Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background Document

to the Opinion on the Annex XV dossier proposing restrictions on Calcium cyanamide

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

ECHA/SEAC/[Opinion No (same as opinion number)]

EC Number	CAS Number
205-861-8	156-62-7

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Glossary of terms

AOEL	Acceptable Operator Exposure Level
a.s.	Active substance
BPR	Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.
BPC	ECHA's Biocidal Products Committee
bw	Body weight
$CaCN_2$	Calcium cyanamide
CAP	Common Agricultural Policy, EU
CAS	Chemical Abstract Services
CLP Regulation	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CRF	Controlled release fertiliser
CSA	Chemical safety assessment
CSR	Chemical safety report
d	Day
DCD	Cyanoguanidine (also known as dicyandiamide)
dw	Dry weight
ECHA	European Chemicals Agency
EU	European Union
FOCUS	Forum for the coordination of pesticide models and their use
GLP	Good Laboratory Practice
h	Hour
ha	Hectare
EC10 or EC50	The concentration at which 10% (or 50%) effect was observed or derived statistically when compared to the control group.
ETO-RAC	Ecological Threshold Option - Regulatory Acceptable Concentrations
ERO-RAC	Ecological Recovery Option - Regulatory Acceptable Concentrations
NOEC	No Observed Effect Concentration
NOEAEC	No Observed Ecologically Adverse Effect Concentration

PEC	Predicted Environmental Concentration
PEC_{twa}	Time Weighted Average Predicted Environmental Concentration
PERLKA®	Trade name for the formulation in which calcium cyanamide is used as a fertiliser in the EU
PNEC	Predicted No Effect Concentrations
PPP	Plant Protection Product
PPP Regulation	Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market
RAC	ECHA's Committee for Risk Assessment
RCR	Risk Characterisation Ratio
REACH Regulation	Regulation (EC) No 1907/2006 on registration, evaluation and authorisation of chemicals
RRD	REACH registration dossier
RJRD	REACH joint registration dossier
SCHER	Scientific Committee on Health and Environmental Risks
SRF	Slow release fertiliser
ww	Wet weight

Preface

The preparation of this restriction dossier on calcium cyanamide as a fertiliser was initiated on the basis of Article 69(1) of the REACH Regulation on request of the Commission[1].

The proposal has been prepared using version 2 of the Annex XV restriction report format and consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of annexes with more detailed information, analysis and detailed references that underpins the report.

This version of the report has been reviewed for confidential information.

[1] https://echa.europa.eu/documents/10162/13641/calcium_cyanamide_cion_reqst_axvdossier_en.pdf

1 Summary

The use of calcium cyanamide as a fertiliser[2] (Trade Name: PERLKA®) is regulated by Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down the rules on making available on the market fertilising products[3] and therefore benefits from free circulation in the EU Single Market.

Circa 130 000 tonnes of calcium cyanamide are manufactured annually in the EU of which about 53 000 tonnes are for use as a fertiliser, rest largely for industrial use. This is supplied mainly to professional farmers and estimated to be used for fertilising over 230 000 hectares[4].

Calcium cyanamide is a slow release nitrogen fertiliser used for a number of EU agricultural crops. There is some evidence that it is effective in increasing yields of some crops (e.g. cabbage, lettuce), especially when grown in a stressed environment (e.g. large numbers of weeds, lack of rotation). Besides being a fertiliser, the single REACH Registrant for calcium cyanamide, AlzChem Trostberg GmbH (in this report referred as 'the Registrant'), states that calcium cyanamide has herbicidal, fungicidal and molluscicidal side effects, as well as other side effects helping plant growth e.g. by preventing wireworm in potatoes. These side effects, potentially useful for a farmer, are here called as "secondary effects" or "secondary benefits". Several of the consultation comments underlined the existence of such secondary effects. Besides the aforementioned effects, for instance the comment #2945 noted the secondary benefit due to reduced nitrates level in lettuce. However, calcium cyanamide is not approved for use in Plant Protection Products (PPPs), and the Registrant has not applied for such an authorisation for PERLKA®.

Calcium cyanamide is classified as Acute Tox. 4, STOT SE 3 and Eye Dam 1, whilst the closely related substance, 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. Calcium cyanamide breaks down to calcium hydroxide and cyanamide in soil.

The Dossier Submitter has found that the use of calcium cyanamide as a fertiliser (using application rates/methods recommended by the Registrant[5]) 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). 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

[2] In the 2019 Fertiliser regulation 'fertilising product' means a substance, mixture, micro- organism or any other material, applied or intended to be applied on plants or their rhizosphere or on mushrooms or their mycosphere, or intended to constitute the rhizosphere or mycosphere, either on its own or mixed with another material, for the purpose of providing the plants or mushrooms with nutrient or improving their nutrition efficiency;

[3] The Regulation is available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.170.01.0001.01.ENG&toc=OJ:L:2019:170:TOC

[4] 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).

[5] Higher than recommended application rates were also used in some cases to present a worst case situation. This was noted in several consultation comments.

cyanamide, namely urea and cyanoguanidine (DCD[6]). The risks are primarily to aquatic and soil macro organisms (cyanamide), aquatic microorganisms (urea)[7] and soil microorganisms (DCD)[8].

In relation to the risk to groundwater, the Dossier Submitter has modelled the exposure and found that cyanamide and DCD pose a risk to groundwater that is not adequately controlled when calcium cyanamide is used to fertilise apple crop (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[9] and in the EU Drinking Water Quality Directive[10]). Indeed, the threshold value of 0.1 µg/L was exceeded in some of the modelled scenarios.

However, because calcium cyanamide is not being used as a pesticide in this context, the Dossier Submitter has explored an alternative approach: to derive limit values for cyanamide and DCD in drinking water and thereby considered the potential risk to human health by indirect exposure[11]. The Dossier Submitter has relied upon a method for setting limit values in drinking water in the WHO Guidelines for Drinking Water Quality[12]. Using the WHO approach and the DNEL (oral, cyanamide) for the general population, the Dossier Submitter has calculated the drinking water limit value for the general population is 510 µg/L. Cyanamide does not exceed this limit value in the scenarios modelled. However, to be noted 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. Additional information are reported in paragraph 3.2.11. Risk Characterisation.

Cyanamide has been identified as an endocrine disruptor for human health and non-target organisms by the Biocidal Product Committee (BPC) in December 2019[13]. Following the adoption of the BPC opinion, the European Commission may proceed to decision making within a few months, this would further strengthen the case that the use of calcium cyanamide as a fertiliser leads to a risk that is not adequately controlled. This might have implications for the

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[6] DCD is a trade name of cyanoguanidine which is also known as dicyandiamide.

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

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

[9] Directive 2006/118/EC of the European Parliament and Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19).

[10] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption; (OJ 330/32 of 5.12.98) or the proposed amendment: COM(2017) 753 final 2017/0332 (COD) of 1 February 2018.

[11] Assuming the groundwater is used as a source of drinking water.

[12] WHO Guidelines for drinking water quality, 4th edition (2017): https://www.who.int/water_sanitation_health/publications/drinking-water-quality-guidelines-4-including-1st-addendum/en/.

[13] 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.

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. Additionally, it might also impact the workers' exposure which might need to be reassessed. Based on these findings, the Dossier Submitter has 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. Other restriction options considered would not adequately control risks in both the aquatic and terrestrial compartments, as follows:

- A restriction that sets a concentration limit is not relevant as additional product can be applied to reach the required application rate;
- A generic application rate limit value can be established to protect soil[14] of 0.49 kg/ha PERLKA® above which adverse effects occur on soil-dwelling organisms, but this is well below the lowest application rate recommended by the Registrant of 100 kg/ha; and
- For the protection of watercourses adjacent to fertilised crops a limit value would be very difficult to establish in practice because individual limits would be needed for each crop, application rate, application method, soil type, with or without the use of risk management measures such as vegetated buffer strips etc. and in any case such limit values would only control the risk from run-off to the aquatic environment but not the risk to the terrestrial compartment.

By extension, the restriction should also include use by consumers because such use, if permitted, would also entail a release to the environment.

The proposed restriction would result in significant impacts for affected farmers. The general impact in terms of costs to the manufacturer and reduced profits to end users (farmers) due to decreased quantity and quality of yields is expected to be substantial. Whereas the price of calcium cyanamide tends to be higher than those of alternative fertilisers and soil improvers, potential increase (value of the) yield as well as potential cost savings arising from less use of PPPs generally more than compensate for the higher costs.

The value of the benefits from the proposed restriction cannot be quantified but qualitatively have been assessed to include better environmental quality in surface water adjacent to the fertilised fields and better soil quality (based on the positive effects on soil invertebrates and micro-organisms) compared to the use scenario. It is assumed by the Dossier submitter that farmers would predominantly move to a combination of a different fertilisers and PPPs, and therefore the overall risk reduction potential is uncertain. Basically, end-users can replace $CaCN_2$ fertilisers with other slow-release or "non-slow-release" fertilisers. Slow-release alternatives are expected to be able to provide similar release properties, however, one needs to pay attention how they are manufactured. The use of non-slow-release alternatives tend to pose risks to the environment from increased nitrate leaching. Neither of these type of alternatives offer the so called secondary benefits (sanitary, phytosanitary effects, improved plant health) claimed by the $CaCN_2$ users. However, as the very mechanism and the extend of the secondary benefits are unknown, the use of authorised PPPs is preferred and potential adverse environmental effects from them are expected to be less than or at the most equal comparing to the use of calcium cyanamide.

The proposed measure is effective in removing the calcium cyanamide-induced risk from the total current use area. The Dossier Submitter has noted that not all farmers use calcium cyanamide even for the same conditions and crops and altogether the $CaCN_2$ is used on only

[14] See Annex A.10.3.

about 0.2% of the EU arable land. This is taken to reveal that there are (approved) alternatives available and in use. Most of the farmers use general N-fertilisers like urea, or ammonium nitrates, however, also more sophisticated industrial slow-release fertilisers are on the market.

The risk to soil organisms has been demonstrated based on risk assessment approaches outlined in REACH guidance, supplemented by FOCUS modelling; a modelling tool that is used when there is an intentional application of a substance to the environment and is normally used for PPP assessments. The Dossier Submitter understands that the protection objective during a PPP assessment is to maintain populations of soil-dwelling organisms, which is not considered to be different from the protection objective under a REACH-based assessment. Nevertheless, if a less stringent environmental protection objective was applied to agricultural soils, a restriction would still be justified on the basis of the risks predict to occur in the aquatic environment (i.e. in watercourses adjacent to treated fields). In a scenario where only aquatic risks are considered, appropriate risk management could comprise of a requirement to use a specific application method (i.e. deep placement) in combination with vegetated buffer strips at the field margins. The Dossier Submitter has qualitatively assessed this risk management option, and hopes to receive further information on this option in the consultation.

The proposed restriction is simple and clear and, as such, it is implementable and enforceable. It directly affects one manufacturer and indirectly a large number of farmers. However, as the restriction is on placing on the market (and on the use), there are no monitorability or enforcement concerns at the end user level. The Dossier Submitter has concluded that a transition period of 36 months is needed such that the manufacturer as well as the end users have reasonable time to adjust to the change. To manage the costs of the restriction, the manufacturer as well as retailers should be able to sell materials currently in stock, and end users should have enough time to acquire knowledge as well as potential machinery needed to use any of the alternatives or to move to alternative crops or production methods.

The restriction may also affect the EC Regulation annex where all the approved EC Fertilisers are listed.

If the manufacturer continues production of the fertiliser for exports, the enforcement will have to account for that.

The restriction is manageable and monitorable.

Proposed restriction

Brief title: restriction on the use of calcium cyanamide as a fertiliser

Column 1	Column 2
Calcium cyanamide EC number: 205-861-8 CAS number: 156-62-7	1. Shall not be placed on the market as a substance on its own or in a mixture for use as a fertiliser; 2. Shall not be used as a substance on its own or in a mixture as a fertiliser; 3. The restriction shall apply after dd/mm/yyyy[15]

[15] The Dossier submitter proposes a 36-month transition period to utilise products now on the shelves, and for end-users to acquire information, machinery and knowledge of alternative technologies to be able to replace $CaCN_2$ use.

2 Report

3 The problem identified

3.1 Introduction

This restriction concerns the placing on the market of calcium cyanamide used as a fertiliser and the use of calcium cyanamide as a fertiliser where the Dossier Submitter has identified that risks are not adequately controlled in the aquatic compartment adjacent to fertilised fields and in agricultural soils to which the fertiliser is applied. Risk management is required at the Union level.

Calcium cyanamide is used as a (slow-release) nitrogen fertiliser and sold in the EU under the trade name 'PERLKA®'. Calcium cyanamide is regulated by Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down the rules on making available on the market fertilising products and hence benefits from free circulation in the EU Single Market.

Concerns about the possible health and environmental risks of calcium cyanamide as a fertiliser were raised in a report by the Scientific Committee on Health and Environmental Risks (SCHER) in 2016 (SCHER 2016). SCHER concluded that harmful effects for humans and the environment could not be excluded.

In light of this report, the European Commission requested ECHA to carry out a preliminary assessment of the risks posed by calcium cyanamide to human health and the environment. The preliminary assessment was published in January 2018 (ECHA 2018) and concluded that previous assessments may have underestimated the risk that the use of calcium cyanamide as a fertiliser poses to the environment. ECHA's concern was that a risk may be apparent in a greater number of the aquatic exposure scenarios than previously identified and that these risks may occur for a longer period after the application of the fertiliser than previously understood. Because of the limited data set used by SCHER, there were also uncertainties associated with the possible risk of calcium cyanamide to a wider range of terrestrial organisms. In addition, the ECHA assessment noted that that SCHER, may have overestimated the potential for worker exposure in their assessment. Although a much smaller proportion of the total use, SCHER pointed out the risk associated with the powdered form of calcium cyanamide needed to be further investigated on account of the significantly smaller particle size of this form, which could pose a correspondingly greater risk to human health. In the absence of data, neither SCHER nor ECHA were able to assess the risk posed by this form [16].

Based on the findings reported by ECHA in the final draft, the European Commission requested ECHA, in November 2017, to prepare an Annex XV restriction dossier limited in scope to the possible risk to the environment of using calcium cyanamide as a fertiliser.

The hazard and risks of one of the primary transformation products of calcium cyanamide, cyanamide, have also been recently reviewed under other regulatory regimes. The proposed biocidal product and plant protection product (PPP) use of cyanamide has undergone several separate regulatory assessments within the EU in recent years leading to an approval under the Biocidal Products Regulation (BPR, 2016) and the non-inclusion in the list of approved

[16] The SCHER report mentioned inhalation concerns connected to use of a powdered form of PERKLA. However, the registrant informed the Dossier Submitter on 14 Dec 2017 that the sale of the powdered version PERKLA was to end in January 2018. The Registrant's REACH registration dossier (Alzchem, 2019a) states that the powdered form of calcium cyanamide is a use that is advised against.

active substances for use in plant protection products (PPP) (PPP, 2008-10). Also, in 2015, cyanamide was assessed for a harmonised classification under the CLP Regulation[17] (CLH 2015).

For the preparation of this report, ECHA has mainly used REACH registration data, supplemented with information from scientific studies and the aforementioned regulatory processes, including the assessment made by SCHER 2016.

During the preparation of this report, the Registrant has made eight major updates[18] to its REACH registration dossier, most recently on 27 June 2019. The updates either provided new information that was intended to inform this assessment, or in some cases replace previously submitted information e.g. the exposure modelling provided in the May 2018 update was replaced by further exposure modelling in the October 2018 update. In addition, the Registrant provided the Dossier Submitter separately various updates to on-going studies also during consultation. Further details are provided in the relevant sections of this report. In general, the data included in the June 2019 registration dossier update have been taken into account for the purposes of preparing this report, unless specified otherwise.

The report also takes into account all the available information on the transformation products of calcium cyanamide: primarily cyanamide, the primary transformation product, as well as other environmentally-relevant transformation products, such as urea and cyanoguanidine (DCD). Calcium cyanamide is known to be used outside of the EU as a fertiliser, and cyanamide as an active substance in biocidal products and PPPs.

The Biocidal Products Committee (BPC) on 9-13 December 2019 concluded that cyanamide is an endocrine disruptor for human health and non-target organisms[19]. Following the adoption of the BPC opinion, the European Commission may proceed to decision making within a few months. This conclusion supports the Dossier Submitter's conclusion that the use of calcium cyanamide as a fertiliser leads to a risk that is not adequately controlled. The Dossier Submitter will provide updates to RAC and SEAC when the biocides process advances.

Also noteworthy, is that the Registrant informed ECHA that it had stopped the sales of the powdered form in December 2017 because its small market size did not warrant the expense of preparing an elaborated risk assessment. The registration dossier was subsequently updated and the powdered form is now listed as a use that is advised against.

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[17] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures OJ L 353, 31.12.2008, p. 1–1355: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32008R1272

[18] 27 October 2017; 15 May 2018; 11 July 2018; 19 July 2018; 5 October 2018; 28 December 2018; 8 March 2019; and 27 June 2019.

[19] On 4-5 June 2019 the Endocrine Disruptor Expert Group (ED EG) agreed that the information available was sufficient to identify cyanamide as an endocrine disruptor for human health. In September 2019 both Biocides Working Groups (WGs) for Human Health and Environment concluded that cyanamide meets the criteria for endocrine disruption for the human health and for non-target organisms in the environment.

3.2 Hazard, exposure/emissions and risk

3.2.1 Identity of the substance(s), and physical and chemical properties

Calcium cyanamide is used as a fertiliser in the EU in a commercial formulation referred to as 'PERLKA®', which contains approximately 44% w/w calcium cyanamide. PERLKA® is a grey-black granulated, or 'pearl', formulation (solid at 20°C and 1 013 hPa) that is manufactured and placed on the EU market solely by the Registrant.

Calcium cyanamide dissociates in aqueous solution into calcium and cyanamide ions. Calcium cyanamide and cyanimide itself are closely related substances and the identifiers of both substances are shown below (Table 1 & Table 2). In moist soil calcium cyanamide is transformed into cyanamide and calcium hydroxide (primary transformation substances). Cyanamide is further transformed in the environment into secondary transformation substances, including urea and cyanoguanidine (DCD). Urea is further transformed in soil, via ammonium carbonate, to nitrates which are used by crops as a nitrogen source (fertiliser effect). For this reason, the identifiers for urea and DCD are also provided below (Table 3). Cyanamide, urea and DCD are environmentally-relevant transformation products and are considered throughout this assessment.

In addition to 44% calcium cyanamide, the PERLKA® formulation also contains a number of other constituents. As this study is focuses upon calcium cyanamide, any other constituents are considered outside of the scope of this report.

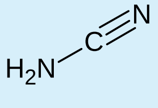
Table 1. Identifiers for calcium cyanamide[20]

[20] The information included in the REACH registration dossier indicates that the composition of the registered substance does not follow the rules for mono-constituent substances as defined in the ECHA

EC number	205-861-8
EC name	Calcium cyanamide
CAS number	156-62-7
CAS name	Cyanamide, calcium salt (1:1)
IUPAC name	Calcium cyanamide
Molecular formula	CN2.Ca
Molecular weight range	80.1021
Structural formula	Ca^{2+} $^{-}N=C=N^{-}$

(Source: ECHA website)

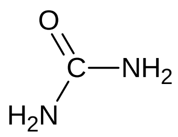
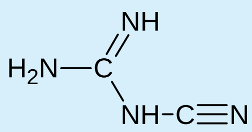
Table 2. Identifiers for cyanamide

EC number	206-992-3
EC name	Cyanamide
CAS number	420-04-2
Molecular formula	CH_2N_2
Molecular weight (g/mol)	42.041
Structural formula	

(Source: ECHA website)

Table 3. Identifiers for urea and cyanoguanidine

Guidance for identification and naming of substances under REACH and CLP. For the purpose of this assessment, the purity of the substance is not considered relevant in this context.

Urea (carbamide)	
EC number	200-315-5
EC name	Urea
CAS number	57-13-6
Molecular formula	CH4N2O
Molecular weight (g/mol)	60.06
Structural formula	
Cyanoguanidine (dicyandiamide)	
EC number	207-312-8
EC name	Cyanoguanidine
CAS number	461-58-5
Molecular formula	C2H4N4
Molecular weight (g/mol)	84.08
Structural formula	

(Source: ECHA website)

The identity and physicochemical properties of calcium cyanamide are detailed in Annex A.1.

3.2.2 Classification and labelling

The harmonised classification and labelling (CLH) of calcium cyanamide and environmentally-relevant transformation substances are given in Table 4. Self-classifications from the classification and labelling (C&L) Inventory are provided in Annex A.3.2.

The Dossier Submitter notes that because of the rapid breakdown of calcium cyanamide to cyanamide (see section 3.2.6), a revision of the harmonised classification for calcium cyanamide is also likely to be justified. The Dossier Submitter further notes that the Registrant has self-classified calcium cyanamide and PERLKA® as Aquatic Chronic 3 in line with the CLH of cyanamide.

Table 4. Entries in Annex VI of the CLP Regulation for relevant substances

International Chemical Identification	EC #	CAS #	Harmonised classification	Hazard Code and phrase*
Calcium cyanamide	205-861-8	156-62-7	Acute Tox. 4 STOT SE 3 Eye Dam. 1	Not applicable.
Cyanamide	206-992-3	420-04-2	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	H412. Harmful to aquatic life with long lasting effects.
Cyanoguanidine	207-312-8	461-58-5	Not classified.	Not applicable.
Urea	200-315-5	57-13-6	Not classified.	Not applicable.

(Source ECHA website, C&L Inventory). Notes: *Environmental endpoints only.

3.2.3 Reliability of the studies cited in this report

The studies reported in this report have been retrieved from the Registrant's REACH registration dossier (Alzchem, 2019a & 2019b[21]), previous EU regulatory reviews: (BPR, 2016; CLH, 2015; PPP 2008-10; SCHER, 2016), other relevant REACH registration dossiers (RRD urea, 2017 and RJRD DCD, 2015) and other relevant literature sources. Unpublished study reports were provided by the Registrant to the Dossier Submitter during consultation of

[21] To the extent possible.

interested parties. In general, the Dossier Submitter has assumed if the study has been acceptable in another EU regulatory process then they can be considered reliable. The key studies in the hazard assessment in this report have all been accepted in other EU regulatory processes. Studies carried out after BPR, 2016 and SCHER, 2016 have been cited occasionally in this report, usually studies that have been done on behalf of the Registrant e.g. Fraunhofer, (2018 a-d). Of these studies, those that have been used by the Dossier Submitter have been assessed on a case-by-case basis for their reliability (see text below).

3.2.4 Fate, behaviour and transformation in the environment

This section summarises the environmental transformation of calcium cyanamide in the environment. It also considers the environmental fate and behaviour of the transformation products of calcium cyanamide, i.e. cyanamide, urea and DCD. The analysis is primarily based upon the data provided in the REACH registration dossier for calcium cyanamide (Alzchem, 2019a)[22], unless otherwise indicated. A more detailed description is provided in Annex A.4.

3.2.5 Summary of fate, behaviour and transformation of calcium cyanamide in the environment

Table 5. Summary of the fate and behaviour properties of PERLKA®/calcium cyanamide and environmentally-relevant transformation products

Parameter	PERLKA®/calcium cyanamide	Cyanamide	Urea	Cyanoguanidine (DCD)
DT50 aerobic freshwater/sediment	1.0 days at 12ºC	4.3 days at 20ºC	4.8 days at 20ºC	>28 days
DT50 aerobic soil	1.45 days at 12ºC	Mean: 2.9 days at 12ºC*	Mean: 7.5 days at ~16ºC	72 days at <10ºC (+/- 14d)
Soil adsorption/ mobility potential	Quite mobile	Very mobile	Very mobile	Reasonably mobile
Bioaccumulation potential	Unlikely	Unlikely	Unlikely	Unlikely
Relevance for environmental risk characterisation	Yes	Yes	Yes	Yes

(Source: REACH registration dossiers and published literature – see text)

Table note: *A longer DT50 value using soil with low organic content - up to 12 days.

3.2.6 The fate, behaviour and transformation of PERLKA® and calcium cyanamide in the environment

In its REACH registration dossier (Alzchem, 2019a), the Registrant has assumed that calcium cyanamide in PERLKA® rapidly hydrolyses to cyanamide, but that the release of cyanamide

[22] March 2019 update.

from PERLKA® granules is slowed down by the granulated form.

The transformation of calcium cyanamide to cyanamide in water appears to be rapid. On account of this rapid hydrolysis, in many cases the Registrant presents data from environmental studies using cyanamide as the test substance and then reads across these results to calcium cyanamide. The Dossier Submitter agrees with the Registrant that the results of studies using cyanamide as the test substance can be read across to calcium cyanamide for environmental endpoints.

The delayed release of cyanamide because of the granulated form of PERLKA® is supported by a study by Becher & Winkler (2018) in which PERLKA® granules were continually washed with tap water. After 24 hours, ~65% of the calcium cyanamide had dissolved as determined by cyanamide release. Because of the rudimentary nature of this study, an approximate half-life (DT50 value) for PERLKA® in surface water is assumed by the Dossier Submitter in its exposure assessment to be 1 day at 12ºC. This is the same value that has been used by the Registrant for its exposure modelling in surface water[23].

The release of cyanamide from PERLKA® in soil has been modelled by Güthner (2018). In this study the DT50 value for PERLKA® in aerobic soil was reported to be 1.45 days at 12ºC. The Dossier Submitter accepts this value and has used it in its exposure modelling. A further study (Fraunhofer Institute 2019a) using a range of soil types, soil moisture conditions and soil pH values, reported DT50 values for PERKLA® that remained close to the values used by the Dossier Submitter[24].

Some comments (#2755, 2759, 2777, 2769, 2770, 2929) received during consultation underlined the importance of the different DT50 values for PERLKA® used by the DS and the Registrant, resulting in updated PEC values by the Registrant and leading to all calculated scenarios being safe. The Dossier Submitter has assessed the results presented in Fraunhofer (2019a) and concluded that the median value for the DT50 is close to the value used by the Dossier Submitter. Additionally, the DS underlines that such new data were not available when the modelling was conducted by the DS, therefore could not be taken into account in the exposure calculations presented in this report.[25]Urea and cyanoguanidine (DCD) concentrations were also measured after the application of PERLKA® to soil in a study reported by Güthner (2018). However, according to the Registrant the study did not account for a significant portion of the released nitrogen. Nevertheless, the results indicate maximum concentrations of urea and DCD in soil of 959 ppm and 342 ppm, respectively. These findings were used by the Dossier Submitter as supporting evidence to investigate the environmental relevance of urea and DCD. That significant quantities of urea and DCD are present following the transformation of PERLKA® in soil were supported by Fraunhofer (2019a) in which up to 15% of recovered nitrogen was in the form of urea and up to 20% DCD.

PERLKA® appears to be very stable in air and is not further considered by the Dossier

[23] In Fraunhofer (2019b) provided by the Registrant in June 2019 the temperature was adjusted to 20ºC.

[24] In Fraunhofer (2019b) provided by the Registrant in June 2019 the value was adjusted to 0.721 days at 20ºC. However based upon the results presented in Fraunhofer (2019a) the range of DT50 values was between 0.60 and 2.51 days; median 1.56 days i.e. close to the value used by the Dossier Submitter. The range was apparent with differing soil types and moisture values.

[25] The relevance of the different DT50 values used by the Dossier Submitter and by the Registrant in the modelling has been addressed by the RAC in the RAC opinion, concluding that the PEC values as predicted by the Registrant using the updated half-lives and the PECs predicted by the DS are within the same magnitude, resulting in RCRs > 1.

Submitter in this compartment.

3.2.7 The transformation of cyanamide and its transformation products in the environment

3.2.7.1 Aquatic compartment: surface water and sediment

The Registrant has presented aerobic aquatic (pond, river and sediment) transformation simulation studies using radio labelled [14C] cyanamide (Völkl, 2000)[26]. A mean half-life (DT50) value was proposed by the Registrant for the water phase of 4.3 days at ~20ºC. The Dossier Submitter uses this value in its risk assessment.

In the (Völkl, 2000) study the Registrant reported that following the degradation of the parent substance (cyanamide), urea was the only significant metabolite detected, at maximum amounts of 13.4% of applied radioactivity[27] after 1 day in a pond system and up to 6.7% in a river system after 2 days. Urea was no longer detectable at day 21 of the study. This is consistent with the conclusions of the PPP (2008-10) and BPR (2016) assessments and also with the evidence presented in the REACH registration for urea (RRD urea, 2017). From the concentrations observed, and the potential longevity of urea in the aquatic compartment, the Dossier Submitter has concluded that the possible risk of urea should be considered in the aquatic risk assessment. A mean DT50 urea of 4.8 days at 20ºC has been used by the Dossier Submitter in its risk assessment.

In the Güthner (2018) study (see section 3.2.6) DCD is formed when cyanamide is transformed in soil moisture. The BPR assessment (2016) also noted that DCD was found in sediment at levels of 0.3% of applied radioactivity (Völkl, 2000). When it occurs in surface water/sediment systems DCD is likely to be reasonably persistent and from the data presented in the Joint REACH registration for DCD (RJRD DCD, 2015), a DT50 value has been derived by the Dossier Submitter of >28 days at 22ºC.

In its REACH Registration dossier, the Registrant concluded that biological degradation plays the most important role for cyanamide transformation in aquatic systems and soils, whereas hydrolysis and photolysis are relatively minor processes. This is based upon significantly longer half-lives in abiotic degradation studies than in biological studies. The Dossier Submitter accepts these conclusions.

