

SEAC notes that the Dossier Submitter has highlighted that calcium cyanamide delivers specific added value compared to other nitrogen fertilisers. Besides the slow-release nature of the nitrogen, an additional advantage of using calcium cyanamide relates to the secondary effects – attributed to the transformation products of calcium cyanamide, namely, cyanamide and cyanoguanidine. These secondary effects could be regarded as Plant Protection Product (PPP)functions e.g. herbicidal, fungicidal, molluscicidal and pest and spore-germination suppression[29]. As an illustration, the Dossier Submitter refers to a scientific study by Dixon et al., (2017) which shows how calcium cyanamide reduces plant diseases caused by soil-born microbes. Similarly, information from the consultation and the registrant emphasised the secondary benefits as one justification for using calcium cyanamide. In the consultation on SEAC draft opinion several comments (#519; #559; #568; #572; #573; #587; #589; #594; #595; #634) implied that calcium cyanamide has PPP-type attributes, through highlighting that the restriction could lead farmers to increase the use of inputs such as herbicides, pesticides and fungicides. These responses contribute to answering parts 1(d) and 2 (d) of the specific information requested in the consultation on the SEAC draft opinion. In contrast, other comments (#519 and #579) suggested that calcium cyanamide is not used as a PPP. Furthermore, several comments (#519; #542; #559; #576; #617; #636; #634)

[29] Plant Protection Products, as defined according to Regulation (EC) No 1107/2009, are intended for one of the following uses: (a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products; (b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient; (c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives; (d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants; (e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plant.

described the benefits of using calcium cyanamide in terms of improved nitrogen efficiency, reduced nitrate leaching, improved soil fertility and productivity and also higher quality marketable farm output (#634). SEAC considers that this information contributes to support the farmer benefits of calcium cyanamide as a specialised nitrogen fertiliser, the type of responses of farmers and also farmer level losses if calcium cyanamide was no longer available.

SEAC notes several points related to the Dossier Submitter's partial analysis of the main farm level profit losses:

1) The Dossier Submitter's quantitative analysis of farmer profit losses focused mainly on the value added of calcium cyanamide as a nitrogen fertiliser and the costs associated with farmers switching to alternative nitrogen fertilisers. The Dossier Submitter used quantity and cost information for fertilisers and quantity, quality and price information of output to estimate profit losses to the farmer. Here the Dossier Submitter performed detailed cost analysis across a range of scenarios, which SEAC subsequently evaluated. A summary of this analysis is presented in *Table* 5. SEAC estimated farm level profits to be € 10-16 million/year i.e. somewhat lower than the Dossier Submitters estimates of € 35-50 million/year. SEAC acknowledges comment(s) submitted in the consultation on the SEAC draft opinion suggesting greater costs due to farm level productivity losses. However, considering the evidence presented, SEAC does not view this information to affect the numerical estimates *per se*, but rather views this as a support to use both the original cost estimates provided in the restriction proposal and the estimates by SEAC. However, SEAC notes a wide range of cost estimates and a limited evidence base from which they were derived to contribute to the uncertainties related to the farm level cost analyses.

2) The Dossier Submitter did not quantitatively or monetarily account for the effects of the proposed restriction on farm profits arising from farmers potentially increasing their use of authorised PPPs or alternative farm production measures to derive the value added related to the secondary effects from calcium cyanamide (e.g. pesticidal, herbicidal, fungicidal, molluscicidal and pest and spore-germination suppression). In the consultation on SEAC draft opinion several comments (#589; #595; #631) discussed alternative farm measures, such as application of burnt lime, soil steaming, mechanical control). Alternative measures such as application of burnt lime or hydrated lime were suggested to be not as effective as fertilisation with calcium cyanamide (#520); #547). These comments contribute to answering part 1(d) of the specific information requested in the consultation on the SEAC draft opinion. SEAC considers that this information could contribute to the evidence base to assess the costs and effectiveness of alternative measures but notes that the representativeness of the information is unclear.