In its REACH registration dossier, the Registrant argues that it is not relevant to assess the risk to sediment-dwelling organisms because cyanamide has a low predicted persistence in water/sediment systems. Urea and DCD are not considered by the Registrant (Alzchem, 2019a). The Dossier Submitter agrees neither cyanamide or urea are particularly persistent in the aquatic compartment. However, since cyanamide and urea can be present for 4 days or more in the aquatic compartment, toxic effects may occur, particularly if run-off into surface water occurs over a prolonged period. Sediment toxicity of cyanamide and urea are therefore considered further. Although only being found in low concentrations, DCD is comparably persistent and on this basis should be investigated further.

Based upon the evidence above, the environmentally relevant transformation products of calcium cyanamide in the aquatic compartment are, primarily, cyanamide and, secondarily, DCD and urea. These substances are transported to the aquatic compartment via run-off from the surface of fertilised fields adjacent to surface waters or via drainage through soil under

[26] Study carried out by RCC on behalf of the Registrant.

[27] i.e. 13.4% of the original radiolabelled cyanamide.

fertilised fields. Theoretically, calcium cyanamide itself could enter adjacent surface water and then degrade, but most likely the degradation process will have already begun before a run off event, hence cyanamide and it transformation substances will enter adjacent surface water.

3.2.7.2 Terrestrial compartment

Simulation studies of the degradation of cyanamide in soil in the laboratory were reported by the Registrant (Schmidt, 1990 & 1991) using radio-labelled cyanamide [14C]. The Registrant has also provided further simulation studies by Güthner (2018) and Fraunhofer (2018a). The results of these studies were similar and on the basis of the most recent study available (Güthner 2018), the registrant has used in its risk assessment a mean DT50 value cyanamide in aerobic soil of 2.9 days at 12ºC. It is noted, however, that the soil type can increase the DT50 value for cyanamide, for example in sandy soil (low organic content) the DT50 value is increased to 12 days (Hess, 1978; Rieder,1978).

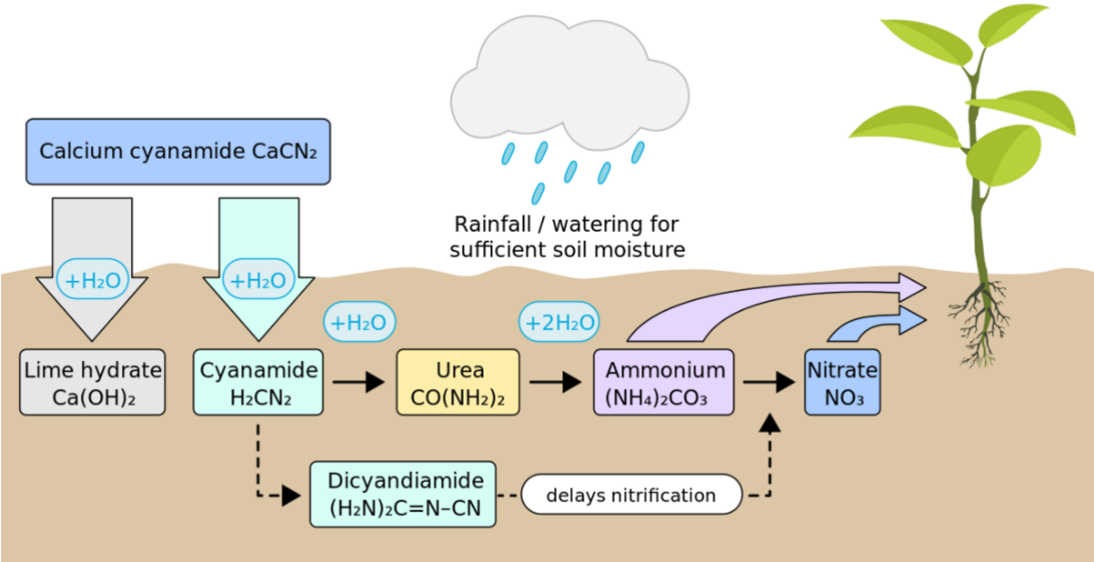
The transformation pathway of cyanamide in aerobic soil conditions has been described by Dixon (2017) – see Figure 1. In one pathway, cyanamide dimerises into DCD (6-11%) which acts as a delayed source of nitrogen. This delayed source of nitrogen is one of the beneficial properties of PERLKA® reported by the Registrant compared to other nitrogen-based fertilisers. Complete degradation of DCD is reported in the REACH registration dossier for DCD (RJRD DCD, 2017) to take between 3 days and 34 weeks depending upon temperature, soil moisture and soil type. Other studies (Kelliher et al, 2008) report mean DT50 values of 72 days at <10ºC +/- 14 days. The Dossier Submitter has used this DT50 value in its risk assessment. Given its persistence in soil and that it is present in significant quantities, DCD is considered environmentally relevant by the Dossier Submitter for the risk characterisation of soil. Some consultation comments (e.g. #2773, 2786) were observing that a DT50 for DCD of 72 days (+/- 14 d) at temperatures below 10°C seems too high. However the DS notes that according to Kelliher et al, 2008, DCD should be applied when soils are relatively cool to maximise its longevity. Low soil temperature maximises the effectiveness of DCD and thus DCD is expected to be used when soil is experiencing such environmental temperatures[28].

In the other degradation pathway for cyanamide reported by Dixon (2017), urea is first formed (89-94%) which is then transformed to nitrates via ammonium carbonate. The Registrant has proposed a DT50 value of urea in aerobic soil of 5-10 days (at ~11 - 22ºC) based on a study by Vilsmeier and Amberger (1978). The Dossier Submitter accepts these study results and a DT50 urea used by the Dossier Submitter was the mean value of 7.5 days at ~16ºC[29].

Based upon the evidence above, the environmentally relevant transformation substances of PERLKA® in soil are primarily cyanamide and secondarily DCD and urea.

[28] The DT50 value for DCD is also discussed in more detail by RAC in the RAC opinion.

[29] For FOCUS surface water modeling the model inserts a default value of 30 days for a readily biodegradable substance.



(Source: Dixon, 2017)

Figure 1. Proposed breakdown of calcium cyanamide in aerobic soil

3.2.7.3 Atmospheric compartment

In the PPP assessment (2008-10) cyanamide was reported to have the potential for volatilisation when used in a liquid formulation (Dormex®) for outdoor air-blast spraying for the stimulation of bud opening of grapes and kiwifruit. The atmospheric half-life of cyanamide was reported as significantly longer than 2 days. In the BPC assessment (2016) both the product types considered (PT 3 and 18) were a liquid formulation containing cyanamide for use in indoor animal housings. However, none of the uses considered in these regulatory reviews are believed to be applicable to the context of solid PERLKA® granules used as a fertiliser.

However, after partial or full transformation of PERLKA® to cyanamide in the presence of soil moisture, it is possible that some liquid cyanamide could volatilise in sunlight, albeit in limited amounts. For this reason, a very limited amount of loss via volatilisation has been included in the soil exposure modelling carried out by the Dossier Submitter. Because of the very low vapour pressures of urea and DCD[30] and the low concentrations present compared to cyanamide, the Dossier Submitter did not investigate the possible fate of urea and DCD in the atmospheric compartment.

3.2.7.4 Soil adsorption and mobility

The adsorption coefficient (Koc[31]) for calcium cyanamide has been estimated by the Registrant using an HPLC retention time method (Seibersdorf Labor GmbH, 2010). On this basis the Registrant explains that calcium cyanamide is not expected to have a significant potential to adsorb to soil and instead is 'quite mobile'. For cyanamide, the Registrant presented data from an adsorption/desorption screening study (Ruedel, 1990). The derived Koc ratio values for cyanamide were between 0 and <6.8. On this basis, the Registrant noted that cyanamide is likely to be 'very mobile' in soil. The Adsorption coefficients of urea and DCD have also been derived in the REACH registration dossiers for these two substances (RRD urea, 2017; RJRD

[30] Urea 0.002 Pa at 298K; DCD 0.0000085 Pa at 298K.

[31] Adsorption coefficient normalised for organic carbon content.

DCD, 2015).

These findings are consistent with the findings of the PPP assessments (2008-10), SCHER (2016) and the BPR assessments (2016). Because of this potential for high mobility and on the basis of FOCUS groundwater modelling results reported in the PPP assessment (2008-10), it was concluded there is a high potential for cyanamide to reach groundwater after representative uses in a wide range of geoclimatic conditions. On the basis of the adsorption coefficient of calcium cyanamide and FOCUS groundwater modelling results SCHER (2016) concluded that the high concentrations [of calcium cyanamide] in groundwater that occur after the application of calcium cyanamide may pose a risk. However, on the basis of the results of lysimetric and column leaching studies presented by the Registrant, SCHER considered the risk to be acceptable. However, the Dossier Submitter considers these studies may not have been sufficiently robust to adequately assess the risk of calcium cyanamide and its transformation products from reaching groundwater.

The Dossier Submitter has considered the available evidence and because of the potential mobility of calcium cyanamide and its transformation products, the Dossier Submitter has investigated the possibility of groundwater contamination following the application of PERLKA® to soil.

3.2.8 Bioaccumulation

Based on a low estimated log octanol/water coefficient (Kow) and bioconcentration values for calcium cyanamide, cyanamide, urea and DCD the Dossier Submitter considers bioaccumulation is unlikely for these substances.

3.2.9 Hazard assessment

3.2.9.1 Data available to the Dossier Submitter

For the purposes of carrying out an environmental risk assessment the Dossier Submitter has relied upon available data for both calcium cyanamide, cyanamide as well as for DCD and urea. These data have been retrieved from the Registrant's REACH registration dossier (Alzchem, 2019a & 2019b[32]), previous EU regulatory reviews: (BPR, 2016; CLH, 2015; PPP 2008-10; SCHER, 2016), other relevant REACH registration dossiers (RRD urea, 2017 and RJRD DCD, 2015) and other relevant literature sources. The Registrant provided the Dossier Submitter during consultation with an outdoor aquatic mesocosm higher tier study report (Hommen, 2019), a report on a field study to evaluate the effects of granulated calcium cyanamide fertiliser (PERLKA®) on collembola in central europe (Stegger, 2019) and the results of a *daphnia magna*, reproduction test with modified exposure in a water sediment system (based on OECD 211) (Brüggemann, 2019). These studies have been taken into account in the preparation of current background document. Various consultation comments received (e.g #2921, 2925, 2929, 2930, 2957) underlined the relevance and importance of such studies in the hazard assessment of calcium cyanamide. The Dossier Submitter has considered the comments received and provided DS's responses in the RCOM to each comment, while the studies have been assessed and reviewed in sections 3.2.9.2.1 and 3.2.9.2.5 of this report.

PNEC	Cyanamide	Urea	DCD

[32] To the extent possible.

PNECfreshwater, species & key study	10.44 µg/L Daphnia magna Murrel & Leak 1995	470.00 µg/L Microcystis aeruginosa Bringmann & Kuhn 1978	2500.00 µg/L Daphnia magna Environment Agency Japan 1998b
PNECsed, species & key study	66.4 µg/L Chironomus riparius Heintze 2001	No data	No data

(Source: see text)

3.2.9.2 Calcium cyanamide / cyanamide

A total of 16 studies (11 acute or short-term and 5 chronic) in the aquatic compartment are available to the Dossier Submitter, mainly from the Registrant's REACH registration dossier (Alzchem, 2019a). Where necessary, the results of these studies have been checked against previous regulatory reviews. These studies span three trophic levels (including a chronic study for sediment-dwelling organisms). A representative sample of the study results (most sensitive organisms over all trophic levels available) is provided below in Table 6 and the full list is provided in Table 33.

Table 6. Summary of representative aquatic compartment studies for calcium cyanamide/cyanamide

Species	Test substance	Test/duration	NOEC/NOAEL mg/L	Reference
Surface water				
Anabaena flos-aquae (cyanobacteria)	cyanamide	chronic (72 h)	0.11	Hertl (2000a)
Scenedesmus capricornutum (algae)	cyanamide	chronic (90.5 h)	1.1	Schoot Uiterkamp, A.J.M. (1988)
Daphnia magna (invertebrates)	cyanamide	acute (48 h)	1.6	Adema, M. (1983)
Daphnia magna (invertebrates)	cyanamide	chronic (21 d)	0.1044	Murell et al. (1995)

Cyprinus carpio (fish)	cyanamide	acute (96 h)	29.9	Bowmann and Herzig (1990a)
Oncorhynchus mykiss (fish)	cyanamide	chronic (21 d)	3.7	Bowmann and Herzig (1990b)
Lemna gibba (plant)	cyanamide	short-term (7 d)	0.5	Hertl (2000b)
Sediment				
Chironomus riparius (insect)	cyanamide	chronic (28 d)	6.64 based on development	Heintze, A. (2001)

(Source: Alzchem, 2019a and other EU regulatory reviews – see text)

Of all these studies, the most sensitive organism in freshwater chronic studies is *Daphnia magna* using cyanamide as the test substance. The Dossier submitter has chosen the key study to be a chronic 21d *D. magna* (Murrel & Leak, 1995) using cyanamide as the test substance because this resulted in the lowest NOEC values for aquatic organisms. The NOEC is reported as 0.1044 mg cyanamide/L[33]. Chronic studies are available for three trophic levels so an AF of 10 was used, in line with ECHA Guidance, to derive a PNECfreshwater. On this basis the PNECfreshwater cyanamide used by the Dossier Submitter was 10.44 µg/L.

The same study was used as the key study in the PPP (2008-10), CLH (2015) and BPR (2016) assessments. It was also used as the key study by the Registrant for assessing the risk to surface water of calcium cyanamide released from industrial manufacturing and use.

The Registrant has derived three PNECfreshwater values for use in their registration based on different studies. The three PNECs are: (1) PNECfreshwater for industrial manufacturing and use of the substance, associated with potential continuous release of calcium cyanamide/cyanamide to surface waters; (2) PNECfreshwater for intermittent release of calcium cyanamide/cyanamide; and (3) PNECfreshwater for fertiliser use. Both industrial manufacturing and intermittent releases fall outside of the scope of this report but further details are provided in Annex A.7.1.

For fertiliser use (3), the Registrant draws upon the results of two studies conducted to specifically assess potential adverse effects of the transformation product cyanamide under exposure conditions that realistically reflect the actual exposure of ecosystems related to the typical agricultural use of the fertiliser product PERLKA®. These studies are an outdoor mesocosm study (Hommen, 2019) and a non-standard *D. magna* 21-d reproduction study (Brüggemann, 2019). The aquatic outdoor mesocosm study (Hommen, 2019) is considered by the Registrant as the key study as lower effect values are reported for the most sensitive organism (*algae*) in comparison to the results for *D. magna* obtained by Brüggemann (2019). The justification by the Registrant is that the agricultural use of calcium cyanamide in the form of PERLKA® is invariably restricted to a single application once a year, resulting in short-term

[33] Value used in CLH, 2015.

exposure of adjacent surface waters to the transformation product hydrogen cyanamide. The Registrant's justifications are the exposure regime in the mesocosm study matches realistic agricultural use conditions; and the high diversity of taxa in the mesocosm study significantly reduces the uncertainty in the evaluation of toxic effects. On this basis the Registrant reduces the assessment factor (AF) to three or four (EFSA, 2013), which it claims is in accordance with the PPP legislation. Moreover, the Registrant claims that due to the large species diversity covered by the mesocosm study, in combination with a realistic exposure pattern, the results of the mesocosm study are associated with only little uncertainty. On these basis, the Registrant concluded that it is justified to reduce the AF to 3 specifically for the fertiliser use of PERLKA®. Considering the effect concentration of 0.32 mg cyanamide/L for the ecological recovery option (ERO) at which *acceptable short-term effects* are observed (obtained from the results of the outdoor mesocosm study), the PNECfreshwater (fertiliser use) derived by the Registrant is 0.107 mg cyanamide/L (107 µg cyanamide/L).

Under REACH, well conducted mesocosm studies can be used in a weight of evidence approach to refine or replace the PNEC derived from chronic aquatic toxicity data. However, during the evaluation of the aquatic mesocosm study by EFSA, some uncertainties were identified. In relation to the ecological threshold option (ETO), it was observed that:

- The most sensitive group from the tier-1 laboratory data (Cladocera) presented rather low abundance, despite acceptable MDD levels for some taxa.
- The most sensitive insects among the one tested (Diptera/*Chaoborus sp.*) presented decreasing abundance during the study (also in the control), which is likely linked to large share of animals emerging before the exposure phase or soon after. Hence, most animals were likely not exposed during the most sensitive life stage (early instars).
- In general, when assessing the ability of a mesocosm study to cover for vulnerable species, great attention is paid to the presence of so-called EPT (Ephemeroptera, Plecoptera, and Trichoptera). In the present study, only the mayfly *Cloeon dipterum* was present. Nevertheless, this did not show particularly adverse effects up to the 1 mg/L level.

Overall, the PNEC for the ETO-RAC[34] option (based on zooplankton PRCs[35]) corresponds to 0.016 mg/L (0.032 mg/L/2).

In relation to the ERO option, the same uncertainties discussed for the ETO option apply and additionally it was observed that:

- At the proposed NOEAEC[36] 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 certain degree of uncertainty remains.

In conclusion, the PNEC for the ERO-RAC[37] option (based on Diptera/Chaoborus sp. and phytoplankton PRCs.) corresponds to 0.025 mg/L (0.1 mg/L /4).

Due to the methodological difficulties explained in relation to the mesocom study, the Dossier Submitter decided to use as key study for the PNECfreshwater derivation the chronic 21d *D. magna* (Murrel & Leak, 1995) with cyanamide as the test substance (PNECfreshwater of 0.01

[34] ETO-RAC: Ecological Recovery Option - Regulatory Acceptable Concentration

[35] PRCs: Principal Response Curves

[36] NOEAEC: No Observed Ecologically Adverse Effect Concentration

[37] ERO-RAC: Ecological Recovery Option- Regulatory Acceptable Concentration

mg cyanamide/L).

The Dossier Submitter has conducted a sensitivity analysis exploring the significance of the size of the assessment factor used to derive the relevant PNEC value. The results of this sensitivity analysis show that applying the assessment factors that would be used if the substance were being assessed under the PPP legislation still results in risks to surface water and soil that are not adequately controlled. For surface water the PPP risk characterisation results are identical to those derived from an assessment under REACH. For further details please refer to Annex A.10.4.

Overall, based on the reasoning above and the uncertainty underlined, the mesocosm study is considered by the Dossier Submitter not to be adequate and reliable enough to be used to refine or replace the PNECfreshwater derived from chronic aquatic toxicity data. In addition, Annex I to REACH only requires a single PNEC to be derived rather than three. Further details are provided in Annex A.7.1.

3.2.9.3 Urea and DCD

The PNECfreshwater for urea was obtained from studies reported in the joint REACH registration dossier for urea (RRD urea, 2017). The most sensitive species found in the aquatic compartment was *Microcystis aeruginosa* (algae) in a chronic 192 hour study[38] resulting in a toxicity threshold of 47 mg/L (Bringmann & Kuhn, 1978). Based on these data, the registrant derived a PNECfreshwater of 0.47 mg/L (using an assessment factor of 100). The Dossier Submitter has taken this value forward for risk characterisation.

The Dossier Submitter notes that, in general, urea is considerably less toxic to aquatic species than cyanamide.

RAC BOX

RAC did not support the use of the Bringmann, G. & Kuhn, R. study (1978) as point of departure for $PNEC_{freshwater}$ derivation for urea. RAC judged that this study is a non-standard species study and when it was performed OECD and GLP guidelines were available. The combination of study limitations and poor reporting, as compared to current OECD and GLP guidelines, render this study as not reliable for risk assessment purposes. Based on the Klimisch scale a Klimisch factor of 3 is appropriate. Apparent limitations of the study are presented in the RAC Final Opinion. Consequently, RAC did not derive $PNEC_{freshwater}$ for urea due to insufficient data.

The PNECfreshwater for DCD was obtained from studies reported in the joint REACH registration dossier for DCD (RJRD DCD, 2015). The most sensitive aquatic species was found to be *Daphnia magna* in a 21-day study measuring reproduction in which the NOEC was found to be 25 mg/L (Environment Agency Japan, 1998b). On this basis the Registrant derived a PNECfreshwater of 2.5 mg/L (using an assessment factor of 10). The Dossier Submitter has taken this value forward for risk characterisation.

A more detailed summary of the studies available to the Dossier Submitter for urea and DCD is provided in Annex A.7.1.1.4.

3.2.9.4 Sediment

Although not required under REACH, the Registrant has derived a log octanol/water partition coefficient value (log Kow) -0.72 (see Table 30) for cyanamide and read across these results for calcium cyanamide. The Registrant concluded that because of this value and the low persistence of cyanamide in water/sediment systems (see 3.2.7.1) no hazard is identified and

[38] Cell multiplication inhibition test.

hence a sediment effects assessment is not required. Nevertheless, the Registrant presents a chronic study[39] by Heintze, 2001 (see Table 6) using *Chironomus riparius* (midge). In this study a NOEC (28d) value of 6.64 mg/L was derived based upon the development rate of the midges.

In the BPR (2016) and PPP (2008-10)[40] assessments a risk characterisation for cyanamide or other transformation products was not carried out for sediment-dwelling organisms, possibly on account of the low estimated persistence of cyanamide in sediment. However, in the BPR assessment (2016) a PNEC sediment (PNECsed) for cyanamide was derived from the PNECfreshwater using equilibrium partitioning, resulting in PNECsediment for cyanamide of 9.16 µg/kg w/w.

As described in section 3.2.7.1 the Dossier Submitter has considered the possible ecotoxic effects of calcium cyanamide and cyanamide on sediment-dwelling organisms in its risk assessment, but as supporting information. A chronic study is available and the NOEC from this study was 6.64 mg/L. As this is the only study in sediment available an AF of 100 is applied (see ECHA (2008)) resulting in a PNECsed for cyanamide of 66.4 µg/L. This is used by the Dossier Submitter in its risk characterisation.

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.

It was not possible to derive a PNECsed for urea or DCD as relevant data were not available.

3.2.9.5 Terrestrial compartment

Table 7. Summary of data used to derive the terrestrial predicted no effect concentration (Source: Alzchem, 2019a)

PNEC	Cyanamide	Urea	DCD
PNECsoil, species & key study	0.15 mg/kg soil Folsomia candida Moser & Scheffczyk (2009)	Insufficient data to derive PNECsoil	0.25 mg/kg soil Soil microorganisms in OECD guideline 216 Foerster (2014b)

3.2.9.5.1 Ecotoxicity of PERLKA® /cyanamide to soil-dwelling organisms assessed by the Dossier Submitter

There are 17 studies available to the Dossier Submitter for soil-dwelling organisms – 8 acute or short-term and 9 chronic. The source of the studies is mainly the Registrant's REACH registration dossier (Alzchem 2019a), but also cross-referenced with the assessments reported under the BPR (2016), CLH (2015), PPP (2008-10), SCHER (2016). A representative sample of the study results (most sensitive organisms over all trophic levels available) is provided below in Table 8. The full data set is provided in Annex A.7.2.

[39] Based upon draft OECD test 219 and GLP-certified.

[40] The Heintze, 2001 study was considered acceptable in the PPP (2008-10) assessment.

Table 8. Summary of representative terrestrial compartment studies for calcium cyanamide/ cyanamide in soil

Species/ material	Test substance	Test/duration	NOEC/NOAEL mg/kg soil[$$]	Reference**
Soil dwelling organisms				
Inoculum soil microorganisms	cyanamide	chronic (28 d)	27.2	Reis, 2002 BPR (2016)
Eisenia fetida (Annelid)	cyanamide	short term (14 d)	LC50 111.3	Lührs, 2001
Eisenia fetida (Annelid)	PERLKA®	chronic (56 d) reproduction	82.0 derived NOEC cyanamide[$$$]: 18.9	Scheffczyk, 2016a
Folsomia candida (Arthropod – springtail)	cyanamide	chronic (28 d)	EC10: 1.515[&] reproduction	Moser and Scheffczyk, 2009
Eisenia fetida (Annelid)	cyanamide	chronic (56 d)	>/=1.05*	Scheffczyk, 2016b
Abablemma bilineata (Coleopteran – soil-dwelling beetle)	cyanamide	chronic (28 d) reproduction	</= 0.3 kg cyanamide/ha application rate Derived NOEC cyanamide in soil***: 0.4 mg/kg soil dw	Röhlig, 2006a
Terrestrial plants				

Monocots: Zea mays, Avena sativa, Allium cepa, Lolium perenne. Dicots: Brassica oleracea, Daucus carota, Crocus sativus, Lactuca sativa, Lycopersicon Esculentum.	cyanamide	Short term (14 d)	<0.02 (*A.cepa*) shoot dry weight	Meister, 2001 (BPR 2016)
Avena sativa, (Monocot.) Brassica rapa (Dicot.)	cyanamide	chronic (28-39 d)	50.0 (both)	Förster, 2009

(Source: Alzchem, 2019a, PPP 2008-10, BPR 2016)

Table notes: General note: $ some studies included in Alzchem 2019a do not have a reference source and are not included in this table. *highest concentration of 50% cyanamide solution used in the study; **source Alzchem, 2019a unless indicated otherwise in brackets; [$$] unless indicated otherwise. ***In order to use in the risk assessment carried out by the Dossier Submitter, where a threshold value in the table above is given as kg per hectare, for the most sensitive organisms a soil concentration (dry weight) has been calculated (see Table 36); [$$$] concentration of cyanamide derived from PERLKA® (see Table 36); [&] EC_{10} and $NOEC_{Reproduction}$ values were derived in this study and the EC_{10} value of 1.515 mg cyanamide/kg soil dw was confirmed by the German Competent Authority at the 95% confidence limits. In BPR, 2016 a point of departure for the PNECsoil of 0.133 mg cyanamide/kg soil ww was utilised for the terrestrial assessment.

The most sensitive soil organisms and hence the study chosen to be the point of departure for PNECsoil derivation by the Dossier Submitter is the long-term reproduction study with the a soil collembolan *Folsomia candida* (Springtail) (Moser & Scheffczyk, 2009) using cyanamide as the test substance. The results from this study are a 28-day EC10 for reproduction of 1.515 mg cyanamide/kg soil dw. Since long-term studies on cyanamide are available for three trophic levels (soil microorganisms, soil macroorganisms and plants) an assessment factor of 10 was used. The PNECsoil for cyanamide used by the Dossier Submitter was 0.15 mg cyanamide/kg soil dw. This study was also chosen as the key study for the terrestrial compartment in the BPR assessment (BPR, 2016).

Reference to Table 8 indicates that studies resulting in more stringent NOEC values than that found in Moser & Scheffczyk, 2009 have been reported. However, these data were not considered to be sufficiently robust by the Dossier Submitter to be used as the point of departure for the PNECsoil. The rationale for this is explained in more detail in Annex A.7.2.1. Similarly, the experimental NOEC value (28 days) from the Moser & Scheffczyk, 2009 study was 0.4 mg/kg soil dw, but the recommended EC10 value (ECHA, 2008) was used instead.

In addition, the studies shown in Table 8 indicate *A. cepa* (onion) is particularly sensitive to cyanamide in short-term studies on seedling emergence. Other species of plants also showed sensitivity to cyanamide in chronic studies. However, for the purpose risk characterisation these studies are considered supportive, partly because the Registrant advises against using PERLKA® as a fertiliser at seedling emergence for certain crops, and also because the granulated form of PERLKA® it is unlikely that other plant species will be exposed to PERLKA® outside of the field being fertilised.

3.2.9.5.2 Ecotoxicity of PERLKA®/cyanamide to soil-dwelling organisms assessed by the Registrant

In its March 2019 REACH registration dossier update (Alzchem, 2019a)[41] the Registrant proposed two PNECsoil values: (1) PNECsoil for exposure from industrial sources; and (2) PNECsoil for the use of calcium cyanamide as a fertiliser[42]. For exposure from industrial sources (1) the study by Moser & Scheffczyk, 2009 was chosen as the key study and the Registrant derived the same PNECsoil as the Dossier Submitter has used in its risk characterisation of the terrestrial compartment.

For the agricultural application of calcium cyanamide as a fertiliser (2) the Registrant has derived a PNECsoil value on a very different basis than that for industrial applications. The Registrant argues that the study by Moser & Scheffczyk, 2009 is unsuitable for assessing the risk to soil of calcium cyanamide used as a fertiliser. Instead, the Registrant argues that the PNECsoil (fertiliser use) should be derived using 'less stringent environmental protection goals' (Alzchem, 2019a) than normally applicable under REACH and instead the protection goals should be aligned with those for the assessment of PPPs under the PPP Regulation i.e. applicable to intensively cultivated and heavily modified soils which cannot be presumed to be 'natural' or 'pristine' ecosystems. However, the Dossier Submitter understands that the protection objective during a PPP assessment is to maintain populations of soil-dwelling organisms, which is not considered to be different from the protection objective under a REACH-based assessment.

A PNECsoil for fertiliser use has been derived by the Registrant from two sources 1) preliminary results from a seven-year field study (Ebke, 2018) on the effects of PERLKA® on the populations of soil-dwelling organisms such as *F. candida* and *E. fetida*, which are known to be sensitive to cyanamide; and 2) soil exposure modelling using ESCAPE v 2.0. The Ebke study was replaced by a new Field Study to evaluate the effects of granulated calcium cyanamide fertiliser (PERLKA®) on collembola in central Europe (Stegger, 2019) which was initiated in September 2018, two interim results were reported to the Dossier Submitter in June 2019 and November 2019 through consultation while the final study report was submitted in March 2020 through consultation.