3) As a consequence of 1) and 2) above, SEAC regards the cost analysis performed by the Dossier Submitter to be a partial analysis. SEAC notes that a more balanced cost assessment could have been achieved by the analysis of a range of scenarios where farmers switched to either authorised PPPs or alternative farm production measures to replace the aforementioned secondary benefits. In practice, this would have required the Dossier Submitter to analyse cost scenarios where farmers would achieve the same or similar secondary effects, either through the use of PPPs or other farm production measures, for example, crop rotation or mechanical treatments. However, SEAC also notes some comments claiming that some of the plant protection type attributes provided

by calcium cyanamide fertilisers cannot be replaced by currently authorised plant protection products.

Table 6: Dossier Submitter Cost Analysis – focused on profit losses associated with farmers switching to an alternative nitrogen fertilisers.

Assumption	Dossier Submitter	SEAC sensitivity
Volume of fertilisers containing calcium cyanamide in a concentration of 44%, tonnes	70 000[30]	Same
Distribution between high value crops/low value crops	50/50	35/65
Average application rate for low value crops and high value crops, kg/ha	300/300	400/250
Average yield (baseline) – cabbage/rape – tonnes/ha	90/4	Same
Increase in yield due to calcium cyanamide, high value crops/low value crops – percent	4%/9%	3%/5%
Output value – high value crops/low value crops € per tonne	€150/360	€110/360
Cost decrease per ha using ammonium nitrate (40% price reduction), high value crops/low value crops	€205[31]/61	€113/61
Cost decrease per ha using ammonium nitrate (20% price reduction), high value crops/low value crops	€376/82	€151/82

The Dossier Submitter estimated yield losses based on the following elements:

- Estimated loss of yield when using other fertilisers instead calcium cyanamide (different assumptions for different types of crops).
- Assumptions of prices for farm output.
- Differences in prices between calcium cyanamide and other fertilisers (with respect to nitrogen).
- Calculation of arable land treated with calcium cyanamide.
- Assumption on a share of land used for cultivating high value crops and low value crops.

SEAC concurs with the overall approach of estimating the costs to the farmers of switching to an alternative fertiliser to be correct. The Dossier Submitter performed analysis using a high value crop; a low value crop; prices for farm outputs, discounts, and varying application rates. SEAC concurs with this approach to developing scenarios. The Dossier Submitter described a main uncertainty related to change in output yield for the two crops when using calcium cyanamide fertilisers instead of other fertilisers with the same amount of nitrogen. SEAC notes this uncertainty. SEAC performed some sensitivity analysis across a range of assumptions, which are detailed in the above table.

SEAC's sensitivity analysis estimated a yearly profit loss of €16 million, compared to the Dossier Submitter who estimated the yearly profit loss at 50 million Euros. If the average discount on prices of fertilisers was lowered (from 40% to 20%), the estimated loss would be €10 million, compared to €35 million. SEAC notes that the manufacturer submitted a confidential paper on the profitability of calcium cyanamide used as a fertiliser. In this paper higher yield losses are mentioned for several crops. However, this is not supported by scientific studies and while SEAC cannot exclude that this may materialise, it has not been taken forward in SEAC's assessment. SEAC notes that the Dossier Submitter suggests that the calcium cyanamide use volumes are not expected to increase in the short term – although

[30] The PERLKA® tonnage, 70 000 tonnes, appears higher than the tonnage 'calcium cyanamide used as a fertiliser', 53 000 tonnes, because the concentration in PERLKA® is lower.
[31] Including saved cost for the calcium content of the fertiliser. The cost for calcium carbonate is 32€/t, which, for an application of Perlka of 500 kg/ha, would mean €17/ha. For the considered application rates of 300 and 400, the additional cost for calcium carbonate would be €10/ha and €14/ha.

no detailed market analysis was performed to support this information. SEAC notes that it cannot be ruled out that a reduction of secondary effects of calcium cyanamide protecting against harmful organisms for some crops might entail higher farm level costs and thus affect specific groups of farmers in the short term.

Regarding the secondary effects from the use of calcium cyanamide, SEAC notes that the calcium cyanamide produced by the manufacturer is not approved as an active substance for use in Plant Protection Products (PPPs). SEAC concurs with the Dossier Submitter that to replace the secondary effects of calcium cyanamide, farmers may decide to use authorised PPPs or alternative farm production measures. In the consultation on SEAC draft opinion several comments (#559; #587, #589, #634; #636) suggested that farmers' use of PPPs will increase in the face of a ban on calcium cyanamide and others (#589; #595; #631) discussed alternative farm production measures. These inputs contribute to answering points 1(d) and 2(d) in the specific information requested in the consultation on the SEAC draft opinion. SEAC notes that farm productivity and thus profits are affected by a wide range of variables, such as crop choice, soil type, production capacities, use of fertilisers and PPPs. SEAC cannot exclude that the restriction may impose some costs on some farmers due to loss of yields for certain crops.

SEAC cannot exclude that farmers may incur reduced profitability in the short to medium term while transitioning production to (a combination, as relevant) use of alternative nitrogen fertilisers and authorised PPPs or alternative farm production measures, for example through the use of crop rotation. For example, in the consultation on the Annex XV report the German Farmers Association (#2748) indicated possible severe problems for the production of some crops (asparagus and apples and cabbage), as higher need for hydrated lime (calcium hydroxide), soil steaming or use of PPP would be needed, and that for some producers the only solution would be to change crops. SEAC notes that these impacts may materialise, but that the impacts likely relate to a small subset of farmers in the EU and a small subset of crops. As discussed above, several comments to the consultation on the SEAC draft opinion suggested that vegetable, rice and fruit growers would be impacted by the restriction.

As mentioned above, the Dossier Submitter's estimates account only the difference in fertiliser and not for the impact of the farmers productivity (and profit losses) as a result of switching to a combination (as relevant) of authorised Plant Protection Products (PPPs) or alternative farm production measures to achieve similar secondary benefits. In this regard, SEAC considers that the Dossier Submitter analysis of productivity and consequent profit losses using on nitrogen fertilisers are partial. Other effects are only qualitatively described. SEAC notes that without information from a representative sample of farmers the actual response to the removal from the market of calcium cyanamide is uncertain. Similarly, SEAC notes that developing scenarios which account for the impact of switching could enable the Dossier Submitter to arrive at a more balanced cost assessment. For example, scenarios where farmers switch to authorised Plant Protection Products (PPPs) or alternative farm production measures to achieve the secondary benefits (e.g. pesticidal, herbicidal, fungicidal, molluscicidal and pest or spore-germination suppression). Given this, SEAC considers that the Dossier Submitter may have overstated the costs related to farmer productivity and profits.

To add to the cost analysis, SEAC also calculated a cost per tonne of removed calcium cyanamide as a fertiliser. This was done by using the aggregate farm level profit loss estimates related to substitution of calcium cyanamide with alternative nitrogen fertiliser - €16m-€50m per year (estimates by SEAC and the Dossier Submitter respectively) - and the volume (53 000 tonnes) of calcium cyanamide used. The calculation results in costs of €300-

€943 per tonne of calcium cyanamide removed. However, this does not account for potential costs associated with farmers switching to a possible combination of alternative nitrogen fertilisers and plant protection products. Furthermore, as previously discussed, SEAC highlighted the uncertainties related to the (farm level) cost analyses.

2. Cost to the manufacturer of calcium cyanamide

SEAC concurs that there will be financial consequences directly on the manufacturer in the short to medium term. However, SEAC considers that the profit losses of the manufacturer do not consider the possibility of mitigating actions that could reduce the net economic impacts (e.g. human and financial capital being redeployed by the manufacturer) and may overstate the impacts.

3. Cost to EU economic activity

SEAC considers that changes in profits made by the manufacturer do not necessarily reflect net changes in economic surplus across the EU economy, as manufacturers of other nitrogen fertilisers and authorised Plant Protection Products (PPPs) may gain market share as a result of the restriction. SEAC notes also a consultation comment on potential impacts due to the proposed restriction on the use of cyanamide products as intermediates for the production of other (non-fertiliser chemicals). However, SEAC is not in the position to assess the significance of this.

4. Cost to society – job losses

SEAC concurs that job losses at the manufacturer's site are likely to occur. However, SEAC considers that reporting job losses over a long period do not consider the possibility of workers obtaining new jobs or being redeployed by the manufacturer. SEAC considers that job losses at the manufacturer's site may overstate the long-term societal impacts. SEAC notes that the Dossier Submitter did not quantitatively or monetarily account for a possible increase in jobs at (competing) manufacturers of nitrogen fertilisers and authorised Plant Protection Products (PPP) or those who work with alternative measures to achieve the secondary benefits.