In the study by Ebke, 2018, adverse effects were measured on the populations of soil-dwelling organisms after an initial eight month time period and the results presented in the registration dossier (Alzchem, 2019a). Two adjacent plots of agricultural land were treated with fertiliser, one with PERLKA® (application rate 400 kg/ha) and the other with a fertiliser reported to be a 'standard nitrogen fertiliser'. After eight months the difference in numbers of soil-dwelling organisms were compared in the two adjacent plots. The Registrant reports there was no

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[41] Two PNECsoil values maintained in the 27 June 2019 dossier update.

[42] This is maintained in their latest registration dossier update REACH (2019b).

statistical difference between the number of animals trapped/sampled in the two plots. Exposure modelling was then carried out for PERLKA® applied at varying application rates (see 3.2.10.4.2). An application rate of 400 kg/ha, resulted in time-weighted average (28-d) PERLKA® concentrations in soil of 11.9 mg/kg. On this basis the Registrant argues the PNECsoil (fertiliser use) should be set as 11.9 mg/kg and concludes that all agricultural scenarios can be considered safe. Additionally, the Registrant claims that the results are supported by results of the Collembola field study (Stegger, 2019) where PERLKA® was applied to soil plots at 200 and 400 kg/ha. In comparison to the nitrogen fertiliser control, the endpoint number of collembola showed single short-term effects after the application of the substance, but these effects were followed by recovery. The data do not provide evidence that collembola are adversely affected in the longer term under realistic field conditions and for realistic application rates by the test item PERLKA® at application rates of 200 and 400 kg/ha. Thus, this worst-case application of PERLKA® at a rate of 400 kg/ha with no incorporation is considered safe for non-target organisms, including collembola which were identified as the most sensitive species. However, it can be seen from the study results that a statistically significant lower abundance for total collembolans was observed on day 28 after the first and after the second application followed by recovery of the population.

Under REACH, higher-tier studies may be used to refine a PNECsoil that is derived from chronic ecotoxicity studies. However, the approach taken by the Registrant, of comparing exposure data with field study results to derive a PNECsoil, is not supported in REACH.

EFSA has confirmed (EFSA, 2018) the field study (Ebke, 2018) appears to have significant methodological difficulties which render the study not adequate and reliable enough to be used to refine a PNECsoil derived from chronic terrestrial toxicity data. These include: 1; 1) the application rate in the study is 100 kg/ha lower than the highest recommended application rate of PERLKA®; 2) pre-sampling of test species was not carried out; 3) the results were not presented at the species level, potentially masking the results of particularly sensitive species; 4) there was significant variability of the results; 5) concentrations of PERLKA® were not measured in the treated soil; and 6) an assessment factor of 5 would be used if this assessment were being carried out under the PPP legislation as confirmed by EFSA. In addition to the above, EFSA has provided a number of detailed comments. Additional information are provided in Annex A.7.2.1.2.

ECHA assessed the Field Study to evaluate the effects of granulated calcium cyanamide fertiliser (PERLKA®) on collembola in central Europe (Stegger, 2019) and observed that fertilisation by nitrogen seems to have an influence, generally beneficial, on the abundance of collembolans: the comparison of untreated control and fertiliser control samples revealed several statistically significant differences for both pitfall traps and soil cores samples. Therefore, the evaluation of the effects from the test item was done in comparison to the untreated control and to the fertiliser control separately.

ECHA underlined some uncertainties related to the Field Study on collembola (Stegger, 2019). Firstly, it evaluates the effect of calcium cyanamide on collembola only, no other terrestrial species is evaluated at the same time. Field studies normally evaluate the effect of a substance on the whole population present in standard conditions in the soil. Additionally, it is a non guideline study. Finally, due to the likely endocrine disruption properties of cyanamide, the risk to soil might not be removed. Overall, on the basis of the methodological difficulties described above for the field study (Ebke, 2019) and of the uncertainties on the field study on collembola (Stegger, 2019), the Dossier Submitter does not consider the field studies and results to be appropriate to be used as the point of departure to derive the PNECsoil values. The approach taken by the Registrant to derive the PNECsoil by comparing exposure data with the field study results is not supported under REACH. Concerning the relative stringency of the environmental protection goals under REACH and PPPs, the Dossier Submitter understands that the protection objective during a PPP assessment is to maintain populations of soil-dwelling organisms, which is not considered to be different from the protection objective under a REACH-based assessment. Further details are provided in Annex A.7.2 and for comparison purposes a sensitivity analysis has been carried out by the Dossier Submitter which supports this – see Annex A.10.4.

3.2.9.5.3 Terrestrial ecotoxicity of PERLKA®/calcium cyanamide / cyanamide to non-soil-dwelling organisms

There are 15 studies available to the Dossier Submitter for non-soil-dwelling terrestrial organisms – 12 acute or short-term – 3 chronic. The source of the studies is 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 includes a study on rats, which has been used in previous regulatory reviews as a surrogate for small terrestrial mammals (PPP 2008-10). A representative sample (most sensitive organisms over the trophic levels available) of these studies is summarised in Table 9 and the full set is provided in Table 37.

Table 9. Summary of representative terrestrial ecotoxicity studies for non-soil-dwelling organisms of PERLKA®/calcium cyanamide/cyanamide in soil

Species/ material	Test substance	Test/duration	NOEC/NOAEL mg/kg soil**	Reference*
Chrysoperla carnea (Homoptera – leaf-dwelling lacewing - predator)	Cyanamide	short term (18 d)	2.5 kg/ha	Röhlig, 2006c
Typhlodromus pyri (Acari, leaf-dwelling predatory mite)	Cyanamide	short term (7 d)	1.02 kg/ha	Röhlig, 2007a

Aphidius rhopalosiphi (leaf-dwelling parasitic wasp)	Cyanamide	short term (14 d)	>=0.58 kg/ha	Röhlig, 2007b
Aphis mellifera (Hymenoptera – honeybee)	Cyanamide	Acute (72 h)	LC50: <51.6 µg/bee (feeding study)	Kleiner, 1991
Colinus virginianus Virginia Quail - Insectivorous bird	Cyanamide	short term (14 d)	62 mg/kg bw Endpoint based on behaviour	Robaidek, 1985
C. virginianus	Cyanamide	chronic (22 weeks)	13.3 mg/kg body weight (bw)/day	Johnson, 2001
Rat (Sherman Rat)	calcium cyanamide purum	chronic (17-50 weeks)	NOAEL: 1.3 mg/kg bw/d (oral in feed)	Benitz and Salamandra, 1960 Cavallo, 1960

Table notes: General note: *some studies included in Alzchem 2019a do not have a reference source and are not included in this table; **unless indicated otherwise.

From Table 9 it can be seen that a number of terrestrial organisms exhibit adverse effects when they are exposed to cyanamide at application rates above: 0.58 kg/ha e.g. *A. rhopalosiphi*; *C. virginianus* 13.3 mg/kg body weight (by ingestion); small mammals 1.3 mg/kg bw/d (by ingestion) and bees at less than 51.6 µg/bee (by ingestion). For comparison purposes the Registrant recommends an application rate of PERLKA® at between 100-500 kg/ha (23.1 – 115.5 kg/ha cyanamide[43]). However, whether these organisms will be at risk depends upon whether they are actually exposed in practice. This aspect is discussed further in section 3.2.11.10. In general, these studies have not been used for the PNECsoil derivation and are not considered a key driver for the terrestrial risk assessment carried out by the Dossier Submitter, but instead are used as supporting information.

PPP 2008-10 reviewed the terrestrial effects of cyanamide on non-soil-dwelling organisms and noted the particular sensitivity of bees, certain birds and small mammals to cyanamide. The possible long-term risk to the reproduction of birds after ingestion of Dormex® was identified as a critical data gap and the acute and long-term risk by ingestion to small mammals such as *Microtus arvalis* (common vole) and *Apodemus sylvaticus* (wood mouse) was thought to be high on the basis of acute and long-term oral studies in rats. SCHER 2016 also considered the risk of calcium cyanamide when used as a fertiliser to bees but, in the absence of toxicity data

[43] 100 kg/ha PERLKA® = 100 x 0.44 x 42.04/80.11 kg/ha cyanamide = 23.1 kg/ha (assuming average concentration of calcium cyanamide in PERLKA®=44%, molecular weight of calcium cyanamide = 80.11 g/mole & molecular weight of cyanamide = 42.04 g/mole).

for calcium cyanamide and bees, concluded that bees would not be exposed during the time of application of calcium cyanamide as a fertiliser.

3.2.9.5.4 Urea and DCD

In the REACH registration dossier for urea (RRD urea, 2017) there are only two relevant studies reported. The first is a chronic study by Wei-Chun, Brussaard, & de Ridder (1990) on *oligochaetes* and *Lumbricidae* carried out over 20 years in uncultivated turf grass plots on loamy sand soil and dosed at 60, 120 and 180 kg nitrogen/ha/year. The conclusions of this study were that urea fertiliser reduced the number and biomass of earthworms and lowered the soil pH. In addition, the application of nitrogenous fertilisers for long periods may have a deleterious effect on earthworms in the absence of liming. The second study (Krogmeier, M.J. et al, 1989) presented in RRD urea, 2017 on *Glycine max. (L.) Merr*. (Soy Bean plants) derives a NOEC of 9 mg/leaf/day based on leaf tip necrosis.

On the basis of the data above, the Registrants for urea conclude the following. Urea is of inherently low toxicity and is rapidly assimilated into the nitrogen cycle by soil microorganisms; exposure is therefore limited. The substance is widely used as a plant nitrogen source in fertilisers, hence toxicity is unlikely. The results of a study in Soy Bean plants confirm the low toxicity of urea. Because of the inherently low toxicity to microorganisms testing of toxicity to soil microorganisms is not justified and a PNECsoil has not been derived.

From the available data, the Dossier Submitter cannot derive a PNECsoil for urea and can rely only upon the qualitative remarks in the study by (Wei-Chun, Brussaard, & de Ridder, 1990). The Dossier Submitter notes that the deleterious effects observed in this study may be absent when PERLKA® is used since it releases calcium hydroxide. Nevertheless, the absence of data presented by the Registrants points to the need to fill in gaps such as the long-term effects of urea on soil macro invertebrates including arthropods and soil microorganisms.

From the joint REACH registration dossier for DCD (RJRD DCD, 2015), there are studies available for soil microorganisms, soil macro organisms and for terrestrial plants (see Table 38). The key study was considered by the Dossier Submitter to be that of Foerster (2014b) in which a soil nitrate transformation was carried out. The NOEC (28 d) from this test was 2.5 mg/kg soil dw. Because there are studies conducted at three tropic levels, the AF is 10 and on this basis the PNECsoil DCD is 0.25 mg DCD/kg soil ww.

3.2.9.5.5 Secondary effects of calcium cyanamide

The Registrant has provided the Dossier Submitter with an account of the so called ‘secondary effects’ of calcium cyanamide when used as a fertiliser. The claimed effects are herbicidal, fungicidal, molluscicidal and protection from parasites. However, studies demonstrating these effects are not available. Whilst these secondary effects may be seen as beneficial by farmers, the Dossier Submitter has considered them as supporting evidence for the purposes of assessing the hazard of calcium cyanamide to environmental organisms.

These secondary effects are summarised in Table 10 and the full account provided by the Registrant is included in Appendix 2.

Table 10. Secondary effects of calcium cyanamide

Secondary effect	Description of effects	Benefit to farmers	Potential negative effects on the environment*

Herbicide (phytotoxic)	Scorching of plant leaves and germinating plant seeds due to the high alkalinity (minimised using PERLKA®)	Kills weeds around crops e.g. Ragwort	Damage to other plants surrounding crops.
Herbicide (phytotoxic)	Phytotoxicity by cyanamide uptake	Reduces weed pressure in orchards and some vegetable crops such as asparagus, brassicas, onions and leek.	Damage to other plants surrounding crops.
Fungicide	Increases the pH and available calcium in the soil. This increases beneficial microbial activity, which makes the soil suppressive to soil borne plant pathogens such as clubroot	Reduces the incidence and severity of fungal diseases	Unknown.
Mollusicide	Kills slugs and snails by raising the pH	Kills slugs and snails that can damage crops.	Reduces biodiversity
Kills some plant pathogens e.g. wireworm	Appears to drive out wireworms from soil areas with potato crops	Reduces the amount of potato crops killed by wireworm	Unknown.
Kills some endoparasites of grazing animals	Infectious larvae of gastrointestinal worms, when present on the soil surface, are sensitive to the application of calcium cyanamide fertiliser.	Reduces the number of endoparasites in grazing animals	Unknown.

(Source: the Registrant) Table note: *Deduction by the Dossier Submitter.

In addition to the secondary effects outlined above, 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 apparent efficacy of cyanamide as a biocide supports the observation of ecotoxic effects in other (non-target) terrestrial organisms described in the preceding sections.

3.2.9.6 Atmospheric compartment

In section 10 above the Dossier Submitter concluded volatilisation of PERLKA® is unlikely but there may be a limited possibility for the volatilisation of cyanamide in sunlight. On this basis the Dossier Submitter concluded there is a low risk to the atmospheric compartment. This limited volatilisation has been taken into account in the soil exposure modelling presented in section 3.2.10.4.2[44].

3.2.10 Exposure assessment

For most of the exposure studies, the parent substance was calcium cyanamide and the predicted environmental concentrations of cyanamide are derived as the first transformation substance. The transformation of calcium cyanamide to cyanamide in water appears to be rapid. On account of this rapid hydrolysis, in many cases the Registrant presents data from exposure studies as predicted environmental concentrations (PECs) of cyanamide, rather than calcium cyanamide. The Dossier Submitter agrees with this approach and has followed the same approach.

The exposure data presented by the Registrant in the March 2019 dossier update are used, unless stated otherwise. Detailed data from exposure modelling by the Registrant and Dossier Submitter are provided in Appendices 1 and 5-10.

3.2.10.1 Summary of the results of surface water exposure modelling for cyanamide, urea and DCD performed by the Dossier Submitter

Table 11. Summary of the maximum surface water concentrations of cyanamide, urea and DCD using FOCUS modelling.

Application method of PERLKA®[$]	Application rate of PERLKA®* (kg/ha)	Cyanamide (PECsw µg/L) No buffer strip**	Cyanamide (PECsw µg/L) Effect of a buffer strip**	Urea (PECsw µg/L) No buffer strip**	DCD (PECsw µg/L) No buffer strip**
Soil surface /top dressing	100-500 (cyanamide simulations) 300-700 (urea and DCD simulations)	206.0-5 161.8	Reduction from 0 – 66% (66% is still above PNECfreshwater) (0% for drainage scenarios, 66% for run off scenarios)	253.4-5 813.3 (run off scenarios)	2 516.6-4 451.5 (run off and drainage scenarios)
Uniform incorporation (0cm to 10cm or 0cm to 15cm)	100-500 (cyanamide simulations) 300-500 (urea and DCD simulations)	19.8-503.9	Reduction from 0-66% (66% is below the PNECfreshwater) (0% for drainage scenarios, 66% for run off	39.7-161.3 (run off scenarios)	182.7 (run off scenario)

			scenarios)		
Deep placement (15 cm)	100-250	<<1.0	No simulation carried out	No simulation carried out	No simulation carried out

(Source: Dossier Submitter)

Table notes: PECsw means predicted environmental concentration in surface water. PNECfreshwater cyanamide = 10.44 µg/L; PNECfreshwater urea = 470.0 µg/L and PNECfreshwater DCD = 2 500.0 µg/L. *Application rates recommended by the Registrant are between 100-500 kg/ha PERLKA® (44-220 kg calcium cyanamide/ha) (see Appendix 3);** Run-off scenario refers to a FOCUS simulation of run off across the soil surface and very top layer of soil; drainage scenario refers to a FOCUS simulation of drainage through soil; $ application of PERLKA® can be: (1) to soil surface i.e. onto a bare soil surface or top dressing i.e. applied onto growing crops, (2) uniform incorporation i.e. uniformly distributed from the soil surface down to a specific depth in the soil e.g. 0-10cm; (3) deep placement - PERLKA® is placed via a tube at a particular soil depth e.g. 15cm.

The summary of the results of the surface water exposure modelling carried out by the Dossier Submitter in Table 11 show the following:

For cyanamide, the primary transformation product of calcium cyanamide:

1. The method of application of PERLKA® is an important factor in determining the concentrations of cyanamide occurring in adjacent surface water:
    a. The PECsw values for cyanamide are high when PERLKA® is applied to the soil surface or by uniform incorporation to various crops across the range of application rates recommended by the Registrant
    b. Application of PERLKA® to the soil surface seems to elevate PECsw values, compared to uniform incorporation
    c. Application by deep placement results in very low PECsw values for cyanamide
2. Run off appears to be main cause of surface water exposure with cyanamide
3. Vegetated buffer strips can significantly reduce run off of cyanamide, although in most cases the concentration in surface water remains above the PNECfreshwater value for cyanamide, indicating a risk.

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

1. The method of application of PERLKA® is an important factor in determining the concentrations of secondary transformation substances e.g. urea and DCD occurring in adjacent surface water

2. The PECsw urea and DCD are sometimes high when PERLKA® is applied to the soil surface to various crops at or above application rates recommended by the Registrant

3. Uniform incorporation of PERLKA® into the soil results in very low PECsw values for

urea and DCD.

4. Run off appears to be main cause of surface water exposure with urea
5. Run off and drainage appear to be main cause of surface water exposure with DCD.

3.2.10.2 Cyanamide in surface water and sediment

3.2.10.2.1 Cyanamide in surface water

EUSES modelling is commonly used by REACH Registrants to model surface water and sediment exposure. However, it is not yet considered appropriate for predicting the environmental concentrations following the intentional application of a substance to soil e.g. calcium cyanamide when used as a fertiliser (ECHA, 2018b). Instead, FOCUS modelling has been used by both the Registrant and the Dossier Submitter to derive predicted environmental concentrations (PEC) of calcium 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. A more comprehensive description of FOCUS modelling, its application and limitations is given in Annex A.9.

In its registration dossier updates in 2018, the Registrant provided two papers by the Fraunhofer Institute[45] which presented the results of FOCUS Step 3[46] modelling to predict surface water and sediment concentrations of cyanamide after the application of PERLKA® in various scenarios. The most recent Fraunhofer study (Fraunhofer, 2018b) is used for the purposes of this report because it was still current at the March 2019 registration dossier (Alzchem, 2019a) update. Fraunhofer, 2018b presents maximum PEC surface water (PECsw) values ranging from <1 µg/L to 1900.4 µg/L, depending upon the crop being fertilised, the application rate and the method of application. A summary of these results is shown in Table 12 and the full set of results are provided in Appendix 6.

A further update of the surface water modelling was provided in May 2019 and then updated in the Registrant's registration dossier update of 27 June 2019 (Fraunhofer, 2019(b)). These data were provided to the Dossier Submitter too late to be taken into account for this report, but are very similar (within the same order of magnitude) to those reported in Fraunhofer 2018b and those presented by the Dossier Submitter. New in Fraunhofer, 2019(b) are the results of FOCUS Step 4 modelling looking at the effects of vegetated buffer strips on predicted cyanamide concentrations reaching adjacent surface water. These results are of the same order of magnitude and decrease in a similar way with increasing buffer strip width as those of the Dossier Submitter.

The Registrant has confirmed that PERLKA® is applied as a fertiliser in granular form mainly in three different ways by farmers (see Figure 3), depending upon the crop: (1) surface application –onto a (bare) soil surface (usually broadcast i.e. spread evenly); 2) uniform incorporation i.e. incorporated from the soil surface down to a specific depth e.g. 10 cm; (3)

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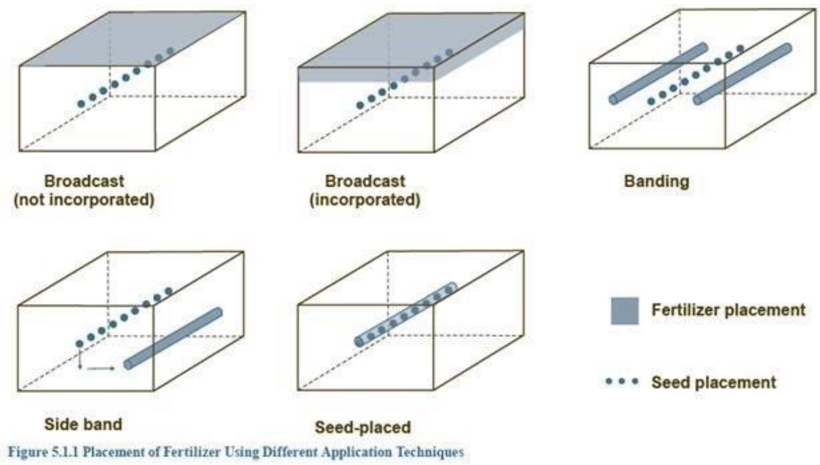
[45] The October 2018 registration dossier update included Fraunhofer (2018b)

[46] FOCUS modeling can be carried out in four steps, 1-4 with increasing refinement. Steps 1 and 2 are considered to be a screening level, Step 3 is a more refined modeling and Step 4 offers the highest level of refinement which includes the effect of risk management measures (RMMs) such as vegetated buffer/filter strips.

deep placement - PERLKA® is placed via a tube at a particular soil depth e.g. 10 cm. In reality, application by deep placement always entails some variability in the soil depth where PERLKA® is placed. The Registrant assumes PERLKA® is placed in a soil layer 5 cm thick. A further method of application exists for fertilisers known as banding. Figure 2 also shows banding and side banding methods of application. From the information provided by the Registrant PERLKA® is not applied by these banding methods, so these are considered not relevant for the risk assessment. A list of crop types and application methods recommended by the Registrant are shown in Appendix 3.



(Source: Registrant)

Figure 2. Recommended application methods for PERLKA®

The exposure modelling done by the Registrant and the Dossier Submitter can be considered as *reasonable worst case scenarios:*

- *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 (PECsw) 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.

The results in Table 12 show for various crops across the range of recommended application rates, when PERLKA® is applied by uniform incorporation or at the soil surface, the highest PECsw values are in the range 17.4 – 1900.4 µg/L[47]. Soil surface application of PERLKA®

[47] The results presented in Table 12 are from Fraunhofer 2018b. The STEP 3 results from Fraunhofer (2019b) are either closely similar to those from the previous year or the same order of magnitude.

seems to elevate PECsw values, compared to uniform incorporation. Soil surface application to grassland results in particularly high PECsw values. Conversely, application by deep placement results in PECsw values consistently below 1 µg/L.

High maximum PECsw values are generally observed with runoff (R) scenarios, rather than drainage (D) scenarios[48], with the exception of PERLKA® applied to grassland in which a drainage scenario results in the very high PECsw value. The PEC sediment results are discussed in section 3.2.10.2.2.

The Registrant has not provided PECsw values for known transformation products of cyanamide such as urea or DCD.

The Dossier Submitter has carried out its own FOCUS modelling at both steps 3 and 4 (see footnote 16). This was done for several reasons: (1) it was initiated on the basis of the May 2018 registration update in which the Registrant claimed maximum PECsw cyanamide values significantly below the PNECfreshwater value; (2) the Registrant has not modelled transformation products such as urea or DCD or (3) assessed the effects of introducing risk management measures (RMMs) such as vegetated buffer strips[49].

The scope of the Step 3 FOCUS modelling carried out by the Dossier Submitter in some respects is wider than that of the Registrant. It covers crops not modelled by the Registrant, a broader range of application rates and also for some scenarios includes the transformation products: urea and DCD. A summary of these results is shown in Table 13, which represent a *reasonable worst case scenario* for the same considerations as those made by the Registrant. The full set of results are shown in Appendix 5.

A comparison of the Dossier Submitter's FOCUS modelling results with those of the Registrant indicate they are of similar magnitude. A direct comparison of the results is only possible for several crop/application rate/ application method/ FOCUS scenario combinations. For example, PERLKA® applied to potatoes at 400 kg/ha by uniform incorporation to 15cm soil depth results in PECsw cyanamide values for the R3,s FOCUS scenario of 503.9 µg/L (Dossier Submitter) and 554.8 µg/L (the Registrant).

Also aligned with the results of the Registrant, in the Dossier Submitter's simulations the run-off (R) scenarios appear to result in the majority of the highest PECsw cyanamide values and drainage (D) scenarios and almost always result in PECsw values for cyanamide well below the PNECfreshwater trigger level. The exception to this is when calcium cyanamide is used to fertilise grassland where surface water is at risk from drainage through soil. Deep placement of PERLKA® up to recommended application rates of 250 kg/ha PERLKA® consistently results in PECsw cyanamide values of <1 µg/L.

[48] 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. Further information is provided in Annex A.9.3.2.5.

[49] Strips of vegetation in which plant protection products are not permitted to be sprayed. They also have some capacity to absorb run off water from fields.

Table 12. Maximum predicted surface water and sediment cyanamide concentrations for different crops, application rates and application methods –*reasonable worst case scenarios*

Crop	Application rate (kg/ha) PERLKA®	Application rate(kg/ha) $CaCN_2$ [$]	Application method	Depth in soil (cm)	FOCUS Scenario	PECsw (µg/L)	PECsed (µg/Kg)
Maize	400	176	Uniform incorporation	10	R4,s	17.4	1.0
Potatoes	400	176	Uniform incorporation	15	R3,s	554.8	26.0
Sugar beet	350	154	Uniform incorporation	10	R3,s	672.8	31.5
Sugar beet	200	88	Deep placement	10	All	<1	<1
Leafy vegetables[$$]	400	176	Uniform incorporation	15	R4,s	45.1	3.5
Cabbage	500	220	Uniform incorporation	15	R4,s	56.4	4.4
Cabbage	320	141	Uniform incorporation	10	R1,s	151.8	9.0
Grassland	300	132	Soil surface	0*	D2,d	1900.4	375.5
Strawberries	200	88	Uniform incorporation	15	R4,s	5.9	<1
Strawberries	200	88	Soil surface	0	R4,s	37.5	3.3

(Source: the Registrant October 2018 using FOCUS step 3 modelling)

Table notes: *No incorporation/0cm = soil surface/top dressing; $ Assuming PERLKA® contains 44% $CaCN_2$; $$ Leafy vegetables was modelled assuming 20% crop interception. FOCUS scenarios: R means run-off, D means drainage through soil, s means stream variant and d means ditch variant.

Table 13. Summary of maximum predicted surface water concentrations of cyanamide for different crops, application rates and application methods - *reasonable worst case scenarios*.

Crop	Application rate (kg/ha) PERLKA®	Application rate(kg/ha) $CaCN_2$[$]	Application method	Depth in soil (cm)	FOCUS Scenario	PECsw (µg/L) Cyanamide	10m buffer strip	20m buffer strip
Winter oilseed rape	500	220	Top dressing	0	R1,s	1030.1	No results	No results
Winter oilseed rape	300	132	Top dressing	0	D2,d	5161.8	5161.8	5161.8
Winter oilseed rape	300	132	Top dressing	0	R1,s	618.0	260.0	132.3
Maize	300	132	Soil surface	0	R4,s	2052.1	No results	No results
Winter oilseed rape	100	44	Top dressing	0	R1,s	206.0	No results	No results
Maize	500	220	Uniform incorporation	10	R4,s	246.7	No results	No results
Leafy veg 1st	500	220	Uniform incorporation	15	R4,s	310.5	140.6	73.6

Crop	Application rate (kg/ha) PERLKA®	Application rate(kg/ha) $CaCN_2$$	Application method	Depth in soil (cm)	FOCUS Scenario	PECsw (µg/L) Cyanamide	10m buffer strip	20m buffer strip
Leafy veg 2nd	500	220	Uniform incorporation	10	R4,s	34.3	No results	No results
Potatoes	400	176	Uniform incorporation	15	R3,s	503.9	207.1	104.5
Winter oilseed rape	200	88	Uniform incorporation	10	D2,d	19.8	19.8	19.8
Winter oilseed rape	200	88	Uniform incorporation	10	R3,s	41.3	18.9	9.9
Winter oilseed rape	100	44	Uniform incorporation	10	R3,s	20.7	No results	No results
Potatoes	250	110	Deep placement	15	All	<<1	No results	No results
Leafy veg 1st	200	88	Deep placement	15	All	<<1	No results	No results
Leafy veg 1st	100	44	Deep placement	15	All	<<1	No results	No results
All	Up to 700	Up to 308	All	N/A	D1,D3,D4,D5,D6	<3	No results	No results

(Source: Dossier Submitter using Step 3 & 4 FOCUS modelling)

Notes: $ Assuming PERLKA® contains 44% $CaCN_2$. FOCUS scenarios: R means run-off, D means drainage through soil, s means stream variant and d means ditch variant.

The last two columns of Table 13, indicate the effect of using vegetated buffer strips as buffer zones to adjacent surface waters. This was modelled using FOCUS Step 4 modelling. It is observed that in some cases the PECsw values decrease with increasing buffer strip width. These findings are consistent with the STEP 4 results provided by the Registrant Fraunhofer (2019b).

RAC BOX

To be noted that the calculated PEC values were erroneously reported in µg/ml while the correct unit obtained through the FOCUS calculation is µg/Kg of dry weight sediment.