In the consultation on the SEAC draft opinion additional data estimating direct job losses in manufacturing as well as in agriculture was provided (#634), using a range of scenarios (optimistic case, realistic case and worst case) and estimated the impact on workers employed by the registrant to be between the range of €25m to €134m. Additional information was also provided suggesting categories of workers that are likely to be affected (i.e. full time workers, contract workers and seasonal workers). SEAC considers that this data could contribute to an evidence base from which to assess job losses at the manufacturer's site and as such it contributes to an understanding of possible local/regional unemployment effects and possible categories of workers affected. However, SEAC considers it a partial analysis as it does not account for adjustments in the economy (e.g. impacts on producers of alternatives, changes in other, related input use) and as such it does not describe net effects to the society.

5. Cost to the supply chain

SEAC concurs with the Dossier Submitter that the impacts on the supply chain would not be significant as the inputs used in the production of calcium cyanamide are likely to be used in alternative manufacturing processes.

6. Supply risk to the pharmaceutical industry

In the consultation on SEAC draft opinion several comments (#518; #580; #585) referred to a possible EU-based supply risk for the pharmaceutical industry (for the production of metformin, which is an anti-diabetic drug product) in the case that the registrant shuts down the entire production of calcium cyanamide, implying a dependency on imports from non-EU countries. Furthermore, according to (#518) the manufacturer supplies specialist NCN-chemicals for detection of viruses in the diagnostic industry in EU. SEAC notes that the restriction is on the use of calcium cyanamide as a fertiliser and as such, the indirect effects of the use of calcium cyanamide in the pharmaceutical industry are difficult to assess as they depend on interactions/adjustments of several parties. While described impacts may materialise, SEAC has an insufficient evidence base from which to assess the importance of potential impacts on the pharmaceutical industry.

2.3.3.2. Benefits

Summary of proposal:

The Dossier Submitter highlighted various benefits of the restriction. The first category of benefits relate to the environment and accrue as a result of a reduction in risks to soil micro-organisms, macro-organisms (e.g. spiders or beetles), aquatic organisms and non-target species (i.e. species that are not intentionally targeted for control by a pesticide or herbicide, but which may suffer damage because of exposure to it) associated with the use of calcium cyanamide as a fertiliser. There are also potential benefits to human health through the protection of groundwater used for drinking water supply. A second category of benefits relate to regulation and the functioning of the internal market.

SEAC conclusions:

SEAC concurs with the Dossier Submitter that the net change in environmental risks as a result of the proposed restriction is uncertain as the potential environmental risks of the alternatives were not fully assessed by the Dossier Submitter. SEAC recognises that the net (overall) benefits of the restriction are defined by both the environmental benefits as well as any potential disbenefits i.e. arising from the use of alternatives to calcium cyanamide. However, as the net changes in environmental risks have not been assessed, it is not feasible to determine or monetise the net change in environmental benefits or disbenefits. Based on this, SEAC considers that the net change in environmental benefits and resource benefits (the status of groundwater bodies and drinking water quality) as a result of the proposed restriction is uncertain.

SEAC supports the Dossier Submitter assumption that the restriction could contribute to regulatory control of fertilisers and PPPs, market surveillance and the functioning of the single market (e.g. competition effects). The benefit categories are summarised in *Table* 7.

Table 7 Benefit Categories, Estimates and Uncertainties

Benefit Categories	Benefit Estimates	Uncertainties/assumptions
Environmental risk reduction	Quantified modelled data provided from RAC stating that the risk exists. No description of impacts. No monetised benefits data provided.	Impact: risk would be removed from 230 000 hectares. Net environmental risk reduction is uncertain. Qualitative data provided, assuming that farmers would switch to alternatives (e.g. nitrogen fertilisers, PPPs or alternative methods). The use of alternatives to calcium cyanamide would also result in environmental risks. In the consultation on the SEAC draft opinion several comments were received (#519; #589; #595) suggesting types of environmental risks that could arise from the use of alternatives.
Regulatory control	No quantified or monetised data provided.	Assumed to contribute to regulatory control of fertilisers and PPPs.
Positive functioning of the internal market	No quantified or monetised data provided.[32]	Qualitative data provided on PPPs regulation, which aims to improve the functioning of the internal market through harmonisation of rules associated with placing of PPPs on the market. The Fertilising Product Regulation (2019/1009) complements this in terms of the management of dual function fertilisers. Assumed to improve competition in the EU and market surveillance.
Endocrine disrupting properties	No quantified or monetised data estimates provided.	Only mentioned, not assessed in the Annex XV report as the regulatory process for identifying the endocrine disrupting properties of cyanamide was still on-going at the time of the submission of the Annex XV report. Increases uncertainties. Qualitatively described that on the societal level, the identification of cyanamide as having endocrine disrupting properties, would imply further avoided costs (i.e. additional benefits for society) due to the restriction.

Key elements underpinning the SEAC conclusions:

1. Environmental risks

SEAC's evaluation considered two main elements of the Dossier Submitters' assessment. Firstly, related to the assumption that, in the event of the proposed restriction, farmers would switch from using calcium cyanamide to (a combination, as relevant) of alternative nitrogen fertilisers and PPPs and, secondly, the characterisation of environmental risks.

1.1. Switching

SEAC concurs with the Dossier Submitter that as a result of farmers switching from calcium cyanamide to some combination of alternative nitrogen fertilisers and PPPs, the overall net environmental risk reduction of the proposed restriction is uncertain. SEAC's assessment is based on the hypothesis that as a result of the proposed restriction, farmers who today use calcium cyanamide would instead use other farming inputs, based on some combination of authorised PPPs and alternative nitrogen fertilisers or other farm production measures that are specific to their farming needs. SEAC notes that the Dossier Submitter states that there

[32] Some supporting evidence for this is found in a recent assessment that shows that the administrative costs created by national sector-specific requirements in the areas of regulated business services and construction services can go up to € 10 000 and more. Per company level total compliance costs for European businesses are estimated to amount to 0.48 % of turnover.[32] SEAC notes however, that no specific estimates have been provided by the Dossier Submitter for the agricultural/fertiliser sectors.

is no information on the actual use of PPPs and application rates that would be needed to provide similar 'secondary effects' to calcium cyanamide under different agronomic and environmental conditions. In the consultation on the SEAC draft opinion several comments (#559; #587, #589, #634; #636) suggested that farmers would use increased quantities of PPPs as a consequence of a ban on calcium cyanamide and others that calcium cyanamide has PPP-type attributes/services. Others (#589; #595; #631) discussed alternative farm production measures. These inputs contribute to answering points 1(d) and 2(d) in the specific information requested in the consultation on the SEAC draft opinion.

1.2. Environmental risks

SEAC acknowledges RAC's evaluation that environmental risks associated with the use of calcium cyanamide relate to macro organisms in soil and the aquatic environment and soil microorganisms. SEAC notes that there is an absence of site level evidence, any unintended or unplanned environmental pressures, risks and impacts on specific environmental media, including soil, groundwater and surface water. Therefore, it is not possible to describe environmental impacts, estimate the magnitude of the impacts, or value the impacts (in quantitative or monetary terms). In the consultation on SEAC draft opinion comment #634 attempted to estimate the environmental costs of nitrate leaching and NO_x emissions due to the use of alternative fertilisers rather than calcium cyanamide. The cost was stated to be slightly over €100m per year. SEAC acknowledges that as an indirect consequence of the restriction, due to use of some alternatives, there is likely to be an effect on other environmental risks[33]. Similarly, additional input was received (#519; #542; #577) suggesting that substitutes for calcium cyanamide will contribute to environmental risks. SEAC considers that information provided in the aforementioned comments contribute to an evidence base from which to assess environmental risks.

2. Functioning of the internal market and harmonisation of rules.

SEAC notes the dual function of calcium cyanamide fertiliser: the fertiliser effect and the secondary effects. SEAC also notes that calcium cyanamide is not approved as an active substance for use as a Plant Protection Product (PPP), and that the manufacturer has not applied for such authorisation for their fertiliser product (PERLKA). Under a do-nothing baseline scenario, the manufacturer is expected to continue to supply fertiliser product containing calcium cyanamide which has PPP-type attributes, without neither having applied for approval of calcium cyanamide as an active substance or authorisation for their product for use as a PPP.