3.2.10.2.2 Cyanamide in sediment

The Registrant has provided PEC sediment (PECsed) values for cyanamide. In most of these simulations the PECsed (cyanamide) appear to range from <1.0 to 31.5 µg/Kg. However, when PERLKA® is applied to grassland (soil surface) the predicted cyanamide levels in sediment increases to 375.5 µg/Kg. Deep placement results in very low PECsed (cyanamide) values.

3.2.10.2.3 Urea and DCD in surface water and sediment

The modelling of predicted urea and DCD concentrations in surface water was carried out using FOCUS 3 modelling by the Dossier Submitter. The Registrant has not presented data on these transformation substances in surface water.

The Dossier Submitter has modelled the predicted concentrations of urea and cyanoguanidine (DCD) in surface water because they were identified as potentially environmentally significant transformation substances on the basis of their fate and behaviour in the environment (see section 3.2.7.1). A summary of the Dossier Submitter's modelling results for urea and DCD are shown in Table 14 and Table 15, respectively. The results for PERLKA® application rates of 500 kg/ha or lower represent *reasonable worst-case scenarios* (see section 3.2.10.2). At application rates above 500 kg/ha the simulation are *worst-case scenarios*, because they are above the current recommended application rates. It is noteworthy however that during the preparation of this report the Dossier Submitter received a report of application rates recommended locally up to 1 500kg/ha (see section 3.4.1).

From Table 14 it can be seen that the PECsw urea values between 603.3 and 5 813.3 µg/L occur frequently. These occurrences are always in the run off (R) scenarios, whilst drainage (D) scenarios are always below the PNEC value, in most cases considerably below the PNEC. Application at the soil surface of calcium cyanamide to potatoes and leafy vegetables results in the highest predicted surface water concentrations of urea at recommended application rates. Uniform incorporation of a second application[50] of PERLKA® on leafy vegetables significantly lowers the conce*ntration of urea in surface water.* Table 15 summarises the results of the simulations for DCD which are somewhat different from those for urea and cyanamide in that the maximum PECsw DCD values are generally found in D scenarios, rather than R scenarios. At recommended application rates of PERLKA® the maximum PECsw (DCD) values are 182.7 and 1 480.9 µg/L. However, above the 500 kg/ha recommended application rate, the PECsw (DCD) values range from 2 516.6 to 4451.5 µg/L. Unfortunately, FOCUS was not able to simulate certain the PECsw values for drainage scenarios where DCD was a secondary transformation substance (see Annex A.9.3.2.5).

[50] During the growing season.

Table 14. Maximum predicted surface water concentrations of urea after the application of PERLKA® as a fertiliser

Crop	Application rate (kg/ha) PERLKA®	Application rate(kg/ha) $CaCN_2$$	Application method	Depth in soil (cm)	FOCUS Scenario	Maximum PECsw (µg/L)
Maize	700	308	Soil surface	0	R1,s	603.3
Maize	300	132	Soil surface	0	R1,s	253.4
Maize	500	220	Uniform incorporation	10	R1,s	39.7
Potatoes	700	308	Soil surface	0	R3,s	5813.3
Potatoes	300	132	Soil surface	0	R3,s	1948.6
Potatoes	500	220	Uniform incorporation	10	R3,s	241.5
Leafy vegetables	700	308	Soil surface	0	R4,s	2382.2
Leafy vegetables 2nd*	300	132	Soil surface	0	R4,s	1025.0
Leafy vegetables 2nd*	500	220	Uniform incorporation	10	R4,s	161.3
Pome/stone fruit	700,500, 300	308/132/220	All	All	All	<PNEC
All crops	All	All	All	All	D scenarios	<PNEC

(Source: Dossier Submitter, Step 3 FOCUS)

Table notes: *Second application in the growing season; $ Assuming PERLKA® contains 44% $CaCN_2$; FOCUS scenarios: R means run-off, D means drainage through soil, s means stream variant and d means ditch variant.

Table 15. Maximum predicted surface water concentrations of cyanoguanidine (DCD) after the application of PERLKA® as a fertiliser

Crop	Application rate (kg/ha) PERLKA®	Application rate(kg/ha) $CaCN_2$[$]	Application method	Depth in soil (cm)	FOCUS Scenario	Maximum PECsw (µg/L)
Maize	700	308	Soil surface	0	D5,p	3770.3
Maize	300	132	Soil surface	0	D5,p	No results
Maize	500	220	Uniform incorporation	10	D5,p	No results
Potatoes	700	308	Soil surface	0	R3,s	4451.5
Potatoes	300	132	Soil surface	0	R3,s	1480.9
Potatoes	500	220	Uniform incorporation	10	R3,s	182.7
Leafy vegetables[$$]	700	308	Soil surface	0	D4,p	2516.6
Leafy vegetables	300/500	132/220	Soil surface/ Uniform incorporation	0/10	D4,p	No results
Pome/stone fruit (early)	700	308	Soil surface	0	D5,p	3822.6
Pome/stone fruit (early)	300/500	132/220	Soil surface/ Uniform incorporation	0/10	D5,p	No results

(Source: Dossier Submitter, Step 3 FOCUS).
Table notes: $ Assuming PERLKA® contains 44% $CaCN_2$; FOCUS scenarios: R means run-off, D means drainage through soil, s means stream variant and p means pond variant. No results were possible in some D scenarios because of the way in which FOCUS is configured.

3.2.10.3 Cyanamide and transformation products in groundwater

The Registrant provided groundwater exposure modelling results for the first time in its October 2018 update (Fraunhofer, 2018c). The results were produced using FOCUS PEARL modelling[51] and assuming the highest recommended application rates for cabbage and potatoes crops when applied by uniform incorporation. The application rates are 500kg/ha PERLKA®, cabbage and 400 kg/ha PERLKA®, potatoes, i.e. *reasonable worst-case scenarios*. FOCUS PEARL modelling simulates the leaching through soil to groundwater of the test substance and its transformation substances after the application to soil. For the nine pre-set geoclimatic scenarios[52] in FOCUS PEARL in all cases the PEC groundwater (PECgw) cyanamide was significantly below 0.1 µg/L to the nearest 80th percentile. In its conclusions the Registrant concluded cyanamide may reach groundwater by leaching, albeit at low concentrations and has not considered this further. The full results are in Appendix 8. Transformation products other than cyanamide were not modelled by the Registrant.

The reference value of 0.1 µg/L used by the Registrant is the concentration limit set for individual active substances in pesticides, including their relevant metabolites, degradation and reaction products in Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration[53].

The Dossier Submitter has also modelled the PECgw of the transformation products of PERLKA® with FOCUSPEARL for reasonable worst-case scenarios (based upon recommended application rates and methods) as well as at application rates above the recommended levels. This modelling covered additional crops, a broader range of application rates and also included DCD, one of the transformation products of cyanamide. A summary of the results are presented Table 16 and the full results are provided in Appendix 7.

For PERLKA® applied to potatoes and maize, the Dossier Submitter's results were closely aligned to those of the Registrant. However, using a different crop, apples, concentrations of cyanamide were found significantly higher than those in potatoes – in the range of 1-70 µg/L. These values increased if PERLKA® application rates were raised to 700 kg/ha, above the recommended levels[54]. For both the registrant's and Dossier Submitter's results it is evident the method of application of PERLKA® is an important factor in determining the concentrations of cyanamide occurring in groundwater. For example, when PERLKA® is applied to the soil surface the PECgw values for cyanamide are very low, but are elevated when the application method is uniform incorporation. It is also noteworthy that the concentrations of DCD in groundwater appear to be very high compared to cyanamide concentrations.

At recommended application rates, in its modelling the Dossier Submitter found concentrations of DCD ranging between 1377 – 13 802 µg/L. The concentrations increased when using application rates above the recommended levels. The results are as expected from a substance

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[51] A specialised FOCUS model which is designed for predicting concentrations of a test substance in groundwater.

[52] FOCUSPEARL has nine pre-set scenarios which are considered to be representative of locations across the EU.

[53] Directive 2006/118/EC of the European Parliament and Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19).

[54] It is unknown if application rates above recommended levels are used in practice for apple crops but during the preparation of this report there has been one reported case of application rates being used considerably above the maximum recommended application rate (see section 3.4.1).

such as DCD which is considered to be reasonably mobile in soil and is persistent (see 3.2.3). Concentrations of DCD in groundwater are at the upper end of the range when PERLKA® is used for apple crops.

Table 16. Maximum predicted ground water concentrations of cyanamide and cyanoguanidine predicted by the Dossier Submitter

Crop	FOCUS PEARL Scenario*	Application Rate PERLKA® (kg/ha)	Application rate $CaCN_2$ (kg/ha)	Application method	Cyanamide Maximum PECgw** (µg/L)	DCD Maximum PECgw (µg/L)
Potatoes	Chateaudun	300	132	Applied to soil surface	<0.1	4 415.7
Maize	Okehampton	300	132	Applied to soil surface	<0.1	2 030.3
Veg. beans	Porto	500	220	Uniform incorporation to 10 cm	1.44	2 715.0
Apples	Jokioinen	500	220	Uniform incorporation to 10 cm	70.1	11 932.0
Apples	Thiva	500	220	Uniform incorporation to 10 cm	0.26	13 802.2

(Source: Dossier Submitter)

Table note: **PECgw means predicted environmental concentration in groundwater; *FOCUS PEARL is a specialised FOCUS model for groundwater and has nine pre-set scenarios which are considered to be representative of locations across the EU.

3.2.10.4 Exposure modelling in the terrestrial compartment

3.2.10.4.1 Summary of the Dossier Submitter's exposure modelling of cyanamide, urea and cyanoguanidine in soil following the application of PERLKA®

Table 17. Summary of the exposure modelling results showing concentrations of cyanamide, urea and cyanoguanidine in soil following the application of PERLKA®

Application rate PERLKA® (kg/ha)	Application method	Cyanamide TWA* 28-day PECsoil** (mg/kg)	Urea TWA 28-day PECsoil (mg/kg)	DCD TWA 28-day PECsoil (mg/kg)
150-500	Surface application	6.10 - 20.3	27.6 - 92.0	1.88 - 6.26
150-500	Uniform incorporation to 7.5 cm	4.22 - 14.1	20.5 - 68.4	1.42 - 4.72
150-500	Uniform incorporation to 15 cm	2.2 - 7.32	11.4 - 38.1	0.81 - 2.69

(Source: Dossier Submitter)

Table note: **PECsoil means predicted environmental concentrations in soil; *TWA means time weighted averages.

3.2.10.4.2 Exposure modelling in soil

EUSES modelling is not currently considered appropriate for predicting the environmental concentrations covering following the intentional application of a substance to soil (ECHA, 2018b). Therefore, the Dossier Submitter has used an alternative commonly used modelling approach for substances intentionally added to soil (Boesten et al. 1997) to estimate predicted environmental concentrations in soil (PECsoil) values (mg/kg)[55]. The model assumes the test substance is applied uniformly down to a particular depth of soil. For surface application, a 'mixing depth[56]' of 0-5cm is used, thus the predicted concentrations effectively represent the average concentration in the top 5 cm depth of the soil. For uniform incorporation the mixing depth is from the surface down to a specific depth of soil e.g. 10 cm.

The Registrant has used alternative modelling software, ESCAPE[57] (Estimation of Soil

[55] Commonly used for plant protection products.

[56] I.e. the top layer of soil into which it is assumed PERLKA® is applied in practice.

[57] ESCAPE v 2.0 is modelling software that appears to have been developed by a single consultant, but is not widely used in the EU.

Concentration After PEsticide applications), which has been developed by a consultancy to calculate actual as well as time weighted average concentrations in soil for the parent compound and additional metabolites. Consultation comments #2916, 2929 referred to the use of the ESCAPE software, which was originally developed for the environmental protection agency in Germany (UBA, Umweltbundesamt) but it is currently used by various member states to calculate the fate of plant protection products in the EU according to FOCUS (1997). The DS submitter underlines that for the purposes of an EU-level assessment of calcium cyanamide used as a fertilizer in Europe, it was considered that FOCUS has standard combinations of weather, soil and cropping data and water bodies, which collectively represent agriculture in the EU. Finally the DS considers that the FOCUS model can give quite a good representation of the real world fertiliser use in this case.

In its registration dossier (Alzchem, 2019a), the registrant presented results of a modelling study for calcium cyanamide in soil (Alzchem, 2018)[58]. The study assumed PERLKA® is applied at varying application rates, application methods and varying amounts of interception by crops[59]. The modelling method does not appear to differentiate between crop types, except by varying the interception percentage. The Registrant only provided modelling results for calcium cyanamide and cyanamide, and no other transformation substances. The Registrant's results are summarised in

[58] An update to these results was provided by the Registrant in April 2019 Alzchem (2019c), but the results were closely similar or the same order of magnitude.

[59] The Registrant explains when PERLKA® is used on fields where plant growth has already started some fertiliser is intercepted or taken up so fast it does not reach the soil.

Table 18 and the full set of results are presented in Appendix 10.

Table 18 shows maximum (*reasonable worst case*) PECsoilmax values and 28-day time weighted averages (PECtwa) for cyanamide following the application of PERLKA® either to the soil surface or by uniform incorporation (see section 3.2.10.2). PECsoilmax (cyanamide) values ranged from 2.0 – 60.6 mg cyanamide/kg dry soil and PECtwa 28d from 0.4 – 11.8 mg cyanamide/kg dry soil.

The highest values were obtained when applying 400 kg/ha PERLKA® to the soil surface without interception from crops. The values gradually fall with decreasing application rates, and increasing incorporation depths. It is also observed that the 28-d PECtwa values significantly reduce when PERLKA® is applied by uniform incorporation or deep placement. Interception by crops also reduces the 28-d TWA values, presumably because the load reaching the soil is reduced. However, the Dossier Submitter considers 80% interception unrealistically high and instead uses 20% as a reasonable estimate for top dressed crops.

The Dossier Submitter also carried out soil modelling to predict the soil concentrations of cyanamide, urea and DCD. The methodology is detailed in Annex A.9.3.2.7 and the results are summarised in

Table 19. The full set of results are presented in Appendix 9. Crop interception was assumed to be 0% for all the simulations, the modelling assumes moderate losses by leaching and volatilisation[60] and a conversion rate of cyanamide to DCD and urea based upon the figures and transformation pathway reported by Dixon 2017 see section 3.2.7.2.

[60] First order rate constants have been included in the model as estimated by EUSES v2.1.2.

Table 18. Summary of the *reasonable worst case* predicted environmental concentrations of cyanamide in soil following the application of PERLKA® provided by the Registrant.

Application Rate PERLKA® (kg/ha)	Interception Rate (%)	Application method	Cyanamide Maximum PECsoilmax (mg/kg)	Cyanamide Twa** 28-d PECsoil* (mg/kg)
500	0	Uniform incorporation to 15 cm	25.2	4.9
400	0	Applied to soil surface	60.6	11.8
400	20	Applied to soil surface	48.5	9.4
400	0	Uniform incorporation to 10 cm	30.3	5.9
300	80	Applied to soil surface	9.1	1.8
200	0	Applied to soil surface	30.3	5.9
200	0	Uniform incorporation to 10 cm	15.0	2.9
100	0	Deep placement at 10-15cm	2.0	0.4

(Source: Alzchem (2018)).

Table note: *PECsoil means predicted environmental concentrations in soil. **PECtwa means 28-day time weighted averages.

Table 19. Summary of the *reasonable worst case* predicted environmental concentrations of cyanamide, urea and cyanoguanidine (DCD) in soil following the application of PERLKA® predicted by the Dossier Submitter.

Application rate PERLKA® (kg/ha)	Application method	Cyanamide PECsoil Twa 28-d (mg/kg)	Urea PECsoil Twa 28-d (mg/kg)	DCD PECsoil Twa 28-d (mg/kg)
500	Surface application	20.3	92.0	6.26
500	Uniform incorporation to 7.5 cm	14.1	68.4	4.72
500	Uniform incorporation to 15 cm	7.32	38.1	2.69
300	Surface application	12.2	55.2	3.76
300	Uniform incorporation to 7.5 cm	8.45	41.1	2.83
300	Uniform incorporation to 15 cm	4.39	22.8	1.61
150	Surface application	6.10	27.6	1.88
150	Uniform incorporation to 7.5 cm	4.22	20.5	1.42
150	Uniform incorporation to 15 cm	2.2	11.4	0.81

(Source: Dossier Submitter)

Table note: PECsoil means predicted environmental concentrations in soil. PECsoiltwa means 28-day time weighted averages.

The results of the modelling from the Dossier Submitter indicate PECtwa (cyanamide) concentrations are in the range of 2.2 to 20.3 mg/kg soil. The magnitude of Dossier Submitter's results are quite similar to those of the Registrant and concentrations of cyanamide appear to decrease moving from soil surface application to application at progressively deeper depths and generally with decreasing application rates of PERLKA®.

For urea and DCD 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.

3.2.10.4.3 Monitoring data

There is very little environmental monitoring or human biomonitoring data available in the literature for calcium cyanamide or cyanamide. The Dossier Submitter has carried out searches from available sources[61]. In addition, the European Environment Agency has assisted the Dossier Submitter and checked their monitoring databases, a request has been made to the Registrant and a public call for evidence has taken place.

Several publications were found, including a notable study documenting the results of monitoring in sediment around the site of a Canadian company manufacturing cyanamide (Dickman and Rygiel 1993), which examines the impact of the company's discharges to the aquatic compartment on benthic invertebrates. Some species were found to be adversely affected by the discharges but it was unclear whether these effects were caused by cyanamide, its transformation substances or elevated heavy metal concentrations.

3.2.11 Risk characterisation

3.2.11.1 Summary of the risk characterisation when PERLKA® is used as a fertiliser with use conditions recommended by the Registrant

Table 20. Summary of the findings of the risk characterisation when PERLKA® is used as a fertiliser with use conditions recommended by the Registrant

Environmental compartment	Cyanamide$ No buffer strip*	Cyanamide$ Effect of a buffer strip*	Urea$ No buffer strip*	DCD$ No buffer strip*
Surface water	Risk is not adequately controlled	For most scenarios, risk is not adequately controlled	For several scenarios, risk is not adequately controlled	For several scenarios, risk is not adequately controlled

[61] ECHA website, GESTIS, WISER, TOXNET, IARC, Google.

Sediment	The risk characterisation for cyanamide in the sediment compartment could not be performed due the discrepancy between the PNEC and PEC values in respect to their units. The derived PNEC sediment is obtained in µg/ml while the PEC sediment values are obtained in µg/Kg of dry weight sediment	not assessed	not assessed	not assessed
Ground water	risk below safe level	not assessed	not assessed	Risk is adequately controlled
Soil	Risk is not adequately controlled	not assessed	not assessed	Risk is not adequately controlled

(Source: Dossier Submitter)

Table note: *six exposure simulations for cyanamide were carried out by the Dossier Submitter to model the effect of vegetated buffer strips in the run off pathway between a fertilised field and adjacent surface water; $these are substances considered to be environmentally relevant by the Dossier Submitter following the transformation of calcium cyanamide in the environment (see section 3.2.7).

3.2.11.2 Risk characterisation carried out by the Registrant and sensitivity analysis by the Dossier Submitter

In its 27 June 2019 registration dossier an updated risk assessment had not yet been presented by the Registrant. However, for several specific areas, the Registrant has indicated in an annex of the CSR if the risk is adequately controlled.

In addition, a sensitivity analysis for surface water and soil is presented exploring the significance of the size of the assessment factor used to derive the relevant PNEC value. This is informative as assessments under the PPP legislation typically use smaller assessment factors when deriving a PNEC than those outlined in REACH Guidance (see Annex A.10.4).

The results of this sensitivity analysis show that using the PPP approach to PNEC derivation still leads to the conclusion that risks to surface water and soil are not adequately controlled. For soil the risk characterisation[62] results are lower than those under REACH, but remain

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

significantly above the threshold value of 1.

3.2.11.3 Aquatic compartment

3.2.11.4 Risk to surface water from cyanamide when using PERLKA® as a fertiliser

Table 21. Risk characterisation ratios (RCR) for cyanamide using different crops, application rates, application methods and RMMs – *reasonable worst-case scenarios*

Crop	Application rate (kg/ha) PERLKA®**	Application rate(kg/ha) $CaCN_2$ $	Application method&	Depth in soil (cm)	FOCUS Scenario$$	RCR*	RCR 10m Buffer *	RCR 20m buffer *
Winter oilseed rape	500	220	Top dressing	0	R1,s	98.7	No results	No results
Winter oilseed rape	300	132	Top dressing	0	D2&&,d	494.4	494.4	494.4
Winter oilseed rape	300	132	Top dressing	0	R1,s	59.2	25.0	12.7
Maize	300	132	Soil surface	0	R4,s	196.6	No results	No results
Winter oilseed rape	100	44	Top dressing	0	R1,s	19.7	No results	No results
Maize	500	220	Uniform incorporation	10	R4,s	23.6	No results	No results
Leafy veg 1st	500	220	Uniform incorporation	15	R4,s	29.7	13.5	7.0
Leafy veg 2nd	500	220	Uniform incorporation	10	R4,s	3.3	No results	No results
Potatoes	400	176	Uniform incorporation	15	R3,s	48.3	19.8	10.0

identical.

Crop	Application rate (kg/ha) PERLKA®**	Application rate(kg/ha) $CaCN_2$[$]	Application method[&]	Depth in soil (cm)	FOCUS Scenario[$$]	RCR*	RCR 10m Buffer *	RCR 20m buffer *
Winter oilseed rape	200	88	Uniform incorporation	10	D2[&&],d	1.9	1.9	1.9
Winter oilseed rape	200	88	Uniform incorporation	10	R3,s	4.0	1.8	0.9
Winter oilseed rape	100	44	Uniform incorporation	10	R3,s	2.0	No results	No results
Leafy veg 1st	200	88	Deep placement	15	All	<<1	No results	No results
Potatoes	250	110	Deep placement	15	All	<<1	No results	No results
All	Up to 700	Up to 308	All	N/A	D1, D3,D4, D5,D6	<1	No results	No results

(Source: Dossier Submitter; PNECfreshwater cyanamide = 10.44 µg/L)

Table notes: *Bold font denotes a risk to surface water; **Application rates recommended by the Registrant are between 100-500 kg/ha PERLKA® (44-220 kg calcium cyanamide/ha); $ Assuming PERLKA® contains 44% $CaCN_2$.; $$ Run-off (R) scenario refers to a FOCUS simulation of run off across the soil surface and very top layer of soil; drainage (D) scenario refers to a FOCUS simulation of drainage through soil, s means stream variant and d means ditch variant; & application of PERLKA® can be: (1) to soil surface i.e. onto a bare soil surface or top dressing i.e. applied onto growing crops, (2) uniform incorporation i.e. uniformly distributed from the soil surface down to a specific depth in the soil e.g. 0-10cm; (3) deep placement - PERLKA® is placed via a tube at a particular soil depth e.g. 15cm; && D2 scenario is known to be an extreme worst case drainage scenario.

Table 21 shows the results of the risk characterisation for surface water by the Dossier Submitter. The results indicate for a variety of crops calcium cyanamide (PERLKA®) when used as a fertiliser poses a risk that is not adequately controlled i.e. the risk characterisation ration (RCR) in surface water (RCRfreshwater) >1 to surface water ecosystem adjacent to fertilised fields. The application rate and application method appear to be important determinants for the risk.

The risk from cyanamide is not adequately controlled when PERLKA® is applied to the soil surface, onto the soil surface with growing crops, or when uniformly incorporated (i.e. uniformly mixed from the soil surface down to a specific depth e.g. 10 cm) into the soil. The risk occurs because of run off across the surface of the agricultural field and in some cases may also be from drainage through soil. Application rates between 100-500 kg/ha (PERLKA®) are recommended by the Registrant. At these application rates the exposure simulations carried out by the Dossier Submitter predict RCRfreshwater values > 1[63].

Application of PERLKA® by deep placement (i.e. at a specific depth in the soil via a tube) between 100 – 250 kg/ha application rate results in RCRfreshwater values well below one and therefore this application method appears to result in adequately controlled risks to surface water. This implies a REACH restriction could allow deep placement up to an application rate of 250 kg/ha, were it not for the identified risk to soil-dwelling organisms (see section 3.2.10.2.1). However, to protect watercourses adjacent to fertilised crops a limit value would be very difficult to establish in practice because individual limits would be needed for each crop and for application rates above 250 kg/ha, soil type, with or without the use of risk management measures such as vegetated buffer strips etc. The Dossier Submitter has not been able to investigate all these variables.

Generally, simulations which model drainage of cyanamide through soil to adjacent surface water bodies do not result in a risk to surface water. However, there is frequently a risk when simulations have been carried out using the FOCUS D2 scenario, which is known to be a worst case drainage scenario (see Annex A.9.3.2.5).

The last two columns of Table 21 indicate the effect on the risk to adjacent surface water of using vegetated buffer strips (10 m or 20 m wide) as buffer zones to adjacent surface waters. Simulations using buffer strips show that there is a reduction of the RCRfreshwater value for cyanamide in adjacent surface water when it has arrived there by run off. Drainage through soil is unaffected by the use of buffer strips. Increasing the width of the buffer strip reduces further the RCRfreshwater value in run off scenarios.

In simulations where the use of buffer strips result in a reduction of the RCRfreshwater value, in all but one case, the RCRfreshwater value does not fall below one i.e. there is a residual risk even when a buffer strip of 20 m is deployed as a risk management measure (RMM).

Buffer strips wider than 20m are typically not used in agriculture and extrapolation beyond the widths modelled is not possible (EFSA 2018).

3.2.11.5 Risk to surface water from urea and DCD when using PERLKA® as a fertiliser

Table 22. Risk characterisation ratios for urea and DCD using different crops, application rates and application methods – *reasonable worst case scenarios*

Crop	Application rate (kg/ha) PERLKA®**	Application rate(kg/ha) $CaCN_2$ $	Application method&	Depth in Soil (cm)	FOCUS Scenario$$	RCR (urea)*	RCR (DCD)*
Potatoes	700	308	Soil surface	0	R3,s	12.4	1.8
Maize	300	132	Soil surface	0	R1,s	0.5	No results
Potatoes	300	132	Soil surface	0	R3,s	4.1	0.6

63 Using the PNECfreshwater proposed by the Registrant 50% of the RCRfreshwater values are above one.

Crop	Application rate (kg/ha) PERLKA®**	Application rate(kg/ha) $CaCN_2$ [$]	Application method[&]	Depth in Soil (cm)	FOCUS Scenario[$$]	RCR (urea)*	RCR (DCD)*
Pome/ stone fruit (early)	700	308	Soil surface	0	D5,p	No results	1.5
Maize	500	220	Uniform incorporation	10	R1,s	0.1	No results
Potatoes	500	220	Uniform incorporation	10	R3,s	0.5	<0.1
Leafy vegetables 2nd*	500	220	Uniform incorporation	10	R4,s	0.3	No results
Pome/ stone fruit (early)	700/500/300	308//220/132	Soil surface and uniform incorporation	0 & 10	All	<<1 or no results	Not applicable
All crops	All	All	All	All	D scenarios	<<1 or no results	Not applicable

(Source: Dossier Submitter; PNECfreshwater urea = 470.0 µg/L ; PNECfreshwater DCD = 2500.0 µg/L)

Table notes: *Bold font denotes a risk to surface water; **Application rates recommended by the Registrant are between 100-500 kg/ha PERLKA® (44-220 kg calcium cyanamide/ha); $ Assuming PERLKA® contains 44% $CaCN_2$.; $$ Run-off (R) scenario refers to a FOCUS simulation of run off across the soil surface and very top layer of soil; drainage (D) scenario refers to a FOCUS simulation of drainage through soil, s means stream variant and p means pond variant; & application of PERLKA® can be: (1) to soil surface i.e. onto a bare soil surface or top dressing i.e. applied onto growing crops, (2) uniform incorporation i.e. uniformly distributed from the soil surface down to a specific depth in the soil e.g. 0-10cm; (3) deep placement - PERLKA® is placed via a tube at a particular soil depth e.g. 15cm.

Table 22 shows the RCRfreshwater values in surface water for the secondary transformation products urea and DCD following the application of PERLKA® as a fertiliser to various crops using different application methods and at both application rates recommended by the Registrant and above the recommended levels.

It can be seen that the RCRfreshwater value for urea is in excess of one when used at an application rate recommended by the Registrant. Reference to the full set of results in Appendix 5 shows this exceedance occurs for various crops when PERLKA® is applied to the soil surface and run off occurs. This indicates that urea can pose a risk that is not adequately controlled to surface water after the application of PERLKA® at rates recommended by the Registrant. This is presumably either urea that has been formed before the run off event, or will be formed in surface water. At higher application rates, the RCRfreshwater value rises considerably above one. Simulations of drainage through soil results in RCRfreshwater values for urea consistently well below one.

The use of DCD at or below recommended application rates did not result in a risk for surface water. However, at an application rate of 700 kg/ha a risk was evident when PERLKA® was applied to the soil surface.