SEAC notes the Dossier Submitter's comment that "the use of an authorised plant protection product implies that both the active substance and each PPP have been specifically assessed, giving the possibility to risk managers to take decisions based on more predictable assessments of efficacy and potential environmental effects on non-target organisms." SEAC concurs with the Dossier Submitter that regulating calcium cyanamide under relevant regulatory instruments (e.g. Plant Protection Products) would add transparency.

2.3.3.3. Other impacts

See above.

[33] Assuming that alternatives would mostly consist of nitrogen fertilisers already commonly used on most of the arable land in the EU, an effect on "other environmental risks" would basically mean some increase in the currently known environmental risks.

2.3.3.4. Overall proportionality

Summary of proposal:

The Dossier Submitter concluded 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 Dossier Submitter's analysis is mainly concerned with the productivity losses incurred by the end users (farmers) as (i) the productivity loss in farming would directly affect economic efficiency in society and (ii) this appears to be a significant cost element. Proportionality appears to be difficult to demonstrate quantitatively, in practice, as (i) the response of farmers to the proposed restriction is not known and (ii) the net environmental risks of the proposed restriction are not easily quantifiable. This is because the use of any (combination of) alternatives imply their own environmental risks.

Considering only the costs, the profit losses per hectare induced by the restriction appear to be relatively high as provided in the Background Document (€220/ha[34]). Besides these farm level efficiency losses, there are further negative effects due to potential local/regional unemployment and potential efficiency losses in nitrogen use.

On affordability grounds, the Dossier Submitter expects that the effects of the proposed restriction on profits may be significant to the farmers using calcium cyanamide as a fertiliser. However, as most of the EU farmers use other nitrogen fertilisers, switching to alternative fertilisers is, in principle, an option. The Dossier Submitter concludes that, on average, the proposed restriction is feasible to a farmer considering that the continuation of farming activities should be possible using alternatives.

On socio-economic cost-efficiency grounds the Dossier Submitter concludes that the quantitative assessment remains challenging as the size and value of the environmental net impacts are not well understood.

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.

The recent finding, that one of transformation products of calcium cyanamide is an endocrine disruptor would increase the expected benefits. This makes the proportionality assessment more robust and improves the proportionality of the proposed restriction.

RAC and SEAC conclusions:

RAC recommends 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.

SEAC concurs with the Dossier Submitter that, whilst the use of calcium cyanamide is not adequately controlled, the overall net environmental risk reduction of the proposed restriction is uncertain.

[34] This uses aggregate farm level profit loss estimates related to substitution of calcium cyanamide with alternative nitrogen fertiliser calculated by the Dossier Submitter (€50m/year), and the Dossier Submitter's estimate of the number of hectares affected (230 000). The cost per hectare estimate is €70/ha if the SEAC cost estimate of €16m/year is used.

SEAC concurs with the Dossier Submitter that end users (farmers) will be negatively affected by the restriction.

SEAC recognises that there is insufficient information to make definite conclusions on the proportionality of the proposed restriction option, RO4.

SEAC estimates aggregate farm level costs (€16m per year, €70/ha) resulting from productivity losses due to the proposed restriction. SEAC notes that the original Dossier Submitter estimates (€50m per year, €220/ha) are somewhat higher, and also that in the consultation on the SEAC draft opinion even higher cost estimates were suggested in one comment (above €200m per year).

SEAC recognises that the quantitative productivity loss estimates provided in the consultation, noting their generally non-scientific nature, suggest somewhat higher farm level productivity losses than previously estimated by SEAC. As a result, SEAC includes in the further discussion both its own cost estimates (€70/ha) and the cost estimates provided in the original restriction proposal by the Dossier Submitter (€220/ha).

SEAC notes comments received in the consultation on the SEAC draft opinion concerning potential environmental risks of the use of alternatives.

SEAC concurs with the Dossier Submitter that one manufacturer will be negatively affected by the restriction.

SEAC concurs with the Dossier Submitter's assumption that the restriction will contribute to regulatory control of fertilisers and PPPs.

SEAC concurs with the Dossier Submitter's assumption that the restriction will contribute positively to the functioning of the internal market.

SEAC identifies cost elements for assessment of overall proportionality.