3.2.11.6 Risk to sediment from cyanamide when using PERLKA® as a fertiliser

Table 23. Risk characterisation ratios for sediment using different crops, application rates and application methods – *reasonable worst case scenarios*

Crop	Application rate (kg/ha) PERLKA®	Application rate(kg/ha) $CaCN_2$$	Application method	Depth in soil (cm)	FOCUS Scenario	RCR*
Grassland	300	132	Soil surface	0*	D2,d	5.6
Strawberries	200	88	Soil surface	0	R4,s	<0.1
Cabbage	320	141	Uniform incorporation	10	R1,s	0.1
Leafy vegetables$$	400	176	Uniform incorporation	15	R4,s	<0.1
Potatoes	400	176	Uniform incorporation	15	R3,s	0.4
Sugar beet	350	154	Uniform incorporation	10	R3,s	0.5
Strawberries	200	88	Uniform incorporation	15	R4,s	<0.1
Sugar beet	200	88	Deep placement	10	All	<0.1

(Source: PNECsed Dossier Submitter, PECs Registrant; PNECsed = 66.4 µg/L)

Table notes: *Bold font denotes a risk to sediment water; $$ Run-off (R) scenario refers to a FOCUS simulation of run off across the soil surface and very top layer of soil; drainage (D) scenario refers to a FOCUS simulation of drainage through soil, s means stream variant and d means ditch variant.

Table 23 shows the RCRsediment values for cyanamide in sediment following the application of PERLKA® as a fertiliser to various crops using different application methods and at application rates recommended by the Registrant. PNEC sediment is abbreviated to PNECsed.

Generally all the RCR results are below one. However, the RCRsed value for cyanamide in sediment is in excess of one for a single scenario simulated i.e. the application of PERLKA® to the soil surface for grassland at 300 kg/ha, an application rate recommended by the Registrant.

These results generally are indicative that the risk from cyanamide to sediment-dwelling organisms is adequately controlled. Yet in at least one scenario simulated the risk is not adequately controlled. As described in A.7.1.1.13 these finding may under estimate the risk to sediment-dwelling organisms.

The DS acknowledges that RCR values reported in Table 23 are based on an erroneous calculation. The calculated PEC values for cyanamyde, as obtained through FOCUS modelling, were erroneously reported in µg/ml while the correct unit is µg/kg of dry weight sediment, therefore a risk characterisation cannot be performed.

RAC BOX

RAC does not support the risk characterisation for cyanamide in the sediment compartment due the discrepancy between the relevant PNEC and PEC values in respect to their units, as detailed in the RAC Final Opinion.

3.2.11.7 Risk to groundwater from cyanamide and cyanoguanidine when using PERLKA® as a fertiliser

Table 24. Risk characterisation of groundwater from cyanamide and DCD

Crop	FOCUSPEARL Scenario*	Application Rate PERLKA® (kg/ha)**	Application rate $CaCN_2$ (kg/ha)$	Application method	RCR (cyanamide)	RCR (DCD)
Potatoes	Chateaudun	300	132	Applied to soil surface	<< 0.1	0.2
Maize	Okehampton	300	132	Applied to soil surface	<< 0.1	0.1
Veg. beans	Porto	500	220	Uniform incorporation to 10 cm	<< 0.1	0.1
Apples	Jokioinen	500	220	Uniform incorporation to 10 cm	0.1	0.6
Apples	Thiva	500	220	Uniform incorporation to 10 cm	<< 0.1	0.7

(Source: Dossier Submitter)

Table notes: Threshold in groundwater calculated by the Dossier Submitter using WHO guidelines was 510 µg/L for cyanamide and 19 500 µg/L for DCD. *FOCUS PEARL has nine pre-set scenarios which are considered to be representative of locations across the EU; ** Application rates recommended by the Registrant are between 100-500 kg/ha PERLKA® (44-220 kg calcium cyanamide/ha); $ Assuming PERLKA® contains 44% $CaCN_2$.

Table 24 shows the PECgw/threshold values for cyanamide and DCD calculated by the Dossier Submitter following the application of PERLKA® as a fertiliser to various crops using different application methods and at application rates recommended by the Registrant. From these results the risk for groundwater quality appears to be adequately controlled.

In analysing its own groundwater modelling results, the Registrant has used a 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[64] and in the EU Drinking Water Quality Directive[65]. Using this threshold and the results from the Dossier Submitter's groundwater exposure modelling (see predicted exposure levels in Table 16), cyanamide and DCD pose a risk to groundwater that is not adequately controlled when calcium cyanamide is used to fertilise apple crops.

Because calcium cyanamide is not being used as a pesticide in this context, the Dossier Submitter has explored an alternative approach: to derive limit values for cyanamide and DCD in drinking water and thereby considered the potential risk to human health by indirect exposure[66]. Specific limit values for calcium cyanamide, cyanamide or DCD are not present in the EU Drinking Water Directive or Groundwater Directive. Instead the Dossier Submitter has relied upon a method for setting limit values in drinking water in the WHO Guidelines for Drinking Water Quality[67]. 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. It is therefore applicable to the general population. The detailed methodology is shown in Annex A.9.3.2.1.

Using the WHO approach and the DNEL (oral, cyanamide) for the general population, the Dossier Submitter has calculated the drinking water limit value for the general population is 510 µg/L. From the Dossier Submitter's results it can be seen the cyanamide does not exceed this limit value in the scenarios modelled. However, to be noted 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.

The Biocidal Product Committee (BPC) provided an opinion in December 2019 that cyanamide is an endocrine disruptor for human health and non-target organisms[68]. Following the adoption

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[64] Directive 2006/118/EC of the European Parliament and Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19).

[65] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption; (OJ 330/32 of 5.12.98) or the proposed amendment: COM(2017) 753 final 2017/0332 (COD) of 1 February 2018.

[66] Assuming the groundwater is used as a source of drinking water.

[67] WHO Guidelines for drinking water quality, 4th edition (2017): https://www.who.int/water_sanitation_health/publications/drinking-water-quality-guidelines-4-including-1st-addendum/en/.

[68] On 4-5 June 2019, ECHA's Endocrine Disruptor Expert Group (ED EG) reviewed a proposal from the German Competent Authority for cyanamide to be considered an endocrine disruptor (ED) for human health (ECHA, 2019). There was a broad agreement by the ED EG that the information available is sufficient to identify the substance as endocrine disruptor with regard to human health. In September

of the BPC opinion, the European Commission may proceed to decision making within a few months. Agreement on ED properties may have further implications for the contamination of groundwater.

The Dossier Submitter also calculated the limit value for DCD using the same WHO methodology and the DNEL (oral, DCD) for the general population from RJRD DCD, 2015. The resulting limit value was 19 500 µg/L. From the modelling carried out so far the PECgw DCD values resulting from recommended PERLKA® application rates or up to 700 kg/ha do not appear to pose a risk to groundwater, although clearly it may be present in significant concentrations.

3.2.11.8 Risk to the terrestrial compartment

Table 25. Risk characterisation ratios for cyanamide and cyanoguanidine (DCD) in soil using different crops, application rates and application methods – *reasonable worst case scenarios*

Application Rate PERLKA® (kg/ha)**	Application rate CaCN2 (kg/ha)$	Application method$$	RCRsoil (cyanamide)*	RCRsoil (DCD)*
500	220	Surface application	135.3	25.0
300	132	Surface application	81.3	15.0
150	66	Surface application	40.7	7.5
500	220	Uniform incorporation to 7.5 cm	94.0	18.9
300	132	Uniform incorporation to 7.5 cm	56.3	11.3
150	66	Uniform incorporation to 7.5 cm	28.1	5.7
500	220	Uniform incorporation to 15 cm	48.8	10.8
300	132	Uniform incorporation to 15 cm	29.3	6.4
150	66	Uniform incorporation to 15 cm	14.7	3.2

2019, the Biocides Working Groups for Human Health and Environment concluded that cyanamide shall be designated as an endocrine disruptor for the human health and for non-target organisms in the environment.

(Source: Dossier Submitter; PNECsoil cyanamide = 0.15 µg/L; PNECsoil DCD = 0.25 µg/L)

Table notes: *Bold font denotes a risk to soil; ** application rates recommended by the Registrant are between 100-500 kg/ha PERLKA® (44-220 kg calcium cyanamide/ha); $ Assuming PERLKA® contains 44% $CaCN_2$; $$ application of PERLKA® can be: (1) to soil surface i.e. onto a bare soil surface or top dressing i.e. applied onto growing crops, (2) uniform incorporation i.e. uniformly distributed from the soil surface down to a specific depth in the soil e.g. 0-10 cm; (3) deep placement - PERLKA® is placed via a tube at a particular soil depth e.g. 15 cm.

Table 25 shows the RCRsoil values for cyanamide and DCD following the application of PERLKA® as a fertiliser to various crops using different application methods and at application rates recommended by the Registrant.

It can be seen that the RCRsoil values for cyanamide and the secondary transformation product DCD in soil consistently exceed one when used at an application rate recommended by the Registrant for both surface application and uniform incorporation methods. This indicates that cyanamide and DCD poses a risk to soil-dwelling organisms that is not adequately controlled when PERLKA® is used as a fertiliser in recommended use conditions.

From these results it appears the RCRsoil values of both cyanamide and DCD increase when moving from uniform incorporation to soil surface application of PERLKA® and when moving from a uniform incorporation of 15 cm soil depth to 7.5 cm soil depth.

The exposure modelling technique used by the Dossier Submitter did not allow the calculation of PECsoil 28-day time-weighted average (twa 28-d) values for the 'deep placement' application method, but the technique used by the Registrant did allow exposure modelling of cyanamide following application to crops by deep placement at the lowest recommended application rate, i.e. 100 kg/ha PERLKA®. The resulting PECsoil (twa 28-d) cyanamide was 0.4 mg/kg soil (see

Table 18), which results in a PEC/PNEC cyanamide of 1.6 i.e. there is still a risk at the lowest recommended application rate when PERLKA® is applied by deep placement.
A derivation of RCR values for the other secondary transformation substance of interest, urea, were not possible because a PNECsoil urea could not be derived (see section 3.2.9.5.4).

A seven-year field study on the effects of PERLKA® on soil-dwelling organisms was started by the Registrant in April 2018. The preliminary results of this study were received quite late in the preparation of this report (Ebke, 2018). However, a first overview of the results appear to be inconclusive. The results are presented and discussed in Annex A.7.2.1.2. In the June 2019 registration dossier update it was evident the Ebke study has ended and replaced by a new similar study in September 2018. The interim results of the new study have been provided by the Registrant (Stegger, 2019) in its June 2019 registration dossier update. These results were received too late for the preparation of this report and EFSA is assisting ECHA with interpreting the results. As previously indicated, the final study report for the field study on collembolan (Stegger, 2019) was submitted during consultation in March 2020 and the Dossier Submitter has reviewed it (see sections 3.2.9.2.5 and B.7.2.1.2).

3.2.11.9 Atmospheric compartment

Based on the stable pellet form in which calcium cyanamide is used as a fertiliser, the Dossier Submitter concluded there is a low risk to the atmospheric compartment from PERLKA®. However, the Dossier Submitter notes limited volatilisation of cyanamide may occur when PERLKA® is applied to the soil surface i.e. after release from PERLKA® granules and in solution. This was taken into account in the terrestrial exposure modelling carried out by the Dossier Submitter (see section 3.2.9.5).

3.2.11.10 Findings of other relevant regulatory reviews

The findings of the Dossier Submitter concerning the risk of calcium cyanamide/cyanamide are broadly consistent with those found in BPR 2016, PPP 2008-10 and SCHER 2016.

Primarily on the basis of a risk to aquatic organisms, SCHER 2016 concluded that harmful effects from the use of calcium cyanamide as a fertiliser to the environment cannot be excluded. SCHER excluded harmful effects for soil and terrestrial organisms on the basis of studies carried out on earthworms and beetles but did not review the key study identified in this assessment on *F. candida (*Moser & Scheffczyk, 2009). The presence of calcium cyanamide in groundwater was also found using FOCUS Pearl modelling, but SCHER concluded there was no unacceptable risk from calcium cyanamide on the basis of lysimeter studies. SCHER 2016 also highlighted the need to investigate the effects of calcium cyanamide on bees because it was not able to do so owing to the absence of toxicity data for calcium cyanamide on bees.

BPR 2016 adopted positive opinions on the approval of cyanamide for use in liquid form in indoor animal housings as an insecticide and disinfectant. BPR 2016 used the same key studies for aquatic and soil toxicity as used in this assessment. However, the exposure scenarios used in BPR were quite different from those used in this assessment because cyanamide will be applied in a contained indoor space and may only reach the environment via spreading of manure containing cyanamide on fields. Clearly this contrasts with intentionally adding the calcium cyanamide which then degrades to cyanamide directly to fields.

The PPP 2008-10 review assessed whether cyanamide in a liquid formulation called ‘Dormex’[69] could be authorised for use in plant protection products for the stimulation of plant bud

[69] ‘Dormex’ is manufactured by the same Registrant as calcium cyanamide.

opening (plant growth regulator) in kiwifruit and grapes. For this use liquid Dormex containing cyanamide is air-blast sprayed onto outdoor crops at the end of winter period. The Commission decided not to approve the use of this substance in 2008, primarily owing to concerns over harmful effects on human health, especially professional workers. Again, the use of Dormex in the application scenarios considered by PPP 2008-10 is quite distinct from using granulated PERLKA® as a fertiliser.

Subsequently, further information was provided by the Registrant in the PPP 2008-10 process and the European Commission requested EFSA to conduct a further focused peer review in the areas of mammalian toxicology, environmental fate, behaviour and ecotoxicology. EFSA concluded (PPP 2008-10) the operator, bystander and residential exposure estimates are above the AOEL and this was indicated as an area of critical concern.

Of relevance to the present assessment, an issue that could not be finalised in the PPP assessment of Dormex and a critical area of concern was identified in relation to the risk assessment for birds. A low risk to small mammals was concluded on the basis of a higher tier study demonstrating that small mammals are not exposed under field conditions because Dormex is applied at the end of the winter period, when these organisms are absent from area of the treated crops. Nevertheless, Dormex was found to be toxic to small mammals. Similarly, bees were found to be particularly sensitive to cyanamide, but again were not likely to be exposed because they are absent at the end of the winter period. Hence EFSA concluded the risk to bees was also low.

However when PERLKA® is used as a fertiliser, it is typically applied during the growing season of crops i.e. from spring, through summer and to the autumn. As a consequence, theoretically birds, small mammals and bees maybe be exposed to cyanamide, especially if PERLKA® is applied by top dressing[70] or to a bare soil surface and cyanamide is released from PERLKA® in moist conditions. However, without scientific studies to support this theoretical exposure, the Dossier Submitter considers this as supporting information that a concern for the terrestrial environment over and above the non-adequately controlled risk identified may exist.

In addition, EFSA concluded, the potential for groundwater exposure by cyanamide when sprayed on kiwi and grape crops is predicted to be high over a wide range of geoclimatic conditions. Considering the toxicological properties of cyanamide, this was identified as a critical area of concern.

Furthermore, EFSA also used FOCUS modelling to simulate the exposure of aquatic organisms to cyanamide after its application to kiwi and grape crops. The risk of cyanamide to aquatic organisms was considered low, as long as 20m vegetated buffer strips are used as risk management measures for most of the FOCUS scenarios modelled. This conclusion was reached assuming an application rate of only approximately 9 kg/ha cyanamide. This contrasts with the direct application of PERLKA® to soil at rates of between 100-500 kg/ha (approximately 22 – 120 kg/ha cyanamide) that are recommended by the Registrant and were considered by the Dossier Submitter in its assessment. Following the further peer review by EFSA in 2010, cyanamide remains not approved for use as a plant growth regulator.

Outside the EU, Dormex is used as a plant growth regulator (US EPA 2007). In its preliminary assessment of Dormex the US EPA concluded that ‘based on a preliminary analysis of exposure, there may be a concern for direct, acute and chronic effects in freshwater

[70] i.e. applied on the soil surface when crops are already growing above soil level (see section 0).

invertebrates[71]. This may in turn have indirect effects on consumers of invertebrates such as fish and amphibians via a reduction in available food items. [Also] there is a potential risk to plants, unicellular algae, aquatic invertebrates, birds, and mammals, should exposure occur. [And] because of the application timing for cyanamide (30 days before bud break), applications will occur in the winter and early spring. Thus, toxic effects are expected to occur mostly in evergreen plants (e.g., citrus). Leaf loss has been noted in lemon trees exposed to cyanamide. A spray drift buffer to prevent adverse effects in plants will need to be calculated'. Since its preliminary assessment the US EPA has authorised the use of Dormex as a plant growth regulator[72] and a competitor product (Krop-max[73]) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It is unclear however to what extent the above adverse effects were taken into account. Calcium cyanamide is also listed as a 'fish toxicant' by the UN FAO[74].

3.3 Justification for an EU wide restriction measure

Calcium cyanamide (PERLKA®) is regulated by Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down the rules on making available on the market fertilising products[75] and therefore benefits from free circulation in the EU Single Market and is sold in several EU Member States. Because the listing of calcium cyanamide as an EU fertiliser allows its free circulation in the Single Market, any legislation and any potential measures to regulate its use for the protection of the environment needs to be assessed at the Union level. Separate, national policies could result in a distortion of the internal market and potentially unfair market competition.

Another reason to act on a Union wide basis is related to the environmental effects potentially caused by calcium cyanamide. Many Member States share common waterways within EU and therefore, decision made in one country may well affect the environment in other Member States. Therefore, it is important that Member States regulate (the freely traded) fertilisers in the same way throughout the European Union.

Furthermore, as the EU agricultural sector is largely managed through the Common Agricultural Policy (CAP), it is important, that legislation affecting the ways and means of production is also controlled on an EU-wide basis. Therefore, only an EU-wide restriction would avoid any risk of creating unequal market conditions and ensure a 'level playing field' among the EU Member States.

3.4 Baseline

3.4.1 Manufacture and uses

Based on the registration dossier CSR, 130 000 tonnes of calcium cyanamide[76] were annually manufactured in the EU in 2010-2014, reportedly on 1-10 sites. In addition to this, 100 tonnes

[71] https://www3.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-014002_14-Sep-07_a.pdf

[72] https://www3.epa.gov/pesticides/chem_search/ppls/054555-00002-20170927.pdf

[73] Hydrogen cyanamide: https://www3.epa.gov/pesticides/chem_search/ppls/080697-00006-20170927.pdf for a Chinese company.

[74] UN Food and Agriculture Organisation: http://www.fao.org/docrep/003/b0465e/b0465e05.htm

[75] The Regulation is available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.170.01.0001.01.ENG&toc=OJ:L:2019:170:TOC

[76] Technical grade with calcium cyanamide content of 68%.

were imported and 7 000 tonnes exported in the same period. Other manufacturers operate in China and Japan, where their products are used mainly for industrial purposes and as a fertiliser.

About 40% of the total, i.e. 52 000 tonnes/year, was reported to be used by professional users as a fertiliser in agricultural production and 1 000 tonnes/year are used by consumers as a fertiliser for their home crops and lawns. The remaining quantities are reported to be used in industrial processes or exported. Calcium cyanamide is also used as a fertiliser in Asia, however, in a different formulation than PERLKA®. This formulation is not known to be imported into the EU.

Table 26. Uses of calcium cyanamide (source: Alzchem, 2019a: technical grade calcium cyanamide content of 68%)

Activity	Tonnes/year
Manufacture	130 000
Formulation (incl. fertiliser)	130 000
Industrial use – steel, metal industry	45 000
Industrial use – intermediate in chemical manufacture	25 000
Professional use as a fertiliser	52 000
Consumer (fertiliser) use in private properties	1 000
Direct exports	7 000

The two known calcium cyanamide fertiliser products marketed in the EU are both manufactured by AlzChem AG: The powdered form with a typical concentration of calcium cyanamide of about 58%, and PERLKA®, a granulated mixture of calcium cyanamide with other main components. The product with the trade name PERLKA® is sold in granulated form, with a calcium cyanamide content of approximately 44% w/w. PERLKA is widely available in the EU, with a total volume of about 70 000 tonnes per year[77]. SCHER reported PERLKA® to account for 98.5% of the sales, whereas the powdered form was only a minor part of the total. However, as mentioned above the Registrant informed ECHA that it had stopped the sales of the powdered form in December 2017 because its small market size did not warrant the expense of carrying out a risk characterisation. Currently, only the granulated product should be on sale. There is no official data available about the acreage it is used on. However, noting the total tonnage of 70 000 tonnes (in concentration of PERLKA®) and assuming that an average application rate is 300kg/ha the Dossier Submitter estimates that professional users apply the product on about 230 000 hectares, which is about 0.2% of the arable land in the EU given the total area of arable land of 103M hectares 2016 (Eurostat). Observing information in the consultation comments #2754 and #2768, it appears that Germany (with 35 000 tonnes annual use) and Belgium, France and Italy appear to be among the main users.

PERLKA® is generally applied once per growing season. However, there may be other application(s) of nitrogen before or after the application of PERLKA®. It is used for several crops but found to be especially suitable for intensively cultivated high-value crops; e.g. cabbage, potato and lettuce. It is also used e.g. for the production of oilseed rape, strawberry

[77] The PERLKA® tonnage 70 000, appears higher than the tonnage ‘professional use as a fertiliser’ in the above table, 52 000, because the concentration in PERLKA® is lower.

and rice. Due to its slow release characteristics, a single application has a long lasting effect. This reduces the need for reapplication and subsequent driving on a sown field, and in turn saves production costs. Even more importantly, the use of PERLKA® decreases potential quality losses (e.g. in cabbage) as the mechanical disturbance of the crop is minimised and the early application of (slow-release) fertiliser helps to keep the fertiliser away from tainting the end product. PERLKA® is also used for crops like maize and even for grasslands. However, for such crops its comparative advantage to alternative nitrogen fertilisers is less significant.

The registrant advertises calcium cyanamide as a slow-release nitrogen fertiliser and underlines its ability to deliver positive secondary effects (e.g. herbicidal, fungicidal and molluscicidal as well as other side effects) useful for the health of soil and cultivated plants. The registrant states its suitability, especially for high-value crops requiring a long growing period. Consultation comments have also underlined the usefulness of the secondary effects. For instance, comment #2749 points out its effectiveness against fungal asparagus diseases and as a repellent on wireworm and millipedes.

However, PERLKA® has not been approved as a Plant Protection Product in the EU. Based on information provided by the Registrant to the Dossier Submitter, the secondary effects include pesticide and pest suppression effects, as well as plant health benefits (see section 3.2.9.5.5). PERLKA® formulation provides slow- and sustained-release nitrogen (see section 3.2.3)[78] and inhibits the germination of the resting spores of soil-borne pathogens.

Researchers have found calcium cyanamide to be particularly effective on intensively used soils highly infested with soil borne pathogens that cause root and stem rot, and clubroot (Bourbos, Skoudridakis, Darakis, & Koulizakis, 1997; EPA, 2014; Shi, Wang, Zhou, Yu, & Yu, 2009; Dixon, 2017). In a separate use, it has been reported that the addition of calcium cyanamide to cow manure composting significantly shortens the time to inactivate foodborne pathogens (Simujide et al., 2013).

Information from the Registrant on recommended application rates/time/method for the main crops fertilised with PERLKA® are given in Appendix 3. These are also summarised on the website of the Registrant under: https://www.alzchem.com/en/agriculture/calcium-cyanamide-PERLKA®/application/agriculturefarming.

The proposed per-hectare amounts recommended by the Registrant are within the same range as those assumed by the Dossier Submitter in its exposure assessment modelling. Larger application rates were recommended in the past. For example e.g. in Finland in 2017 (see ECHA 2018); e.g. rates for cabbage were 400-1 500 kg/ha before and 300-400 kg/ha after the planting, whereas for other crops the recommendations appeared similar to elsewhere (e.g. for rapeseed 250 kg/ha at fall when seeding). However, the Registrant informed the Dossier Submitter in 2017 that the per-hectare recommendations were reviewed and modified not to exceed 500 kg/ha.

There are several consultation comments, where application rates are generally discussed e.g. #2760, #2950, and others where more specific information is provided. For instance, the comment #2754 provided recommended application rates by the registrant, and underlined

[78] Cyanoguanidine(DCD), a breakdown product of calcium cyanamide, has alone been stated to be capable of slowing down and controlling release of fertilisers and nitrification. http://www.fertiliser.org/imis20/images/Library_Downloads/2010_Trenkel_slow%20release%20book.pdf?WebsiteKey=411e9724-4bda-422f-abfc-8152ed74f306&=404%3bhttp%3a%2f%2fwww.fertiliser.org%3a80%2fen%2fimages%2fLibrary_Downloads%2f2010_Trenkel_slow+release+book.pdf

that no rates over (proposed maximimum of) 500 kg/ha should be used in modelling. The comment #2948 provided application rates for open-air tomatoes in Poland (300-500 kg/ha). However, higher rates can also be possible. The comment #2935 noted that a use of 600 kg/ha (120 kg/ha N) for lettuce crop in Italy. Also, the comment #2762, #2768 explain that for apples only 100-200 kg/ha is generally applied, however, the amount is not evenly applied, but rather 1/3 of the field (line of trees) receives the fertiliser. This means that parts of the fields (line of trees) receive quite high “effective” application rate, whereas the lanes between the trees remain untreated. The comment from Japan, #2950 provides information about application rates used there, however, it is not clear whether that information is directly comparable.

At this point the overall use volume of calcium cyanamide as a fertiliser in the EU appears generally stable. Based on discussions with the Registrant, no specific reasons have been identified to suggest that the presented use volumes would be significantly changing in the near future.

3.4.2 Impact on the environment from the use of calcium cyanamide as a fertiliser

The use of fertilisers, including calcium cyanamide, are often associated with negative environmental impacts on surface water/sediment, groundwater and terrestrial organisms. As demonstrated in section 3.2 of this restriction proposal, the risks for environmental organisms can be assessed using a quantitative risk characterisation. However, the impacts of RCR values >1 are difficult to describe in practical or quantifiable terms and therefore their monetisation is not readily possible.

The European Common agricultural policy (CAP) include measures to reduce negative environmental impacts of agriculture (e.g. leaching of pesticides and nutrients). For instance so called ‘cross compliance measures’[79] guide farmers to use ‘good agricultural practices’ in their production are designed for this purpose, and are mandatory for most of the farmers receiving CAP support.

The objectives of cross compliance measures are commonly agreed and are shared by all EU Member States. However, the exact measures are Member State-specific, such that the local weather, soil and other environmental conditions are taken into account. The measures may include, for instance, the requirement for vegetated field strips around agricultural land, and/or a prohibition of spraying crops adjacent to waterways.

For calcium cyanamide, such measures may help to control potential leaching and the subsequent environmental impacts. However, the effects of these general measures have not been assessed in detail in this report. They may reduce the environmental impacts of calcium cyanamide (and other fertilisers) but are likely to be insufficient to limit the risks to surface

[79] Cross compliance aims at being an effective mechanism to promote sustainable agriculture and at the same time a tool which enhances the CAP's role in meeting the expectations of the society. Payments under the CAP first pillar and some rural development measures have to comply with parts of 19 existing and already implemented regulations or directives, the so-called statutory management requirements (SMR). The SMR cover rules relating to agricultural production, land and activities in the three areas of: the environment; public, animal and plant health; and animal welfare. Secondly, the payments have to comply with good agricultural and environmental conditions (GAEC) which concern the issues of soil erosion, soil organic matter, soil structure, minimum level of maintenance and maintaining the total area of permanent pasture. https://ec.europa.eu/agriculture/sites/agriculture/files/policy-perspectives/impact-assessment/cap-health-check/documents/ia-annex/c2_en.pdf

water to a safe level as suggested by the effects of vegetated buffer strips on run-off as simulated by the Dossier Submitter[80]. Cross-compliance measures will also not reduce the risk to soil-dwelling organisms.

4 Impact assessment

4.1 Introduction

The main role of PERLKA® is to provide slow-release nitrogen fertilisation to crops. As mentioned above, the Registrant states that PERLKA® has several other (beneficial) secondary effects[81] (see Appendix 2). However, PERLKA® does not have an approval under the EU PPP legislation. The Registrant informed the Dossier Submitter that it had not applied for an authorisation for calcium cyanamide for its secondary PPP effects, claiming the product would not be sufficiently efficacious to achieve authorisation. In another context, the Registrant was refused PPP approval for the use of cyanamide[82] as a plant growth regulator for kiwi fruits and grapes because of safety concerns.

One of the reported secondary effects of PERLKA® is the control of clubroot infestation (see e.g. Dixon 2017). Generally, clubroot infestation requires adoption of special crop rotation practices, which results in rigidities in the utilisation of fields (e.g. the same crop cannot be planted for several consecutive years) and therefore an increase in production costs.

For the function of nitrogen addition, generally available nitrogen fertilisers like urea and ammonium nitrate, as well as general N-P-K products, are an alternative to calcium cyanamide. However, such products generally lack the slow-release feature of calcium cyanamide. According to the Registrant, N-P-K fertilisers cannot be considered a suitable replacement for calcium cyanamide because their composition is distinctly different. In addition, N-P-K fertilisers on their own do not contain calcium, which is generally valuable especially where the soil pH is low. In many cases, and especially on acidic soils, farmers use additional liming. N-P-K products supplemented with additional lime could offer a better replacement for calcium cyanamide. However, additional liming would obviously increase the production costs if it required a separate application.

When concentrating on the functional characteristics of slow release, there appear to be also other types of products and alternative technologies available. Trenkel (2010) offers an extensive discussion of different types of slow- and controlled-release fertilisers (SRFs and CRFs), which are here taken to mean fertilisers containing plant nutrients in a form which either delays the availability for plant uptake after application or is available to the plant significantly longer than common nutrient fertilisers (see Terlingen et al. 2016)[83].

Besides efficacy, price differences between different options are especially important in general

[80] Specific risk aspects are discussed in detail in Annex B.

[81] Could be viewed as a primary effect because it occurs at the time of fertilisation.

[82] Cyanamide is an interest here as it is one of the primary transformation products of calcium cyanamide and causes adverse effects in the environment.

[83] Terlingen et al. (2016, p.5) provide definitions for the aforementioned fertilisers: Controlled release fertiliser: Fertiliser in which nutrient release is controlled, meeting the stated release rate of nutrient and the stated release time at a specified temperature. Slow release fertiliser: Fertiliser, of which, by hydrolysis and/or by biodegradation and/or by limited solubility, the nutrients available to plants is spread over a period of time, when compared to a ''reference soluble'' product e.g. ammonium sulphate, ammonium nitrate and urea.

agricultural production with often relatively low-value bulk products. An overall effectiveness of an alternative needs to be weighted with respective production costs – in some cases a potentially less effective fertiliser alternative, if cheaper, may produce a comparable economic result in the end.

Private optimisation may in many cases differ from a social optimisation. For instance in case of controlled-release fertilisers Terlingen et al. (2016) point out potential benefits such as the reduction of fertiliser leaching to air, water and soil, which are all externalities/public goods, not clearly showing in a farmer's decision framework. In the case of calcium cyanamide, the private optimisation may also significantly differ from the social optimum as the 'beneficial secondary effects' of calcium cyanamide (in controlling weeds) desired by a farmer, are the main cause of environmental risks when assessing the environmental impacts.

When assessing the proposed restriction, one needs to therefore carefully distinguish between the net effects of the proposed restriction and the baseline situation. In both cases, private user (net) benefits as well as social (net) benefits need to be taken into account.

4.2 Risk management options

Based on the risk assessment presented in Section 3.2, the Dossier Submitter concludes that the risk to the aquatic and terrestrial environment from the use of calcium cyanamide as a fertiliser is not adequately controlled. Therefore, ECHA has conducted 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.

As a first step, the possibility to address the risks to environment from the use of calcium cyanamide as a fertiliser under other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined. However, these were assessed to be inappropriate to address all potential risks (see Annex C.1.2 for more detail). 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. Below the identified RO are briefly described.

1. Restriction on the physical nature of the product: only granules can be used – the powder form is prohibited.
2. Restriction on the agricultural production method/technique used (e.g. maximum use rate per hectare, use of mandatory vegetated field strips, broadcasting (i.e. spread evenly on crop/soil) restricted, placement into soil required after application to bare soil.
3. A requirement for all farmers using calcium cyanamide as a fertiliser to follow rules of an existing Common Agricultural Policy (CAP) measure of cross-compliance (See Annex D.1.1 for a further explanation).
4. Restricting the placing on the market of calcium cyanamide as a fertiliser and the use of calcium cyanamide as a fertiliser.

The potential ROs are listed below.

Table 27. Considerations related to potential restriction options

Potential restriction option		Risk considerations	Impact considerations	Efficiency considerations	Risk reduction considerations
RO 1	Ban of powder form (inhalation concern)	A Risk assessment for the powder form has not been carried out by the Registrant so its use cannot be supported.	Restricted applicability, Insignificant/ zero use, low cost → proportionate	Practicable, enforceable	Low/zero – mainly human health (if any[84])
RO 2	Detailed regulation of acceptable agricultural production methods: Max kg/ha limit; mandatory adoption of buffer zones; limits for broadcasting on bare land; mandatory incorporation of fertiliser; other	Consistent with the RA as can be tailor-made.	High applicability. Laborious, requires detailed agricultural expertise and complex agriculture sector-specific regulation potentially differentiated by region, crop, soil-type, etc.	Non-practicable as requires very complex sector-specific regulation. Difficult to enforce within the Reach framework methods	Medium/Low – potential risk reduction on some waterways, no risk reduction on terrestrial/soil risk
RO 3	Utilisation of existing CAP measures e.g. a mandatory adoption of cross-compliance measures where calcium cyanamide is used	Potentially/weakly consistent with the RA	Good applicability, but low 'value-added' vs. current situation	Practicable, enforceable	Low – EU farmers largely already follow the cross-compliance rules; may alleviate the problem, however not remove the risk

[84] The manufacturer informed the Dossier Submitter 14 Dec 2017 that the sales of the powder were to be discontinued in Jan 2018.

RO 4	Total ban of $CaCN_2$ use	Consistent with the risk assessment	Substitutes available however w/ risks – increased nitrogen leaching and PPP use. Proportionality questionable if risks of likely alternatives are accounted for	Practicable, enforceable,	High concerning calcium cyanamide induced risk – potentially significant environmental trade-offs due to use of alternative fertilisers and PPPs

Each of these options has been assessed against the main criteria for restriction: effectiveness, practicality and monitorability. As a result of this assessment, RO4 was proposed and the others were discarded. The risk reduction capacity (effectiveness) of RO1 and RO3 was found to be limited i.e. they would not address the risk that was not adequately controlled.

RO2 could address risks to surface waters, but was rejected as it would not be effective in managing the risks to the terrestrial environment and may need to be differentiated per crop, field and location, which was concluded to be too complex and challenging to design, implement and enforce in practice.

RO4 is the only restriction option expected to be capable of adequately controlling the risk from the use of calcium cyanamide. However, depending on the alternatives used, RO4 may cause significant environmental trade-offs. The risk management options and their socio-economic impacts are described further in the Annex C.

4.3 Proposed restriction

Calcium cyanamide shall not be placed on the market or used as a fertiliser.

The requirement for use in granulated form was added due to the concerns surrounding worker exposure by inhalation raised by SCHER (see section 3.1). The registrant has subsequently indicated that use of the powder form is advised against in their registration and no longer supplies this (Alzchem, 2019a).

A transitional period of three years is proposed to allow the manufacturer and retailers to sell current stocks as well as to allow farmers and other end users to find suitable alternatives (alternative fertilisers and/or crops) including obtaining knowledge, technology and any necessary machinery. There are no additional use conditions foreseen by the Dossier Submitter.

Brief title: Restriction on the use of calcium cyanamide as a fertiliser

Column 1	Column 2
Calcium cyanamide EC number: 205-861-8 CAS number: 156-62-7	1. Shall not be placed on the market as a substance on its own or in a mixture for use as a fertiliser; 2. Shall not be used as a substance on its own or in a mixture as a fertiliser; 3. The restriction shall apply after dd/mm/yyyy[85].

[85] The Dossier submitter proposes a 36-month transition period to utilise products now on the shelves,

4.3.1 Justification for the selected scope of the proposed restriction

The proposed restriction is assessed to be the most practical, implementable and monitorable measure to significantly reduce the negative environmental risk occurring from use of calcium cyanamide as a fertiliser. The proposed restriction is administratively feasible as it can be implemented within existing administrative structures in the EU.

The measure is not intended to address leaching of nitrates, although this issue is considered in terms of suitable alternatives.

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 (the proposed derogation for closed-system use is only allowed if cyanamide is in granulated form).

Due to broad availability of alternatives, the substitution of calcium cyanamide as such should not be a problem in Member States. However, potential substitutes also have concerns of their own. It is acknowledged that where (slow-release) calcium cyanamide is substituted with another (non-slow-release) nitrogen fertiliser, nitrogen leaching may increase. The Dossier Submitter was not able to obtain any quantitative or qualitative information on how farmers will react to the proposed restriction. Secondly, the use of calcium cyanamide has been promoted for its secondary effects such as reducing the need to control weeds and fungi on agricultural fields. As potential substitutes do not have such effects, the restriction of calcium cyanamide is expected to increase the use of plant protection products. The net change in environmental risks due to the substitution of calcium cyanamide with another fertiliser potentially combined with an adoption of available approved plant protection products is assumed to be neutral or marginally positive as the PPPs are based on active ingredients specifically authorised for this use. However, there is no direct evidence on this available.

Another potential substitute can be found from industrially produced slow-release and controlled-release fertilisers. However, use of these alternatives have their own concerns. For instance, fertilisers that use polymers to adjust the release rate of nitrogen are associated with the microplastic concern[86], as the polymers may be persist in the environment.

As an alternative to the restriction proposed, the Dossier Submitter has also considered another option (RO2), a restriction limiting acceptable application methods (e.g. banning broadcasting on bare soil) and imposing requirements for vegetated buffer strips on the margins of fields adjacent to surface waterways. However, to fully assess the effectiveness of such measures requires detailed knowledge of intricacies of agricultural production. The measures would also need to be specifically tailored to the environmental conditions of the place of use. In addition, even if such measures could address environmental risks concerning surface water, they will not address the risk to soil-dwelling organisms. Furthermore, use of such measures would require complex enforcement, as normal REACH inspectors would not carry out such inspections. Therefore such a restriction is expected to be administratively costly. However, to enable discussion, a potential RO2 type of restriction is described in

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and for end-users to acquire information, machinery and knowledge of alternative technologies and/or crops to be able to replace CaCN2 use.

[86] Polymers in EC fertilisers will need to be biodegradable in the future under Regulation (EU) 2019/1009, so perhaps less concern here. However, the requirement may affect their availability and/or prices in case biodegradability requirement causes significant further R&D work.

Section 4.10 with an outline of how to assess it.

4.3.2 Enforcement conditions and entry into force

Enforcement of the proposed restriction is expected to be straightforward. If the restriction bans the placing on the market and use of calcium cyanamide as a fertiliser (on its own as a substance or in a mixture), this has to be taken into account in the EU Fertiliser Regulation.

There are numerous analytical methods reported in the scientific literature[87] that are suitable for the determination of calcium cyanamide and its degradation products (urea[88], DCD) in different type of samples e.g. fertilizer, soil, plant samples. The Dossier Submitter concludes that no single technique is dominant in all areas because of the diversity of applications. The limits of detection of calcium cyanamide and its degradation products depend on the analytical methods used.

The following analytical techniques which were used by the Registrant for the analysis and quantification of the substance calcium cyanamide in the REACH registration dossier are listed here to provide some examples. This list reflects some of the currently available analytical techniques but does not intend to be exhaustive. The concentration of calcium can be determined by inductively coupled plasma optical emission spectroscopy (ICP-OES). The content of calcium cyanamide can be determined by the Kjeldahl method while urea and cyanoguanidine (DCD) can be separated chromatographically by HPLC and determined by UV detection.

Given that analytical methods exist, the proposed restriction is considered as enforceable.

In case of RO2, the potential measure would limit behaviour of the end users (farmers) and the enforcement in the REACH framework appears challenging as it could include inspection of land parcels and farming practices on numerous farms in several member states. In case a restriction would affect any farm level practices, it would be preferable that the measures were designed to be part of the general agri-environmental policy as this would allow streamlined enforcement mechanisms.

4.4 Response to the restriction scenario

Upon entry into effect, calcium cyanamide would no longer be available for agricultural field production. The likely alternative would be another industrial nitrogen fertiliser, like urea, ammonium nitrate or ammonium sulphate. Alternatively, if the slow-release characteristics were indispensable, more advanced industrially designed slow-release fertilisers (SRF) and controlled-release fertilisers (CRF) would be needed. Both types of alternatives are marketed in the EU (see the Annex C.2 for more discussion on available alternatives). As calcium cyanamide is used only on a small percentage of agricultural land in the EU, it is expected that the market would provide enough substitutes within a reasonable transition time.

Traditional (non-slow release) alternatives, or less common slow-/controlled-release fertilisers are expected to be readily available within the transition time proposed, such that there will be no shortages of nitrogen fertilisers in the EU agricultural sector. The restriction is not expected to affect the continuation of farming or the choice of crop on aggregate level as the latter depends on many other aspects besides availability of a certain fertiliser (e.g. the availability

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[87] Please see Nagumo, Y. et al. (2009); Chen, S. et al. (1991); Lambert, D.F. et al (2004); Francis, P.S. et al. (2002) ; Huidong Q. et al (2015); Turowski M. et al (2004); Huidong Q. et al (2015b).

[88] To be noted that calcium cyanamide is not the only source of urea in soil; the presence of urea in the soil can be due to the use of other fertilizers, for example.

of machinery, soil type, human capital, contracts, etc.).

4.4.1 Alternatives

In practice, the choice of fertiliser is made based on various factors including soil type, crop choice, market price and climatic conditions. When assessing alternatives, one of the main trade-offs is related to the question of whether a farmer would replace calcium cyanamide by a simple, traditional, inexpensive nitrogen fertiliser like urea or ammonium nitrate, or by a more expensive slow/controlled-release fertiliser. There are a number of products available, where the slow/controlled-release characteristic is built-in into the fertiliser; e.g. via nitrogen inhibition or via the use of a coating.

Slow-release fertilisers where the release is controlled with a plastic coating has been a concern as they may cause some microplastics residues to be left in the environment, potentially causing serious problems when accumulating over time. However, the new fertiliser regulation requires all the plastics used to be biodegradable and therefore, the plastic coating should not be a problem in the future.

Other alternatives using the nitrification inhibitors do not have similar problems, however, responses received in the consultation (e.g. #2750, #2776) inform that those alternatives need to be also carefully assessed as in some cases cyanoguanidine (DCD) may be used as an inhibitor. The Dossier submitter acknowledges the potential concern.

Entec 26 and Agrocote/Agromaster are examples of slow/controlled-release fertilisers on the market. Entec 26 uses nitrification inhibitors (DMPP, 3,4-dimethyl-pyrazole phosphate) to delay the oxidation of ammonium to nitrate in the soil. Agrocote uses a polymer coating, where the release of nutrition is based upon moisture and temperature.

Considering that the so called secondary benefits (sanitary, phytosanitary effects, improved plant health) are found to be an important character in using $CaCN_2$, neither type of the aforementioned industrial slow-release fertilisers offers them. Therefore, when $CaCN_2$ is replaced with another fertilisers, more PPPs may need to be used. Practically, in case of $CaCN_2$, the very mechanism and the extent of (the secondary benefits and) the adverse effects are unknown[89]. Therefore, from the regulatory point of view, the use of authorised PPPs is preferred.

A consultation comment #2932 questions the assessment of alternatives in the dossier. The Dossier Submitter has prepared the dossier with the concern on environmental effects of the calcium cyanamide as a fertiliser as requested by the European Commission. The Dossier Submitter notes, that the risk assessment in this restriction dossier is made and assessed under the REACH legislation, and the dossier as a whole is constructed according to REACH guidelines. Generally, risks of potential alternatives are not studied to the same extent as the substance proposed to be restricted. As the dossier states, there are several alternative fertilisers available on the EU market and in broad use by farmers. Given that the calcium cyanamide is the first nitrogen fertiliser to undergo the restriction process, understanding of the risks of the potential alternatives may still improve in the future.

4.5 Economic Impacts

If the use of calcium cyanamide is restricted and there is a need to use an alternative, the

[89] Comments #2762, #2765, #2772 in the consultation promote the importance of the secondary effects of the $CaCN_2$ and some of them even its usability as part of the integrated pest management, however, they do not clarify the mechanism of the secondary effects.

main impacts identified for the user (farmer) are potentially lower economic returns due to changes in fertiliser effectiveness as well as due to the loss of beneficial 'secondary effects' (which are expected to be replicated by additional use of PPPs). Reductions in production costs could partly offset these impacts, particularly where farmers switched to less expensive fertilisers. On the other hand, lower effectiveness of alternative fertilisers as well as higher requirements for labour and additional demand for PPPs throughout the growing season would likely increase the net (user) costs of production for their part.

As discussed in section 3.2, the potential substitution of calcium cyanamide could also result in detrimental environmental effects. Firstly, possible increases in nitrogen leaching in case alternative slow-release fertilisers are not used and, secondly, environmental effects due to the additional use of plant protection products (e.g. to control clubroot, common weeds etc.) as alternative fertilisers lack the 'secondary effects' of calcium cyanamide.

However, the current use of PPPs alongside the use of calcium cyanamide as a fertiliser is not known, neither it is self-evident whether a combination of PPPs would manage all the issues more efficiently. It should be noted that cyanamide[90] itself has been earlier assessed in the EU as an active substance to be used in PPP, however, it is not currently approved; consequently, the claimed 'secondary effects', as well as their potential benefits and risks, cannot be considered as properly addressed.

The use of approved PPPs 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. EFSA has indicated that in line with current regulatory requirements whilst the effects of the active substance on non-target organisms are assessed at EU level, the assessment of PPP, possible mitigation options and the level of acceptance of potential effects on non-target organisms, is conducted through a zonal system under the responsibility of the Member States.

Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products, established, for soil non-target organisms quantitative criteria only for the lower tier assessment; and no specific guidance is provided regarding the acceptability thresholds when higher tier studies are provided in the application. This leaves some flexibility at the Member State level when authorising PPPs to take account of local conditions.

Currently, there is no centralised information regarding the risk assessments for PPP conducted by the Member States and detailed indications on the applicability of the Uniform Principles by the Member States in the approval process for PPP formulations. Consequently, the Dossier Submitter has not been able to fully assess what level of risk to non-target organisms was permitted at Member State level from authorised PPPs, or make a direct comparison between the observed effects of calcium cyanamide and authorised PPPs.

The claimed need to increase the use of PPP if calcium cyanamide is replaced by other fertilisers has not been substantiated and has been included by ECHA as a working hypothesis only. In addition, there is no information on the actual PPP and application rates that would be

[90] The PPP 2008-10 review assessed the use of cyanamide in a liquid formulation for use in plant protection products for the stimulation of plant bud opening (plant growth regulator) when air-blast sprayed onto outdoor kiwifruit and grapes at the end of winter period in. The use was not authorised primarily owing to concerns on human health (workers). It is to note, that the use considered was quite distinct from use of granulated fertiliser.

needed to provide similar 'secondary effects' under different agronomic and environmental conditions. As a result it is not feasible to make a definitive comparison between the known adverse environmental effects of calcium cyanamide and those of approved PPPs. The net effect (change) in terms of environmental harm is nevertheless expected to be better for products specifically assessed by the Member States for their use as herbicides and fungicides, and Regulation 1107/2209 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 PPP. These regulatory provisions regarding the assessment of induced environmental impacts should be accounted for by the regulator.

However, the Dossier Submitter acknowledges that this is a difficult task as it requires: 1) predicting the behavioural responses of farmers to the restriction of calcium cyanamide, 2) modelling the consequences of these responses in terms of environmental impacts, and 3) comparing these consequences to the environmental impacts of continuing the use of calcium cyanamide.

Given the above discussion, the economic analysis has to include an assessment of private and societal net benefits. Below, parts of the user benefits are described in quantitative terms. However, the analysis is mostly done in qualitative terms due to a lack of relevant quantitative information.

4.5.1 Economic impacts on end users

The main costs attributable to this restriction proposal are due to decreased profitability in farming. Other costs may be encountered at the manufacturing stage if the production of calcium cyanamide significantly decreases due to the proposed restriction.

Based on the confidential calculations provided by the Registrant, the use of substitutes to calcium cyanamide are expected to clearly decrease per-hectare profitability of potato production as well as of other crops (e.g. cabbage). A report by Chohura and Kołota (2014) shows the effectiveness of calcium cyanamide as a nitrogen fertiliser compared with two alternatives, although, the report does not describe economic results.

Dixon (2012) highlights the beneficial secondary effects of calcium cyanamide in controlling weed infestation during the growing season (due to suppression of soil borne pathogens) and reductions in carbon footprint and nitrogen leaching. The abovementioned study by Chohura and Kołota (2014) also provides support on the secondary effects, showing a clear reduction of weeds in their trials due to calcium cyanamide use. More specifically, Dixon (2017) underlines the benefits of calcium cyanamide use on fields infested with clubroot. All these studies state that the use of calcium cyanamide as a fertiliser decreases the need for plant protection inputs and associated costs for labour and material and, as such, generates user benefits in the form of opportunity gains. However, no quantitative cost estimates are available to the Dossier Submitter.

The Registrant provided ECHA with (confidential) profitability calculations comparing economic results of producing several crops with and without calcium cyanamide. The crops include rice, sugarbeet, maize, oilseed rape, potatoes, processed cabbage, fresh cabbage and lettuce. Based on those calculations, a farmer using calcium cyanamide can achieve greater profits from the production of potatoes compared to a case where urea is used as fertiliser. Whilst these calculations compared the value of the crop yield and the necessary production costs, plant protection costs were assumed to remain the same.

Furthermore, Chohura and Kołota (2014) highlight a quality aspect, as they showed that use of calcium cyanamide resulted in the highest marketable yield of cabbage with significantly lower mean content of nitrates in edible parts when compared to the use of Entec 26 or ammonium nitrate as a fertiliser. The study additionally noted that calcium cyanamide reduced weed infestation during the whole vegetation period. However, the weed reduction effect was not monetised. Information from experimental field studies needs to be used with caution, as use amounts and/or field conditions tend to differ from those in common agricultural production.

The information provided by the Registrant shows that when used with a high value crop, calcium cyanamide could increase profit per hectare by over €750/ha when accounting only for impacts on quantity and quality of the harvest. The abovementioned study by Chohura and Kołota (2014), combined with some separate price information (Landor, 2017), was used by the Dossier Submitter to calculate the profit contribution of calcium cyanamide in case of cabbage production. This calculation resulted in a value added of calcium cyanamide of about €375/ha. However, the Dossier Submitter considers that the calculations are likely to have underestimated the real value added as some of the cost elements related to the use of alternatives were omitted. Both calculations were only concerned with yields, neither accounted for potential gains due to secondary benefits or any opportunity costs in terms of detrimental environmental effects from the additional use of PPPs.

Based on the aforementioned information on the per-hectare productivity losses and assuming that calcium cyanamide is used on about 230 000 hectares (about 0.2% of arable land) in the EU to produce a high value crop (e.g. potato, cabbage), it can be estimated that an upper bound estimate of the productivity loss due to the substitution of the calcium cyanamide with another fertiliser could be about €172m. The estimate would be about €86m per year when using the public research information summarised above.

Irrespective of the consideration above, the Dossier Submitter considers that these loss figures overstate the actual costs, as a crop choice strongly affects the aggregate returns from the use of calcium cyanamide. It is expected that not all land fertilised with calcium cyanamide is used for high-value crop production that would yield such large gains in net returns. For instance, economic gains from the use of calcium cyanamide for oil seed rape or maize production are clearly lower than those for potato or cabbage production.

By combining the crop-specific profitability information and the use-area information (hectares of different crops) provided by the Registrant, a more realistic estimate for the total productivity loss was calculated by combining the per-acre profitability losses for different crops with the use-area information. The resulting per hectare profitability losses range from €270/ha to €343/ha and describe the per hectare profit loss from substituting calcium cyanamide with an alternative fertiliser. The total productivity loss from the substitution of calcium cyanamide in a realistic case ranges between €60m and €80m annually using information about crop-acreages received from the registrant.

Table 28. Per-hectare productivity losses due to substitution of PERLKA® with another fertiliser

	High value crop	Lower value crop	Realistic case estimate
	€/ha	€/ha	€/ha
Registrant information	750	27-87	270-343

Public information	375	44-65	152-217

For transparency, the realistic case was also calculated using information publicly available (although, again partly provided by the Registrant on its webpage). To calculate the profitability loss in the realistic case, first the profitability effect in case of oilseed rape production (a lower value crop) was estimated.

Based on (promotional) information available at the manufacturer's (Registrant) webpage (retrieved on 20 November 2018), the application of 40 kg of calcium cyanamide (PERLKA®) is stated to increase the oilseed rape harvest by 350 kg per hectare on average. Using this information and readily available price information (Landor, 2017) and assuming ammonium nitrate or ammonium sulphate as potential alternatives, the increase in profit from the use of calcium cyanamide as a fertiliser is estimated to range from €44 to €65 per hectare. The Dossier Submitter considers this range to represent the value added of calcium cyanamide in the production of lower value crops.

A third estimate is produced by using the aforementioned profitability estimates for the lower value crops based on the promotional information, and the profitability estimates for high value crops from the Chohura and Kołota (2014) study. Furthermore, the calcium cyanamide use area of 230 000 hectares is assumed to be divided 50/50 between the high-value and low-value crops. This results as an indicative estimate for productivity loss from substituting calcium cyanamide with another fertiliser. The value of the estimate ranges from €35m to €50m per year. This is considered to be a realistic case using publicly available information.

Table 29. Total value of productivity losses due to substitution of PERLKA® with another fertiliser

	Maximum productivity loss per annum	Average productivity loss range in a realistic case
Registrant information	€172m	€60m - €80m
Public information	€86m	€35m - €50m

As a sensitivity analysis, the value of the productivity loss in the realistic restriction scenario was re-calculated assuming that the price of the high value crop was doubled – e.g. price of cabbage increasing from €0.15/kg to €0.3/kg – apparently this is not unrealistic. This calculation resulted in profit losses of over €100m per year. This shows that the total productivity losses reported above are sensitive to product price changes. The Registrant has provided ECHA confidential information about acreages of different crops grown with calcium cyanamide. Based on this information, calcium cyanamide is used to produce several different crops, which suggested the combination of high-value and low-value crops assumed in the Dossier Submitter's estimation. Most of the Dossier Submitter's original estimates are fully or partly based on information from the Registrant (manufacturer) as very little other information is available. Estimated economic impacts of the calcium cyanamide use are based on this information. On the other hand, potential savings related to reduction in labour and plant protection and liming products are not accounted for in the calculations[91]. Based on this, both of the range estimates for the realistic case seem plausible.

Consultation comments #2747 and #2867 provided economic information concerning asparagus production in southern Germany. Based on this information non-availability of the calcium cyanamide fertiliser could reduce production profits from asparagus production over 4200 €/ha. The Dossier Submitter acknowledges the information, and notes that even if this is a case of somewhat niche production and concentrated in certain geographical location, profit differences of this magnitude are important to farmers, especially in case of small-size farms. A consultation comment #2924 provided further information about economics of potato production with calcium cyanamide as a fertiliser.

In conclusion, for the total annual value of the productivity loss in agriculture (the user benefit lost) due to the proposed restriction on calcium cyanamide as a fertiliser, realistic case estimates of €35m and €80m can be used. These would translate roughly to annual productivity losses of €150/ha and €350/ha, respectively assuming a total use area of 230 000 hectares in the EU. The potential user value of any beneficial secondary effects as well as some savings in labour costs would be in addition to that. Practically no information was received in the consultation comments concerning monetary value of secondary benefits. There was one comment (#2956) which claimed that a farmer can save around 30% in “soil disinfection” expenses when using calcium cyanamide fertiliser compared to alternatives. However, there was no transparent justification offered to this claim.

However, as only a small proportion of European farmers are using calcium cyanamide, there is some doubt about the relatively high profitability estimates above. At this point, the reader is reminded that the profitability values provided are an outcome of a deterministic calculation. In reality, with production risk and annually varying yields, the higher price of the calcium cyanamide fertiliser (compared to alternative fertilisers) may prevent some farmers from using it in their production processes, even with the given profitability estimates. Besides the high price, the two other concerns that farmers may have need to be mentioned here – suspicions about potential human health concerns and limitations in application timing of the fertiliser[92]. Accounting for such concerns, the values estimated by the Dossier Submitter appear to be more realistic.

SEAC BOX:

SEAC took note of the abovementioned profitability loss calculations by the Dossier Submitter concentrating on the values based on “average productivity loss range” in a realistic case ending up with a range of €35m - €50m. Using the same approach SEAC went further and performed sensitivity analysis across a range of assumptions (lower yield increases, a smaller share of high value crops, lower price for high value crops, and

[91] The difference in profitability only accounts for the higher value harvest (quality and/or quantity) and the difference in the fertiliser costs. Other elements remain the same. For instance, handling costs of harvest may increase with the harvested amount, however, this effect is not accounted for in the comparison.

[92] Previously, there was some concern that the use of calcium cyanamide was potentially hazardous to human health. This concern was linked to the inhalation risk associated with the powder form of calcium cyanamide. Also, some farmers may have avoided its use as the application needs to be aligned with the seeding/planting such that the fertiliser does not harm the main crop. Together, these reasons may have disincentivised farmers to use calcium cyanamide as a fertiliser even if it might have provided clear user benefits in form of more valuable harvest or lower plant protection costs.

higher/lower application rates for high-value/low value crops respectively).

Assumption	DS	SEAC sensitivity
Volume of fertilisers containing $CaCN_2$ in a concentration of 44%, tonnes	70000	Same
Distribution between high value crops/low value crops	50/50	35/65
Average application rate 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 $CaCN_2$, 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[93]/61	€113/61
Cost decrease per ha using ammonium nitrate (20% price reduction), high value crops/low value crops	€376/82	€151/82

The calculations resulted in the profit loss estimates of €10m-€16m. In the SEAC draft opinion SEAC used these estimates for the profit losses for farmers.

During the SEAC draft opinion consultation, SEAC received comments suggesting higher farmer profit losses in some cases. SEAC acknowledges comment(s) submitted in the consultation 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 by the Dossier Submitter and the estimates by SEAC in the final opinion. 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.

4.6 Environmental and human health impacts

The environmental impacts to be addressed by the proposed restriction are summarised below. Based on the preliminary analysis by ECHA (2018) an increased human health risk was possible from the use of the powder form of calcium cyanamide. However, the Registrant has informed ECHA, that calcium cyanamide in powder form had not been placed on the EU market since the end of 2017. Therefore, this formulation no longer appears to pose a risk to human health and, on request of the European Commission, this study looks into the possible risk to the environment only.

Because of the difficulties in measuring or even describing these impacts, a qualitative benefit assessment is considered appropriate.