SEAC notes the absence of estimates of environmental net risks and monetised environmental net benefit estimates from which to compare with the costs of the restriction i.e. absence of suitable benchmark values. For example, comparing only farm level productivity losses (estimated at €70-€220/ha), for the restriction to be proportionate, monetised environmental and resource benefits should be at a similar level. However, typically, monetised information on environmental or resource benefits in the aquatic environment and for water resources is not readily available for use in decision making. Thus, there is an imbalance in the availability of benefit values (versus cost data) for decision making and moreover, for the assessment of overall proportionality.

Concerning the timing, SEAC notes that in case the restriction was undertaken, the transition period of 36 months would be needed for the parties involved to be able to adjust.

Table 8 summarises the opinion in terms of proportionality.

Table 8: Summary of proportionality

Cost	Benefits to society
➢ **Costs to farmers** (farmers will incur profit losses due to the restriction. Partial analysis shows costs of €16-50 million, however, some further costs and benefits are assessed qualitatively). ➢ **Costs to the manufacturer** (manufacturer will incur direct profit losses; however, it is assumed that the manufacturer could redeploy financial and human capital, thus potentially mitigating part of the net impact). ➢ **Costs to EU economic activity**: (limited as it is assumed that the manufacturers' loss in market share will be offset by gains by other manufacturers in the EU). ➢ **Unemployment** (workers will be unemployed, however, temporarily). ➢ **Supply chain** (costs on the supply chain are assumed to be limited).	➢ **Environmental risks** (net environmental risk reduction is uncertain, as it is assumed that the farmers will switch to alternative nitrogen fertilisers and farm inputs to substitute for the secondary effects of calcium cyanamide. SEAC notes that traditional alternative nitrogen fertilisers appear to offer lower nitrogen efficiency, and therefore, adoption of alternatives is expected to increase those environmental costs, and in turn decrease the net environmental benefits from the restriction.) ➢ **Contribution to regulatory control** of fertiliser and PPPs. ➢ **Contribute to functioning of the internal market**. ➢ **Risks associated with potential ED properties**. In December 2019, the Biocidal Product Committee confirmed that cyanamide is an ED for human health and non-target organisms. Due to the timing, this was not part of the Dossier Submitter assessment. This can be seen to add some uncertainties to the opinion.

Key elements underpinning the RAC and SEAC conclusions:

RAC: 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.

SEAC supports the Dossier Submitter assumption that due to the dual function of the calcium cyanamide – nitrogen fertiliser and PPP-type secondary effects - the substitution of calcium cyanamide is likely to be with some combination of nitrogen fertilisers and authorised Plant Protection Products (PPPs) or other production inputs that are specifically assessed and authorised for use under relevant regulatory instruments. In the context of PPPs, this regulation clarifies that substances with intended uses including destroying undesired plants or parts of plants, should be covered by the specific provisions regulating the authorisation and marketing of a Plant Protection Products. SEAC supports the Dossier Submitter assumption that net change in environmental risks will be affected by the substitution of calcium cyanamide with some combination of nitrogen fertilisers and authorised Plant Protection Products (PPPs) or other production inputs that are specifically assessed and authorised for use under relevant regulatory instruments.

SEAC concurs with the Dossier Submitter that one manufacturer will be affected by the proposed restriction. SEAC concurs that the manufacturer would incur some costs in the short term, SEAC cannot exclude that the negative effects on the manufacturer could be mitigated through a combination of actions by the manufacturer, such as redeployment of financial and human capital.

SEAC concurs that the farmers are likely to incur some costs in the short to medium term, however the negative effects on the farmers could be reduced through a combination of actions by the farmers, for example, switching to the use of (a combination, as relevant) of alternative nitrogen fertilisers and authorised PPPs or alternative measures. SEAC concurs with the Dossier Submitter's assumption that substitute products for farmers are generally available on the market. These substitute products are, for example, nitrogen fertilisers and authorised Plant Protection Products or alternative farm measures.

SEAC notes that in case the proposed restriction would be implemented a transition period of 36 months is expected to be needed to allow 1) the manufacturer to plan for possible redeployment of capital (human and financial) resources; and 2) for the users (farmers) to adjust their production processes e.g. potentially moving to new products as/if needed.

2.3.3.5. Uncertainties in the proportionality section

RAC notes that 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.

SEAC notes that it is uncertain how effectively and efficiently the manufacturer could redeploy human and financial resources. SEAC also notes that the proportion of farmers who would be unable to successfully adjust their production is uncertain. Finally, SEAC notes that the ongoing discussion on cyanamide as a potential endocrine disruptor for human health and non-target organisms may affect the proportionality assessment.