4.6.1 Benefits of the proposed restriction for the environment

Based on the risk assessment presented in this report, there is a clear environmental risk to both the aquatic and terrestrial compartment. Specifically, there is a risk to water-dwelling organisms in watercourses adjacent to fields fertilised with calcium cyanamide, and to soil organisms in the terrestrial compartment. There is also evidence that significant quantities of cyanamide and DCD reach groundwater via leaching through soil. Based on this risk

[93] 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.

characterisation, waterways adjacent to fields fertilised with calcium cyanamide as well as the respective agricultural soils are negatively affected by the toxicity of calcium cyanamide (and its degradation products). Based on the assumptions of the Dossier Submitter, this would mean that up to 230 000 hectares of agricultural land could potentially be negatively affected by environmental impacts of calcium cyanamide use. There is no data available about the number of hectares of waterways adjacent to fields fertilised with calcium cyanamide, however.

PPP (2008-10) in its review reported the risk from cyanamide to birds as an area of critical concern and a data gap. For small mammals and bees, a low risk was established despite the toxicity of cyanamide to both groups. This was because cyanamide was applied in a liquid formulation at the end of the winter period when it was considered that neither small mammals nor bees would be exposed to it. It is unclear whether these organisms would be exposed to cyanamide through the use of calcium cyanamide as a (granulated) fertiliser, which is typically applied during the period of February to September.

It is not a trivial exercise to demonstrate an adverse environmental impact for a specific substance in the environment, therefore the main quantitative outcome is that the environmental risk associated with the use of calcium cyanamide would be removed from an area of up to 230 000 hectares.

The section on alternatives explained that limited information is available regarding the net environmental impacts of a farmer switching from calcium cyanamide to an alternative fertiliser. This is because a farmer may use approved plant protection products to achieve the secondary effects of PERLKA®. Hence, the environmental impacts of alternatives (including the additional use of plant protection products) could be largely the same compared to the impacts of calcium cyanamide (where its ‘secondary effects’ make obsolete the use of additional plant protection products). The main difference is that the use of approved PPPs would be more likely to result in a net positive effect in terms of environmental harm compared to calcium cyanamide that has not been approved for use in PPPs in the EU.

4.6.2 Potential harm to the environment

As described in the context of alternatives, there are at least two types of possible harm to the environment that could result from the proposed restriction:

it is possible that nitrogen leaching to adjacent surface water would increase if calcium cyanamide is substituted by e.g. a typical N-P-K fertiliser or ammonium nitrate. Such effects should be compared to the benefits of the proposed restriction to find out the net environmental impact. However, no final study results applicable to calcium cyanamide are available, where the consequent environmental harms (compared to use of alternatives) have been assessed, and therefore we are not able to quantify the effects. Leaching of nitrogen can be assessed using a nitrogen balance[94]. The amount of nitrogen leaching to the environment is inverse to the amount of nitrogen harvested in the crop. In other words if similar amounts of nitrogen applied in form of calcium cyanamide produce larger harvest than when applied using alternatives, the overall nitrogen balance is lower, which means the leaching is lower for

[94] Losses of nitrogen from agricultural land to the environment are commonly measured in terms of a ‘nitrogen balance’. For a description, see e.g. the ‘Environmental Indicator Report 2018’ published by European Environmental Agency: https://www.eea.europa.eu/publications/environmental-indicator-report-2018.

calcium cyanamide.

For instance, using the same study as for the economic impacts (Chohura & Kolota, 2014) it was found that the harvested amount was about 4% higher when using CaCN2 as a fertiliser instead of Entec 26 or Ammonium nitrate. Assuming that nitrogen content stays the same this suggests that the amount of nitrogen “harvested” is about 4% higher and thus the amount released in the environment is smaller.

The result is interesting as in the same time the amount of weeds was significantly decreased with calcium cyanamide use (about 50% less in number per m^2 and over 60% in weight). This suggests that the secondary effect has a clear role in indirectly decreasing the nitrogen release; by controlling weed growth it helps the main crop to better utilise the nitrogen, which in turn decreases nitrogen releases. 2) To replace the secondary effects of calcium cyanamide, the Dossier Submitter assumes that, if calcium cyanamide is substituted with an alternative without secondary effects, a farmer wanting to keep their yield constant would need to use a plant protection product which would have a comparable toxic effect as that of calcium cyanamide. This could be interpreted as suggesting that the net environmental impact of the use of alternatives would not be largely different from the impact of the calcium cyanamide use. This conclusion is however based on the assumption that the environmental impacts of alternatives would be similar to those caused by calcium cyanamide. However, as mentioned above, as the mechanism of the secondary effects is not known, the use of the authorised PPPs is preferred from the regulatory point of view as it may have fewer non-target effects.

As a conclusion, there is a significant uncertainty about the net environmental impacts of the restriction. In practise, the nitrogen leaching due to use of alternatives appears higher, and the environmental impacts due to the secondary effects would be replaced by somewhat more predictable ones from the use of authorised PPPs.

4.6.3 Benefit to human health via environment

As mentioned above, the preliminary analysis by ECHA (2018) found the most likely risk to human health to be related to inhalation exposure to the powder form of calcium cyanamide (when used as a fertiliser). Noting that the manufacturer reported to ECHA that it ceased the supply of the powder form of calcium cyanamide in January 2018, this exposure route can be deemed of little relevance to human health.

However, detrimental effects on humans via the environment have to be accounted for. As discussed above in the context of groundwater contamination, such effects on humans via the environment are less clear. Depending on the limit value chosen to protect groundwater, there may or may not be a risk to groundwater quality and consequently to humans via drinking water. When using the limit value (see section 3.2.10.2.3) chosen by the Registrant, the use of calcium cyanamide as a fertiliser for apple crops does result in a risk to groundwater quality. However, by using an alternative method for setting a limit value based on WHO guidelines for drinking water, it appears that the cyanamide does not exceed the limit value in the scenarios modelled. On the basis of the latter approach, the use of calcium cyanamide as a fertiliser does not appear to pose a risk to groundwater and drinking water quality (if the groundwater is used as a potable source).

Another human health concern is the ED property of the calcium cyanamide. The Biocidal Product Committee provided an opinion in December 2019 that cyanamide is an endocrine disruptor for human health and non-target organisms[95]. Following the adoption of the BPC

[95] On 4-5 June 2019 the Endocrine Disruptor Expert Group (ED EG) reached broad agreement that the

opinion, the European Commission may proceed to decision making within a few months. If the ED property is agreed, the potential harm from the use of calcium cyanamide as a fertilisers could be greater than currently estimated, and therefore the benefits of the proposed restriction would be further increased.

4.7 Wider impacts

4.7.1 Impacts on the Registrant

Calcium cyanamide as a fertiliser is produced by a single manufacturer in the EU, AlzChem Trostberg GmbH, a part of AlzChem Group located in southern Germany. The product is sold under the brand name PERLKA®. According to its own website, AlzChem Group as a whole has several sites within EU, about 1 500 employees and an annual net sales of above €350m and EBITDA of €46M in 2017. There is no information available on the share of the fertiliser sales. Besides PERLKA®, AlzChem's agricultural product range includes cyanamide-based biocides for use in pig pens, as a disinfectant (product type 3) and to control fly larvae (product type 18).

The proposed restriction is expected to have a sizable impact on the company, especially on the subsidiary located in Trostberg, as it is expected to cause a major decrease in the manufacturing of PERLKA® with potential job losses, even if some of the lost sales within the EU could be offset by increased exports.

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 losses incurred by AlzChem. Given the secondary effects of calcium cyanamide, there could also be some gains to producers of PPPs, which would further compensate the manufacturer losses. The net societal loss remains unclear. The Dossier Submitter notes information received in a confidential comment #2920, which suggests that the (employment) gains by producers of alternatives may not be significant in case the current production of the calcium cyanamide fertiliser ends. The information received appears not to contradict with the Dossier Submitter's analysis. A consultation comment #2937 points out some interconnections between calcium cyanamide production and pharmaceutical industry stating that the proposed restriction on calcium cyanamide could affect the secure supply of a diabetics drug in Europe. Details are given in the confidential attachment. The Dossier Submitter acknowledges the comment, however, is not in the position to judge the significance of the problem in practise.

4.7.2 Supply chain impacts

The main inputs in the production of PERLKA® are quicklime (calcium oxide), coal (coke), nitric acid, nitrogen gas, dolomite and calcium nitrate. The manufacturing process requires a significant amount of electricity. Raw materials and inputs are supplied from nearby, mainly from southern Germany and Austria, coal (coke) is sourced from Poland and Hungary. Generally, AlzChem sources raw materials from EU suppliers. The electricity needed is locally produced using waterpower. It is presumed that the inputs used in the production of calcium cyanamide find use in other production processes, and are not left idle.

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information available is sufficient to identify the substance as 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.

On the agricultural sector, it is assumed that the proposed restriction does not significantly affect the volume of agricultural production and the number of hectares used as farmers as end users have alternative fertilisers available. However, the restriction might have an effect on crop selection, as calcium cyanamide is more suitable for some crops than for others.

4.8 Practicability and monitorability

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

4.9 Proportionality to the risk

The last stage of the assessment against the criteria for proportionality of a restriction is an analysis whether the proposed restriction is a sound regulatory measure. According to the ECHA Guidance on the preparation of an Annex XV dossier for a restriction, this entails among others:

- An analysis of whether the effort required from the actors to implement and enforce the proposed restriction corresponds in amount or degree to the adverse effects that are to be avoided;
- An analysis of whether the proposed restriction ensures a good balance between costs and benefits and is cost-effective.

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

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

4.9.1 Affordability

One of the key criteria to demonstrate that the proposed restriction is technically feasible for an end user arises from the fact that most EU farmers are not using calcium cyanamide as a fertiliser. This shows that there are technically and economically feasible alternatives available. Given the information available on relative prices and market shares of alternatives, most EU farmers prefer other fertilisers. This evidence indicates that switching to alternative fertilisers is, in principle, an option to a farmer, however, costly.

Fertiliser costs are only one element in a farmer's production function. However, as shown above, effects on net returns and (for certain high value crops) on profits may be significant. As a result, it is expected that although affordable in a sense that farming may continue, the proposed restriction would significantly reduce profits of farmers that previously used calcium cyanamide.

Similar agricultural equipment is used for spreading alternative (granulated) fertilisers. Therefore, the proposed restriction is not expected to have a direct effect on e.g. the need for the acquisition of new farming machinery. However, concerning potential secondary effects of calcium cyanamide, farmers may need to use additional labour inputs for instance if fertilisers are to be applied more frequently or if more PPPs will be used as a result, and this naturally increases the costs.

The above considerations suggest that, on average, the proposed restriction is feasible to a farmer considering that the continuation of farming activities should be possible using alternatives.

4.9.2 Cost-effectiveness

The proposed restriction is expected to remove the risk associated with the use of calcium cyanamide from about 230 000 hectares of agricultural land in the EU and from waterways/groundwater adjacent/under fields where calcium cyanamide is being used as fertiliser. Substitution of calcium cyanamide with alternatives may in practice replace the risk from calcium cyanamide with risks to the environment from the alternatives: e.g. a possible increase in nitrogen leaching and potential additional use of plant protection products. The net environmental impact is a sum of the above consisting both of beneficial effects due to ceasing the use of calcium cyanamide and of increased effects from the increased use of the alternatives. In theory, the value of the impact could be assessed through valuing the ecosystem services of agricultural land and agricultural soil. However, the description and valuation of ecosystem services is difficult. As a whole, based on the currently available information, it is not clear whether the net environmental impacts would increase or decrease due to the restriction proposed.

Productivity (and thus profit) losses of farmers appear to be the main cost of substitution. The size of such losses largely depends on the crops grown. Based on the calculations provided in Section 4.5.1, in the case of high-value crops the (annual) costs of substitution (lost productivity) could range from €375 to €750 per hectare and in the case of low-value crops the (annual) cost range is €27 to €87 per hectare on average.

The total annual cost is estimated to range from €35m to €50m in the realistic case where the EU-wide use area of 230 000 ha is assumed to be divided 50/50 between high-value and low-value crops. Using the confidential productivity information and the realistic acreage information provided by the registrant the total costs range from €60m to €80m in the realistic case. The endpoints €35m and €80m would translate into about €150/ha and €350/ha respectively.

The values appear significant and the calculation only accounts for the harvest increase. As such, it may ignore some of the costs related to alternatives, e.g. potential savings in terms of costs for PPPs.

As mentioned above, these costs only represent the costs to farmers. The Dossier Submitter has not quantified potential costs to other parties. The quantitative assessment of cost-effectiveness remains challenging as the size and value of the environmental net impacts are not well understood. It remains however, that for the cost-effectiveness, the value of environmental net impacts should be at least as high as cost of substitution.

4.10 A short description of potential restriction option two (RO2)

Based on the previous 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. However, the proportionality of the proposed restriction is not readily quantifiable and depends on the substitution choices made by the users. An alternative restriction option to the ban on placing on the market and use proposed would consist of a requirement for specific limitations on agricultural production methods and techniques when calcium cyanamide is used as a fertiliser. This restriction option (RO2) was discarded by the Dossier Submitter as it would only address a part of the risk. However, it is further discussed here to encourage additional information to be submitted in the consultation on the proposal. Furthermore, it is outlined how to assess its proportionality.

RO2 could consist of following requirements:

i) a deep placement of fertiliser to a specific soil depth e.g. 10 cm in case of a on bare soil,
ii) ii) use of vegetated buffer strips on fields adjacent to waterways, and
iii) iii) ban of the use of calcium cyanamide on sensitive areas and/or specific soil types.

This type of restriction would reduce the risk to surface waters and of contamination of groundwater. However, its effect on the risk on soil organisms is expected to be limited or zero. The benefits would consist of decreased environmental effects specific to calcium cyanamide as well as decreased nitrogen (and soil particle) leaching. Quantification of these benefits tends to be difficult.

Deep placement significantly decreases surface run-off of fertiliser. In doing so, nitrogen leaching to waterways is decreased and fertiliser use-efficiency is improved. Deep placement further improves fertiliser effectiveness by placing the fertiliser and the seed close to each other. Therefore, this feature of RO2 is expected to provide both economic and environmental benefits.

Vegetated buffer strips would reduce the aquatic toxicity effects of calcium cyanamide by limiting their run-off to the waterways. Additionally the strips would decrease leaching of nitrogen (in case of calcium cyanamide and its breakdown products and similarly in case of alternatives) as well as soil particles. In the modelling undertaken by the Dossier Submitter, the vegetated buffer strips appear to decrease run-off. However, the risk was only adequately controlled in a few scenarios modelled (see Table 13) using vegetated buffer strips up to 20m in width. As a summary, the vegetated buffer strips appear to reduce the risk from calcium cyanamide as well as from leaching. However, if it rather induces a farmer to adopt alternatives instead, the environmental effects are unknown.[96] The above discussion underlines the complexity of assessing the impacts of RO2 or a similar risk management measure.

The third requirement, the use ban of calcium cyanamide on sensitive areas or specific soil types would ban its use and reduce related run-off and leaching to groundwater e.g. in case of sandy soils. However, as in the case of the vegetated buffer strips, the measure could decrease the aquatic toxic effects specific to calcium cyanamide, but in turn increase nitrogen leaching if the alternative used was a general nitrogen fertiliser without SRF/CRF features. As a

[96] Curbing the nitrogen leaching should be more important if general alternative fertilisers are used (instead of SRFs/CRFs). The value of a buffer strip requirement for the use of calcium cyanamide would appear questionable, if the requirement caused a farmer to move to general fertilisers (instead of SRF/CRF) which do not require buffer strips and therefore potentially increase nitrogen leaching.

conclusion, the environmental net effect of such a RO2-type restriction would be unclear.

On the cost side, the impacts vary widely by the requirement. Concerning the area applied, the deep placement requirement affects all uses on all fields, causing cost increases where the current practise would need to be altered. The buffer strip requirement is only applicable to fields adjacent to waterways and the requirement concerning the sensitive areas would limit usage on certain fields based on specific, local environmental conditions. The difficulty is that there is no acreage data available enabling the cost calculation.

In the case of the deep placement requirement, the main cost items are expected to be related to the replacement of machinery and/or additional labour costs. In case of this requirement, traditionally used inexpensive disc spreaders would need, in many cases, to be replaced by alternative machinery including an integrated cultivation system or with a deep placement fertiliser machinery costing more than the traditional spreaders. Additionally, use of deep placement machinery will most likely require more labour time, thus adding into labour costs. Potential increases in yields may partly balance the costs. However, a net cost is expected to remain.

If the buffer strip requirement is applied, the costs relate among others to i) a reduction in productive area, ii) a decrease in labour/machinery use efficiency as the average field size is decreased, and iii) an increase in plant protection activities as a buffer strip offers a breeding area for pests and weeds (note: it would also provide biodiversity benefits). The reduction in productive area would in principle be simple to calculate. However, the Dossier Submitter is not aware of data revealing acreage adjacent to water ways.

In case use limitations on sensitive areas/soils are set, farmers are affected as they need to stop or reduce the usage of calcium cyanamide and potentially to replace it with an alternative less preferred fertiliser. In some cases this may lead to another crop choice. The overall costs are related to lower profits and potentially due to some adjustment costs if a change in farming technology is required. The scale of such costs varies.

The RO2 type of restriction may be feasible if the consequent partial risk reduction is deemed acceptable. However, if terrestrial and groundwater risks are also to be removed, RO2 would not ensure adequate risk control. The approach is more flexible than the proposed restriction leaving more room for farmers to take account of site-specific considerations. At the same time, the application of such detailed requirements governing agricultural production methods and technology require a detailed knowledge of agricultural production as well as the implications of different measures.

As discussed above, the design of such a measure is challenging in order that it functions as intended and avoids perverse incentives, e.g. greater use of plant protection products. Secondly, the enforcement of such a restriction would require a complex enforcement mechanism covering numerous production methods and large number of agricultural producers. Compared to e.g. a general ban, the enforcement mechanism for an RO2 type of restriction would be challenging and potentially quite costly.

The Dossier Submitter includes this option to allow further information to be submitted in the consultation of interested parties to provide the Commission and Member States with a better understanding of this option. Importantly, the Dossier Submitter is not proposing the RO2 alongside the proposed restriction as it does not reduce all the risks identified and there are many uncertainties over its implementability.

5 Assumptions, uncertainties and sensitivities

In the risk assessment, as well as in the impact assessment, several uncertainties exist which are mentioned in the analysis above. Here are the main issues listed:

a) There is very little monitoring data available for calcium cyanamide or its transformation products in the environment, or in human biomonitoring. 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;

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 DCD. The conversion rates according to Dixon 2017 have been utilised.

A sensitivity analysis has been carried out on the results of the risk assessment (see section A.10.4). A comparison has been made of the risk characterisation results presented by the Dossier Submitter using a REACH approach with those that would have resulted if the substance were being assessed under the PPP legislation. For the PPP-based risk characterisation, PNECfreshwater and PNECsoil values were derived using the appropriate PPP assessment factors: for soil the risk characterisation results are lower than those under REACH, but remain significantly above the threshold values of 1[97].

Several uncertainties and assumptions have been maintained when assessing the impact and proportionality of the proposed restriction. The main uncertainty is the environmental net impact of replacing calcium cyanamide with alternative fertilisers (and PPPs).

The main assumptions used in the impact analysis are listed below.

a) In the productivity comparison, the cropping patterns are assumed to remain the same;

b) The assessment of difference in productivity (and subsequent profits) when using calcium cyanamide or alternative fertilisers are based on differences in harvest quality and/or quantity and different level of fertiliser costs. Other elements are expected to remain the same. Potential secondary effects have not been separately taken into account in the quantitative impact analysis;

c) Production risks are not accounted for.

[97] For surface water, the input data for the PPP risk characterisation is identical to that used in REACH, hence the results are identical.

6 Conclusion

Annually over 53 000 tonnes of calcium cyanamide are used as a fertiliser with secondary beneficial farming effects on agricultural land in the EU. Its use poses a risk to soil-dwelling organisms as well as to aquatic organisms where fields are adjacent to watercourses. According to the Dossier Submitter's analysis, a restriction on the placing on the market and use of calcium cyanamide for use as a fertiliser is the only measure, which would adequately control the risks from the use of calcium cyanamide.

An alternative restriction option imposing specific agricultural practices could alleviate risks to waterways adjacent to agricultural fields. However, such measures would not adequately control the risk identified to soil-dwelling organisms or potential risks to groundwater. Phasing out the use of calcium cyanamide as a fertiliser is the only practical measure, which would remove these risks.

Furthermore, a restriction that would allow continued use under certain circumstances, but adequately control the risk to watercourses, is difficult to undertake in practice because it would need to establish controls specific to crops, application methods, application rates, soil types as well as specify the use of agricultural practises such as vegetated buffer strips at field margins. However, even when using RMMs the concentrations of cyanamide reaching surface appears still frequently pose an unacceptable risk. The enforceability of such a restriction affecting numerous end users (farmers) is also expected to be challenging.

If a restriction on the placing on the market and use is applied, the most likely alternative nitrogen fertilisers that would be used to substitute calcium cyanamide are expected to increase the leaching of nitrogen to adjacent waterways which could also pose a risk to aquatic organisms.

The use of calcium cyanamide is stated to have 'secondary effects' that are considered to be beneficial to a farmer. It is claimed to control the growth of pests such as weeds and molluscs and have a suppression effect on harmful fungi in fields. It is understood that farmers using calcium cyanamide as a fertiliser place value on these secondary effects. If alternative fertilisers were used, secondary effects would be missing and this could potentially mean that PPPs would be used to compensate.

The decrease in risks due to the proposed restriction and potential increase of other types of risks due to use of alternatives are apparent. However, the environmental net impact appears not possible to estimate. It is not clear whether the environmental net impact would be positive, neutral or negative.

The end user benefits of calcium cyanamide appear sizable especially when applied to high value crops. Similarly, the average end user benefits from the use of calcium cyanamide as a fertiliser appear to be high, €150-€350 per hectare according to the available (deterministic) information (ignoring savings in the use of plant protection products due to the secondary effects of calcium cyanamide).

Such high productivity and profit estimates appear questionable in light of the relatively small market share of calcium cyanamide fertilisers compared to other products which begs the question why only a relatively few farmers are currently using them? Several potential reasons were discussed. First, the timing of fertiliser application is limited with respect to seeding, causing rigidities/lags in the production process. Secondly, the use of calcium cyanamide fertilisers in powder form (in the past) has required some human health precautions farmers may not have been used to. Both of these characteristics may have reduced the desirability of the product. Thirdly, the high price of the fertiliser is of potential concern to farmers even if it would raise profitability and profits, the high price of an input can be prohibitive especially given inherent production risk.

For the proposed restriction to be proportionate, the net reduction in environmental impact should be at least as valuable as the end-user (farmer) cost of substitution (potential net costs e.g. in manufacturing and elsewhere left aside). Proving that such a condition would exist is, based on currently available information, difficult.

The recent finding that calcium cyanamide has endocrine disrupting properties for human health and the environment is expected to improve the proportionality of the proposed restriction.

7 References

Adema, M.M. 1983: The Acute Toxicity of Alzodef to *D. magna* (study report), Testing laboratory: TNO, P.O. Box 217, 2600 AE Delft, Schoemakerstraat 97, The Netherlands, Report no: R 83/198. Owner company; AlzChem AG, Dr.-Alber-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 822-001, Report date: Oct 10, 1983

Adema, D. M. M. (1985). Acute Toxicity of Dicyandiamide to the Worm Species Eisenia foetida. Testing laboratory: TNO Division of Technology for Society, Delft, The Netherlands. Report no.: R 85/059. Owner company: SKW Trostberg AG, Trostberg, Germany. Report date: 1985-02-28.

Alzchem (2018) Predicted environmental concentrations in soil of calcium cyanamide and cyanamide after fertilisation with PERLKA® using ESCAPE V2.0.

Alzchem (2019a). REACH registration dossier for calcium cyanamide dated 8 March 2019. Brief profile information published on ECHA's website: https://echa.europa.eu/brief-profile/-/briefprofile/100.005.330. Some of the preparatory work was carried out on earlier versions of the registration dossier.

Alzchem (2019b). REACH registration dossier for calcium cyanamide dated 27 June 2019. Brief profile information published on ECHA's website: https://echa.europa.eu/brief-profile/-/briefprofile/100.005.330. Some of the preparatory work was carried out on earlier versions of the registration dossier.

Alzchem (2019c) Predicted environmental concentrations in soil of calcium cyanamide and cyanamide after fertilisation with PERLKA® using ESCAPE V2.0. Report 17 April 2019.

Araya Gilberto Calderón Araya1 Roberto Alfaro Portuguez2 Randall Ocampo Chinchilla. 2015. Evaluación de nueve fuentes de fertilizantes nitrogenados en la región de Turrialba, Costa Rica, con las variedades de caña de azúcar B77-95. Promedio de Tres Cosechas. VI Congreso Tecnológico del Departamento de Investigación y Extensión de la Caña de Azúcar (DIECA) Liga Agrícola Industrial de la Caña de Azúcar (LAICA) 20 y 21 de agosto del 2015. Salón de Asambleas de CoopeVictoria R. L., Grecia. Alajuela, Costa Rica.

Arche. (2018). Exposure assessment of calcium cyanamide: use of the fertilisers environmental exposure (FEE) tool. 23 May: Alzchem Trostberg GmbH.

Barrows, B. 1985: The Acute Toxicity of Hydrogen Cyanamide to the Rainbow Trout, Salmo gairdneri (study report), Testing laboratory: Biospherics Incorporated, 4928 Wyaconda Road, Rockville, MD 20852, U.S.A., Report no: 85E-038 RT. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308, Trostberg, Bayern, Germany, Study number: 821-004, Report date: Mar 3, 1985

Bauchhenß, J. 1992: Einfluß von Alzodef und PERLKA® auf Regenwürmer (influence of Alzodef and PERLKA® on earthworms) (study report), Testing laboratory: Bayerische Landesanstalt für Bodenkultur und Pflanzenbau, Report no: not available. Owner company; DOC. No. 833-002, Report date: Dec 31, 1992

Becher, J., Winkler S., 2018. Washing out of cyanamide from PERLKA®. Source: AlzChem Group AG, Dr.-Albert-Frank-Str. 32, 83308 Trostberg, Germany, unpublished report No.: SW-JB-18-13, February 2018.

Benitz, K. F. and Salamandra, I. A. 1960: Calcium Cyanamide: Morphological Studies of a One-year Toxicity Experiments in Rats (study report), Testing laboratory: Lederle Laboratories, Pearl River, New York, Experimental Therapeutics Research; Department of Experimental

Pathology, Report no: project number 18785. Owner company; American Cyanamid Company, Report date: Nov 2, 1960

Boesten et al. (1997) Boesten J, Helweg A, Businelli M, Bergstrom L, Schaefer H, Delmas A, Kloskowski R, Walker A, Travis K, Smeets L, Jones R, Vanderbroeck V, Van Der Linden A, Broerse S, Klein M, Layton R, Jacobsen O-S and Yon D (1987). Soil persistence models and EU registration. The final report of the work of the Soil Modelling Work group of FOCUS (FOrum for the Co-ordination of pesticide fate models and their USe). 29th February 1997.

Bourbos, V., Skoudridakis, M., Darakis, G., & Koulizakis, M. (1997). Calcium cyanamide and soil solarization for the control of Fusarium solani f. sp. cucurbitae in greenhouse cucumber. Crop Protection, 16(4), 383-386.

Bowmann, J., Herzig, R. 1990a: Acute Flow-Through Toxicity to Aqueous Hydrogen Cyanamide 49% (w/w) = 52% (W/V) to Carp (Cyprinus carpio) (study report), Testing laboratory: Analytical Bio-Chemistry Laboratories, Inc., 7200 East ABC Lane, P.O. box 1097, Columbia, Missouri 65205, U.S.A, Report no: 38029. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308, Trostberg, Bayern, Germany, Study number: 821-003, Report date: Mar 9, 1990

Bowman, J., Herzig, R. 1990b: Flow-through Toxicity of Aqueous Hydrogen cyanamide 49 % (w/w) = 52 % (w/v) to Rainbow Trout (Oncorhynchus mykiss) (study report), Testing laboratory: Analytical Bio-Chemistry Laboratories, Inc., 7200 East ABC Lane, P.O. box 1097, Columbia, Missouri 65205, U.S.A., Report no: 38654. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 826-001, Report date: Aug 15, 1990

BPR. (2016). Biocidal Products Committee opinions on active substance approval for cyanamide for use in product types 3 and 18, including supporting documents.

Bringmann, G. & Kuhn, R. 1978: Grenzwerte der Schadwirkung wassergefährdender Stoffe gegan Blaualgen Chemical Safety Report 87 (Microcystis aeruginosa) und Grünalgen (Scenedesmus quadricauda) im Zellvermehrungshemmtest (publication), Vom Wasser 50: 45-60. Report date:

Bringmann, G. & Kuhn, R. 1982: Results of toxic action of water pollutants on *D. magna* Straus Tested by an Improved Standardized Procedure (publication), Zeitschrift fuer Wasser und Abwasser Forschung 15(1): 1-6. Testing laboratory: Institute for Water, Soil and Air Hygiene of the Federal Health Office, Berlin

Brüggemann, M. (2019). Study Report: Daphnia magna, Reproduction test with modified exposure in a water sediment system (based on OECD 211). Report dated 17 May 2019. Sponsor: Alzchem Trostberg GmbH.

Chen S., Ocampo A.P., Kucera P.J. (1991) Liquid chromatographic method for the determination of calcium cyanamide using pre-column derivatization, Journal of Chromatography A, 558 (1) 141-146.