2.3.4. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter concluded that the proposed restriction is implementable and enforceable. It will directly affect one manufacturer (and its supply chain) and indirectly a small proportion of farmers in the EU. Restricting the placing on the market makes the enforcement and monitoring easier compared to an alternative approach which would apply farm level regulatory measures and therefore the enforcement is considered feasible.

RAC and SEAC conclusions:

RAC and SEAC find the restriction to be implementable and enforceable. RAC notes implementation and enforceability of the restriction might be challenged where there are instances of use of stockpiled calcium cyanamide fertilisers by farmers beyond the transition period for placing on the market. 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.

SEAC also notes, that calcium cyanamide is only used by a small proportion of farmers in the EU for growing specific crops. Alternative nitrogen fertilisers and authorised PPPs are available to farmers in the EU. Similarly, additional measures may also be available to the farmers to substitute for the benefits of using calcium cyanamide. SEAC also finds the enforceability to be simpler as the restriction relates to only one manufacturer.

Key elements underpinning the RAC and SEAC conclusions:

RAC: 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, therefore, the enforcement is considered to be reasonably straight forward. This was reflected in the Forum's advice.

SEAC agrees that enforcement of placing on the market could be carried out by REACH inspections in the usual manner.

In case the derogation for closed systems were maintained also enforcement activities related to individual farmers might be relevant.

The original proposal only banned the placing on the market for use but did not ban the use as such. The Dossier Submitter has revised the proposed restriction text to clarify that the use, as such, is also intended to be restricted.

In case of a derogation for use in closed systems, Forum recommended to consider that the derogated use is limited to professional users only and that the fertiliser is not sold to the general public (i.e. only for professional use). However, this is not anymore relevant as the proposed derogation is withdrawn by the Dossier Submitter.

2.3.5. 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. Analytical methods are available which can verify whether a fertiliser contains calcium cyanamide. However, RAC notes that there might be instances of use of stockpiled calcium cyanamide by farmers beyond the transition period and this can only be identified through Member State.

Key elements underpinning the RAC and SEAC conclusions:

RAC notes the Forum view 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. SEAC notes that the proposed restriction in principle follows the conventional way of ensuring that chemicals are used safely. As such, existing procedures can be used.

2.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

2.4.1. 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 is known about the processes that underly 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 DT50 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.

2.4.2. SEAC

Summary of proposal:

The Dossier Submitter notes several uncertainties:

- The net change in environmental risks from restricting the use of calcium cyanamide.
- The net cost to the farmers of replacing calcium cyanamide with alternatives.
- The net cost to the manufacturer of the proposed restriction.

SEAC conclusions:

SEAC concurs with the Dossier Submitter that the net environmental risk reduction from removing calcium cyanamide from the market is uncertain.

SEAC concurs with the Dossier Submitter that there are uncertainties regarding the costs to the farmer of removing calcium cyanamide from the market.

SEAC concurs with the Dossier Submitter that there are uncertainties regarding the costs to the manufacturer from the proposed restriction.

Key elements underpinning the SEAC conclusions:

SEAC notes that the net environmental risk reduction of removing calcium cyanamide from the market is uncertain as the users (i.e. farmers) are likely to switch to some combination of nitrogen fertilisers and authorised PPP-products, which are also associated with environmental risks (to some extent).

SEAC notes that the net cost to the farmer of removing calcium cyanamide from the market is uncertain as 1) the farmers are likely to switch to some combination of alternative nitrogen fertilisers and approved PPP-products, and 2) farmers are likely to adjust their production processes to best match the use of alternative nitrogen fertilisers and approved PPP products.

SEAC supports the Dossier Submitter assumption that substitution of calcium cyanamide is likely to be with some combination of nitrogen fertilisers and authorised Plant Protection Products (PPPs) or other production inputs that are specifically assessed and authorised for use under relevant regulatory instruments.

SEAC notes that the manufacturer will incur costs in terms of loss of market share and profits. However, the net cost to the manufacturer is uncertain and may overstate the short to medium-term cost as the manufacturer maybe able to redeploy human and financial capital to other productive uses, thus limiting the impacts on the manufacturer of the proposed restriction.

3. REFERENCES

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