Chohura Piotr, Eugeniusz Kołota. 2014. Suitability of some nitrogen fertilizers for the cultivation of early cabbage. J. Elem. s. 661–672.

CLH. (2015). RAC opinion and supporting documents. Retrieved from https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18066f464

Dickman and Rygiel (1993) The impact of the Cyanamid Canada Co. discharges to benthic invertebrates in the Welland River in Niagara falls, Canada.

Dixon, G.R.. (2012). Calcium cyanamide - A synoptic review of an environmentally benign fertiliser which enhances soil health. Acta Horticulturae. 938. 211-217.

Dixon, G. R. (2017). Managing clubroot disease (caused by Plasmodiophora brassicae Wor.) by exploiting the interactions between calcium cyanamide fertilizer and soil microorganisms. *The* Journal of Agricultural Science, 155(4), 527-543.

Drexler, A. 2000: Effects of SKW Cyanamid L500 on the reproduction of rove beetles Aleochara bilineata Gyll. (Coleoptera, Staphylinidae) in the laboratory (study report), Testing laboratory: IBACON GmbH, Arheiliger Weg 17, D-64380 Rossdorf, Germany, Report no: 6672070. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 834-004, Report date: May 10, 2000

Ebke K (2018) calcium cyanamide – monitoring of the example field 'Loh' for terrestrial organisms Institute für Gewasserschutz Mesocosm GmbH Interim report dated 21 December 2018.

ECHA (2008) Guidance on information requirements and chemical safety assessment Chapter R.10: Characterisation of dose [concentration]-response for environment: https://echa.europa.eu/documents/10162/13632/information_requirements_r10_en.pdf/bb902be7-a503-4ab7-9036-d866b8ddce69

ECHA (2017) Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7b: Endpoint specific guidance https://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf

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

ECHA (2018b). Report from Workshop on EUSES update needs; Brussels, 4-5 June 2018. https://echa.europa.eu/documents/10162/23516034/euses_worshop_report_en.pdf/2d011e93-bde8-6257-a378-a38062a3688a

ECHA (2019) Summary report of the 14th Endocrine Disruptor Expert Group 4-5 June 2019. https://echa.europa.eu/documents/10162/21877836/flash_report_edeg_14_en.pdf/87bacf03-0a71-c7f2-fc72-32081edcf104

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

EFSA (2013) Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters'; EFSA Journal 2013;11(7):3290.

EFSA (2018) – Inter-Agency communication between ECHA and EFSA during the preparation of this Annex XV report (Nov-Dec 2018).

Environment Agency Japan (1998a). Prolonged Toxicity Test (14-day) of cyanoguanidine in orange killifish (Oryzias latipes). Testing laboratory: Chemicals Evaluation and Research Institute, Japan; Kurume Research Laboratories, Chemical Biotesting Center, Chemicals Inspection and Testing Institute. Report no.: 91910. Owner company: Environment Agency 1-

2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013, Japan. Report date: 1998-03-25.

Environment Agency Japan (1998b). Test of Inhibitory Effects of Cyanoguanidine on Reproduction in Daphnia magna. Testing laboratory: Chemicals Evaluation and Research Institute, Japan; Kurume Research Laboratories, Chemical Biotesting Center, Chemicals Inspection and Testing Institute. Report no.: 91908. Owner company: Environment Agency 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013, Japan. Report date: 1998-04-24.

EPA. (2014). Scottish pollutant release inventory. Retrieved from http://apps.sepa.org.uk/spripa/Pages/SubstanceInformation.aspx?pid=28

Förster, B. 2009: Cyanamide: Chronic toxicity in higher plants (study report), Testing laboratory: ECT, OEKOTOXIKOLOGIE GMBH, Flörsheim, Germany, Report no: Study-No. 08BL1PC. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: Doc. No. 851-007, Report date: May 14, 2009

Foerster, B. (2014a). Cyanoguanidine (Dicyandiamide): Chronic Toxicity in Higher Plants. Testing laboratory: ECT Oekotoxikologie GmbH. Report no.: 13BL3PC. Owner company: AlzChem AG. Report date: 2014-06-10.

Foerster, B. (2014b). Cyanoguanidine (Dicyandiamide): Effects on Soil Microorganisms (Nitrogen/Carbon Transformation). Testing laboratory: ECT Oekotoxikologie GmbH, Floersheim, Germany. Report no.: 13BL1BB. Owner company: AlzChem AG. Report date: 2014-04-02.

Francis P.S., Simon W.L., Kieran F.L. (2002) Analytical methodology for the determination of urea: Current practice and future trends, TrAC Trends in Analytical Chemistry, 21(5) 389-400.

Fraunhofer (2018a). Release and transformation of cyanamide from PERLKA®[in soil]; sponsor: Alzchem Trostberg GmbH.

Fraunhofer (2018b). Predicted environmental concentrations in surface water of cyanamide and PERLKA® after fertilisation with PERLKA® based on FOCUS STEP 3; sponsor: Alzchem Trostberg GmbH. Report dated 2 October 2018. Sponsor: Alzchem Trostberg GmbH.

Fraunhofer (2018c). Predicted environmental concentrations in groundwater of cyanamide and calcium cyanamide after fertilisation with PERLKA® using FOCUS PEARL. sponsor: Alzchem Trostberg GmbH. Report date: 2 October 2018. Sponsor: Alzchem Trostberg GmbH.

Fraunhofer (2019a). Release and transformation of cyanamide from PERLKA®[in soil]. Report date: 20 May 2019. Sponsor: Alzchem Trostberg GmbH.

Fraunhofer (2019b). Predicted environmental concentrations in surface water of cyanamide and PERLKA® after fertilisation with PERLKA® based on FOCUS STEP3 and STEP4. Report date: 14 June 2019. Sponsor: Alzchem Trostberg GmbH.

Fraunhofer (2019c). Cyanamide – outdoor aquatic mesocosm study. Report date: 22 May 2019. Sponsor: Alzchem Trostberg GmbH. This report was subsequently updated on 5 July 2019.

Goßmann, A. 2000: Effects of SKW Cyanamid L500 on the predatory mite Typhlodromus pyri Scheuten (Acari, Phytoseiidae) in the laboratory – Dose response test (study report), Testing laboratory: IBACON GmbH, Arheiliger Weg 17, D-64380 Rossdorf, Germany, Report no: 6676062. Owner company; AlzChem AG, Dr.-Albert-frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 834-013, Report date: Nov 3, 2000

Güthner (2018) washing out of cyanamide from PERLKA® 25 April 2018: at Alzchem Trostberg GmbH.

Hanstveit, A.O., Pullens, M. 1988: The effect of aqueous hydrogen Cyanamide on the growth of the bacterium Pseudomonas putida (study report), Testing laboratory: TNO, Schoemakerstraat 97, 2628 VK Delft, the Netherlands, Report no: R 88/019. Owner company; AlzChem AG, Dr.-Albert_Frank-Straße, 83308 Trostberg, Bayern, Germany, Study number: 841-003, Report date: Jan 11, 1988

Haque, A.; Ebing, W. 1983: Toxicity determination of pesticides to earthworms in the soil substrate (publication), Journal of Plant Diseases and protection 90 ($), 395-408, 1983. Testing laboratory: Biologische Bundesanstalt, 1000 Berlin 33, Germany

Heimbach, F. 1984: Comparison of laboratory methods, using Eisenia foetida and Lumbricus terrestris, for the assessment of the hazard of chemicals to earthworm (publication), Journal of Plant Diseases and Protection; 92 82), 186-193, 1985. Testing laboratory: Bayer AG, Pflanzenschutz-Anwendungstechnik, Institut für Ökobiologie, Leverkusen, Germany

Hertl, J. 2000a: Toxicity of SKW Cyanamid L500 to Anabaena flos-aquae in an Algal Growth Inhibition Test (study report), Testing laboratory: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheiliger Weg 17, 64380 Rossdorf, Germany, Report no: 6677210. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 823-004, Report date: Dec 14, 2000

Hertl, J. 2000b: Toxicity of SKW Cyanamid L500 to the Aquatic Plant in a Growth Inhibition Test (study report), Testing laboratory: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheiliger Weg 17, 64380 Roßdorf, Germany, Report no: 6679240. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 825-001, Report date: Jun 16, 2000

Heintze, A. 2001: Assessment of Side Effects of Cyanamid L500 on the Larvae of the Midge, Chironomus riparius with the Laboratory Test Method (study report), Testing laboratory: Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany, Report no: 2000 1413/01-ASCr. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 824-001, Report date: Aug 27, 2001

Hess 1978; Rieder 1978: Modellversuche zum Abbau des herbiziden Wirkstoffs Cyanamid in drei verschiedenen Böden (Title of the English translation: Model test of the decomposition of the herbicidal substance Cyanamide in three different soils) (study report), Testing laboratory: SKW Trostberg AG, Landwirtschaftliche Abteilung, Römerstr. 6, D-8000 München 40, Germany, Report no: 722-006. Owner company; AlzChem trostberg GmbH, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 722-006, Report date: Jul 10, 1978

Hommen, U. (2019). Study Report -Cyanamide – outdoor aquatic mesocosm study. Report dated 25 July 2019. Sponsor: Alzchem Trostberg GmbH.

Hongprayoon et al (1991) Urea transformations in flooded soil columns. Soil Science Society of America Journal Vol 55, no. 4 (Jul-Aug 1991).

Huidong Q., Dongdi S., Todd M. (2015): Detection Dicyandiamide in Environmental Water by Liquid Chromatography–Mass Spectrometry Combined with Solid Phase Extraction Method, Journal of Liquid Chromatography & Related Technologies, 38 (4) 501-505.

Huidong Q., Dongdi S., Sameera R.G., Jinyan S., Todd E.M. (2015b): Analysis of trace dicyandiamide in stream water using solid phase extraction and liquid chromatography UV spectrometry, Journal of Environmental Sciences, 35, 38-42.

Ipser, A. 2010a: 'CALCIUM CYANAMIDE': Algae (Pseudokirchneriella subcapitata) Growth

Inhibition Test (study report), Testing laboratory: Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria, Report no: SKW371. Owner company; AlzChem Trostberg GmbH, CHEMIEPARK TROSTBERG, Dr.-Albert-Frank-Str. 32, 83308 Trostberg, Germany, Report date: Oct 18, 2010

Ipser, A. 2010b: 'CALCIUM CYANAMIDE': Acute Toxicity Study for *D. magna* (study report), Testing laboratory: Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria, Report no: SKW370. Owner company; AlzChem Trostberg GmbH, CHEMIEPARK TROSTBERG, Dr.-Albert-Frank-Str. 32, 83308 Trostberg, Germany, Report date: Sep 3, 2010

Ipser, A. 2010c: 'CALCIUM CYANAMIDE': Acute Toxicity Study for Fish (study report), Testing laboratory: Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria, Report no: SKW372. Owner company; AlzChem Trostberg GmbH, CHEMIEPARK TROSTBERG, Dr.-Albert-Frank-Str. 32, 83308 Trostberg, Germany, Report date: Nov 5, 2010

Johnson, A. 2001: Cyanamide 50% solution: Assessment to determine the effects on reproduction in the Bobwhite quail (study report), Testing laboratory: Huntingdon Life Sciences, Cambridgeshire, UK, Report no: STB 017/003921. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 813-001, Report date: Aug 24, 2001

Kelliher, F., Clough, T., Clark, H., Rys, G., & Sedcole, J. (2008). The temperature dependence of dicyandiamide (DCD) degradation in soils: a data synthesis. Soil Biology and Biochemistry, 40(7), 1878-1882.

Kemi 2016; Memo of 31 October 2016 The Swedish Chemicals Agency excludes surface runoff from aquatic risk assessments of plant protection products (see here: https://www.kemi.se/en/global/bekampningsmedel/vaxtskyddsmedel/memo-the-swedish-chemicals-agency-excludes-surface-runoff-from-aquatic-risk-assessments-of-plant-protection-products.pdf).

Kleiner, R. 1991: Testing toxicity to honeybee – Apis mellifera L. (laboratory) according to BBA guideline VI, 23-1 (1991) (study report), Testing laboratory: BioChem GmbH, D-7101 Cunnersdorf, Germany, Report no: 92 1048 014. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 832-001, Report date: Nov 18, 1991

Kołota, E & Adamczewska-Sowinska, K. 2009. Efficiency of Entec 26 – a new concept nitrogen fertilizer in white head cabbage production. Veget. Crops Res. Bull., 69: 73-80

Krogmeier, M.J., McCarty, G.W. & Bremner, J.M. 1989: Phytotoxicity of foliar-applied urea (publication), Proceedings of the National Academy of Sciences of the United States of America 86(21): 8189-8191.

Lambert D.F., Sherwood J.E., Francis P.S. (2004): The determination of urea in soil extracts and related samples - a review. Australian Journal of Soil Research 42, 709-717.

Landor, 2017. Grunddünger – Erhaltung der Bodenfruchtbarkeit. Einlagerungs-Aktion Rabatt CHF 2.-/100kg von Mai bis Juni 2017. www.landor.ch

Limacher. (2009). cyanamide soil photolysis study report: Alzchem Trostberg GmbH.

Lührs, U. 2001: Acute toxicity (14 days) of SKW Cyanamid L500 + AHL to the earthworm Eisenia fetida in artificial soil (study report), Testing laboratory: IBACON GmbH, Arheiliger Weg 17, D-64380 Rossdorf, Germany, Report no: 12081021. Owner company; AlzChem AG, Dr.-Albert_Frank_Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 833-003, Report date: Aug 22, 2001

Lynn et al. 1991: Aqueous hydrogen cyanamide solution: A dietary LC50 study with the mallard (study report), Testing laboratory: Wildlife International Ltd., 305 Commerce Drive, Easton, Maryland 21601, USA, Report no: 248-105. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 812-002, Report date: Oct 22, 1991

Lynn et al. 1991: Aqueous hydrogen cyanamide solution: A dietary LC50 study with the northern bobwhite (study report), Testing laboratory: Wildlife International Ltd., 305 Commerce Drive , Easton, Maryland 21601, USA, Report no: 248-104. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 812-001, Report date: Oct 22, 1991

McAllister, W.A., Bowman, J., Cohle, P. 1985a: Acute Toxicity of LH 21,810 A to Rainbow Trout (Salmo gairdneri) (study report), Testing laboratory: Analytical Bio-Chemistry Laboratories, Inc., 7200 East ABC Lane, P.O. box 1097, Columbia, Missouri 65205, U.S.A, Report no: 33402. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308, Trostberg, Bayern, Germany, Study number: 821-001, Report date: Jul 30, 1985

McAllister, W.A. et al. 1985b: Acute Toxicity of LH 21,810 A to Bluegill Sunfish (Lepomis macrochirus) (study report), Testing laboratory: Analytical Bio-Chemistry Laboratories, Inc., 7200 East ABC Lane, P.O. box 1097, Columbia, Missouri 65205, U.S.A, Report no: 33401. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308, Trostberg, Bayern, Germany, Study number: 821-002, Report date: Jul 30, 1985

Mead-Briggs, M. 1990: An Evaluation of the toxicity of PERLKA® granules to the carabid beetle Bembidion lampros. (study report), Testing laboratory: Agrochemical Evaluation Unit, Department of Biology, building 44, The University, Southampton SO9 5NH, UK, Report no: SKW-90-1. Owner company; AlzChem Trostberg GmbH, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Report date: May 14, 1990

Meister, A. 2001: Effects of Cyanamid L500 on the Seedling Emergence of Terrestrial Non-Target Plant Species Tier II: Seedling Emergence Dose Response Test (study report), Testing laboratory: IBACON GmbH, Arheiliger Weg 17, D-64380 Rossdorf, Germany, Report no: 9131088. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 851-003, Report date: Oct 19, 2001

Moll, M. 2001: Effects of SKW Cyanamid L500 on the parasitoid Aphidius rhopalosiphi (Hymenoptera, Aphidiidae) in the laboratory –Dose response test (study report), Testing laboratory: IBACON GmbH, Arheiliger Weg 17, D-64380 Rossdorf, Germany, Report no: 6670001. Owner company; AlzChem AG, Dr.-Albert-Frank-straße 32, 83308 Trostberg, Bayern, Germany, Study number: 834-019, Report date: Jan 22, 2001

Moll m. & Groer M. 2000a: Effects of SKW cyanamide L 500 on the parasitoid Aphidius rhopalosiphi (Hymenoptera, Aphidiidae) in the laboratoy (study report), Testing laboratory: IBACON GmbH, Report no: 834-006. Study number: 6671001, Report date: Aug 10, 2000

Moll M. & Groer M. 2000b: Effects of SKW cyanamide L 500 on the lacewing Chrysoperia carnea Steph. (Neuroptera, Chrysopidae) in the laboratory (study report), Testing laboratory: IBACON GmbH, Report no: 834-003. Owner company; SKW Trostberg AG, Study number: 6673046, Report date: Jul 12, 2000

Moser, T., & Scheffczyk, A. (2009). Cyanamide: Acute and reproduction toxicity to the collembolan species Folsomia candida in artificial soil (two study reports and a recalculation of the EC10 value by UBA in 2009): Alzchem Trostberg GmbH.

Murrel, & Leak. (1995). Chronic Toxicity of Hydrogen cyanamide to *D. magna* Under Flow

Through Test Conditions (study report): Alzchem Trostberg GmbH.

Nagumo Y., Tanaka K., Tewari K., Thiraporn K., Tsuchida T., Honma T., Norikuni O., Sueyoshi K., Takahashi Y., Ohyama T. (2009) Rapid quantification of cyanamide by ultra-high-pressure liquid chromatography in fertilizer, soil or plant samples, Journal of chromatography. A, 1216 (29) 5614-8.

Oldersma, H.; Hanstveit, A. O.; Pullens, M. A. H. L. (1985). The Effect of the Product Dicyndiamide, Techn. Pure, on the Growth of the Green Alga Selenastrum Capricornutum. Testing laboratory: TNO Division for Technology and Society, Delft, The Netherlands. Report no.: R 85/068. Owner company: SKW Trostberg AG,Trostberg, Germany. Study number: 13576. Report date: 1985-03-26.

Oster, et al. 2011: Effects of ammonium nitrate, urea, and sodium nitrate on mosquitofish (Gambusia affinis) survivorship (publication), Bios 82(1) 10 - 12. Testing laboratory: Denison University, Granville, OH 43023, Report date:

Pommeresche and Løes (2014) Diversity and density of springtails (Collembola) in a grass-clover ley in North-west Norway; Norwegian Journal of Entomology. 8 December 2014

PPP (2008-10). Conclusion on the peer review of the pesticide risk assessment of the active substance cyanamide. EFSA Journal, 8(11), 1873 and all supporting documents.

Ramboll. (2018). Cyanamide as a read-across to predict the environmental endpoints of calcium cyanamide: Alzchem Trostberg GmbH.

RJRD DCD (2015). REACH joint registration dossier for dicyandiamide by Henkel Global Supply Chain B.V. Brief profile information for published on ECHA's website: https://echa.europa.eu/brief-profile/-/briefprofile/100.006.649

Reach registration dossier, RRD, urea (2017). REACH registration dossier for urea by an Austrian manufacturer. Brief profile information for published on ECHA's website: https://echa.europa.eu/brief-profile/-/briefprofile/100.000.286

Reis, K. H. 2002: Effects of Cyanamid L500 on the Activity of the Soil Microflora in the Laboratory (study report), Testing laboratory: Laboratory name: IBACON GmbH, Arheiliger Weg 17, D-64380 Rossdorf, Germany, Report no: 12502080. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 841-004, Report date: May 6, 2002

Robaidek, E. 1985: Avian Single-Dose Oral LD50 Bob White Quail (Colinus virgianus) (study report), Testing laboratory: Hazleton Laboratories America, Inc., 3301 Kinsman Boulevard, Madison, Wisconsin 53704, USA, Report no: 6026-507. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 811-001, Report date: Aug 1, 1985

Rodgers, G. A.; Ashworth, J. (1982). Bacteriostatic Action of Nitrification Inhibitors. Can. J. Microbiol., Vol. 28., 1093-1100.

Röhlig, U. 2006a: Screening test with Cyanamid L500 to the rove beetle Aleochara bilineata Gyll under laboratory conditions (non-GLP) (study report), Testing laboratory: BioChem agrar GmbH, Gerichshain, Germany, Report no: 06 10 48513. Owner company; Degussa AG, Study number: 834-020, Report date: Aug 25, 2006

Röhlig, U. 2006b: Screening test with Cyanamid L500 to the spider Pardosa spp. under laboratory conditions (non-GLP) (study report), Testing laboratory: BioChem agrar GmbH, Gerichshain, Germany, Report no: 834-022. Owner company; Degussa AG, Study number:

834-022, Report date: Aug 30, 2006

Röhlig, U. 2006c: Screening test with Cyanamid L500 to the green lacewing Chrysoperla carnea STEPH. under laboratory conditions (non-GLP) (study report), Testing laboratory: BioChem agrar GmbH, Gerichshain, Germany, Report no: 834-021. Owner company; Degussa AG, Study number: 834-021, Report date: Aug 20, 2006

Röhlig, U. 2007a: Dose-response toxicity (LR50) of Cyanamid L 500 to the predatory mite Typhlodromus pyri (SCHEUTEN) under extended laboratory conditions (study report), Testing laboratory: BioChem agrar GmbH, Gerichshain, Germany, Report no: 06 10 48 089. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 834-023, Report date: Jan 25, 2007

Röhlig, U. 2007b: Dose-response toxicity (LR50) of Cyanamid L500 to the parasitic wasp Aphidius rhopalosiphi (DESTEFANI-PEREZ) under extended laboratory conditions (study report), Testing laboratory: BioChem agrar GmbH, Gerichshain, Germany, Report no: 06 10 48 088. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 834-024, Report date: Jan 10, 2007

Ruedel, H. 1990. Determination of the adsorption/desorption of hydrogen cyanamide by the Fraunhofer Institute for Alzchem Trotzberg.

SCHER. (2016). Scientific Committee on Health and Environmental Risks - Final Opinion on Potential risks to human health and the environment from the use of calcium cyanamide as fertiliser.

Scheffczyk, Adam 2016a: Cyanamide: Reproduction toxicity to the earthworm Eisenia fetida in LUFA St. 2.2 soil (study report), Testing laboratory: ECT Oekotoxikologie GmbH, Böttgerstr. 2-14, 65439 Flörsheim, Germany, Report no: 15BL2RR. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Germany, Study number: 15BL2RR, Report date: Apr 18, 2016

Scheffczyk, Adam 2016b: Cyanamide: Reproduction toxicity to the earthworm Eisenia fetida in LUFA St. 2.2 soil (study report), Testing laboratory: ECT Oekotoxikologie GmbH, Böttgerstr. 2-14, 65439 Flörsheim, Germany, Report no: 15BL2RR. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Germany, Study number: 15BL2RR, Report date: Apr 18, 2016

Schmitzer, S. 2000: Effects of SKW Cyanamid L500 on the wolf spider Pardosa spec. (Aranae, Lycosidae) in the laboratory (study report), Testing laboratory: IBACON GmbH, Arheiliger Weg 17, D-64380 Rossdorf, Germany, Report no: 6675065. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 834-014, Report date: Oct 24, 2000

Schmitzer, S; Stork, N. 2000: Effects of SKW Cyanamid L500 on the carabid beetle Poecilus cupreus L. (Coleoptera, Carabidae) in the laboratory (study report), Testing laboratory: IBACON GmbH, Arheiliger Weg 17, D-64380 Rossdorf, Germany, Report no: 6674006. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 834-007, Report date: Oct 4, 2000

Schönborn 1990: Untersuchung über die Auswirkungen von PERLKA® auf die Aktivität der Bodenmikroflora (study report), Testing laboratory: Battelle-Institut e.V., Am Römerhof 35, Frankfurt/Main, Germany, Report no: BE-S-77-89-01-DEH-01. Owner company; AlzChem Trostberg GmbH, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Report date: Apr 27, 1990.

Schoot Uiterkamp, A.J.M. 1988: Effect of Hydrogen Cyanamide on the Growth of the Alga Selenastrum capricornutum (OECD 201 and EPA EG8) (study report), Testing laboratory: TNO, P.O. Box 217, 2600 AE Delft, Schoemakerstraat 97, 2628 VK Delft, The Netherlands, Report no: 823-001. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 823-001, Report date: Sep 16, 1988

Schmidt (1990 & 1991) two studies on the aerobic soil metabolism of 14C cyanamide on behalf of Alzchem Trostberg GmbH.

Seibersdorf Labor GmbH (2010). Carbon dioxide evolution test for ready biodegradability by Seibersdorf Labor GmbH for Alzchem Trotzberg.

Seyfried, B. 2000: Toxicity of Cyanamid L500 to Pseudokirchneriella subcapitata (formerly: Selenastrum capricornutum) in a 96 hour Algal Growth Inhibition Test (study report), Testing laboratory: RCC LTD, Environmental Chemistry & Pharmaanalytics Division, CH-4452 Itingen/Switzerland, Report no: 744963. Owner company; AlzChem AG, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Study number: 823-003, Report date: Jul 24, 2000

Shi, K., Wang, L., Zhou, Y.-H., Yu, Y.-L., & Yu, J.-Q. (2009). Effects of calcium cyanamide on soil microbial communities and Fusarium oxysporum f. sp. cucumberinum. Chemosphere, 75(7), 872-877.

Simujide, H., Aorigele, C., Wang, C.-J., Manda, B., Lina, M., Wu, M.-Y., Bai, T.-R.-G. (2013). Reduction of foodborne pathogens during cattle manure composting with addition of calcium cyanamide. Journal of Environmental Engineering and Landscape Management, 21(2), 77-84.

Snider and Butcher (1973) The Great Lakes Entomologist Volume 6 Issue 4 -- Winter 1973 Issue 4 -- Winter 1973 Article 1 The Life History of Folsomia Candida (Willem) (Collembola: Isotomidae) Relative to Temperature Renate M. Snider Michigan State University James W. Butcher Michigan State University

Spanjers, M.T.; Til, H.P. 1984: Determination of the acute oral toxicity of PERLKA® in japanese quail (study report), Testing laboratory: Centraal Instituut Voor Voedingsonderzoek, Utrechtseweg 48, Zelst, Netherlands, Report no: B83-0060/56. Owner company; AlzChem Trostberg GmbH, Dr.-Albert-Frank-Straße 32, 83308 Trostberg, Bayern, Germany, Report date: Jan 19, 1984

Stegger, P (2019): Field study to evaluate the effects of granulated calcium cyanamide fertiliser (PERLKA®) on collembola in Central Europe. Report dated 7 June 2019. Sponsor: Alzchem Trostberg GmbH.

Terlingen L., S. Radersma, R. Out, J. Hernández-Martínez, E. Raemakers-Franken. (2016). Current Developments in Controlled Release Fertilisers.

Trenkel, M. E. (2010). Slow-and controlled-release and stabilized fertilizers: an option for enhancing nutrient use efficiency in agriculture: IFA, International fertilizer industry association.

Turowski M., Deshmukh B. (2004): Direct Chromatographic Method for Determination of Hydrogen Cyanamide and Dicyandiamide in Aqueous Solutions, Analytical Letters, 37 (9) 1981-1989.

US EPA 2007 preliminary problem formulation for the ecological risk assessment to be conducted as part of the Registration review of the plant growth regulator cyanamide.

https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/014002/014002-

2007-09-14a.pdf

Vilsmeier and Amberger 1978 Anorganisch-katalytische Umsetzungen von Cyanamid und dessen Metaboliten in Quarzsand II. Cyanamidabbau unter dem Einfluß von Metalloxiden und Temperatur Journal of Plant Nutrition and Soil Science

Völkl, S. (2000). [14C] cyanamide route and degradation in aerobic aquatic systems study report: Alzchem Trostberg GmbH.

Wei-Chun Ma., Brussaard, L. & de Ridder, J.A. 1990: Long-term effects of nitrogenous fertilizers on grassland earthworms (Oligochaeta: Lumricidae): Their relation to soil acidification (publication), Agriculture, Ecosystems and Environment 30(1-2): 71-80.

Annex A. Information on hazard and risk

A.1. Identity of the substance(s) and physical and chemical properties

The Registrant, formerly produced and placed on the EU market a powdered formulation for use as a fertiliser (also known as calcium cyanamide 20.5 because of its nitrogen content). This formulation contains approximately 58% calcium cyanamide. This was mainly used in specialised professional agricultural/horticultural applications. The Registrant has informed ECHA that it ceased producing and placing on the EU market the powdered form from the end of 2017.

The Registrant's REACH registration dossier (Alzchem, 2019a) also refers to other formulations containing calcium cyanamide including 'Kalkstickstoff' (approximately 68% w/w calcium cyanamide). These formulations are used by industry in a variety of uses and are not relevant when considering the use of calcium cyanamide as a fertiliser. However, the Dossier Submitter notes some of the scientific studies presented by the Registrant appear to have been carried out using these different formulations, hence it is questionable whether they are fully representative of the effects caused by calcium cyanamide contained in PERLKA®.

A.1.1. Name and other identifiers of the substance(s)

See report.

A.1.2. Composition of the substance(s)

See report.

A.1.3. Physicochemical properties

Table 30. Physicochemical properties of calcium cyanamide and cyanamide

Property	Value used for CSA / Discussion	Description of key information
Physical state	solid at 20°C and 101.3 kPa	Calcium cyanamide, technical grade (Kalkstickstoff) is a black solid with a characteristic odour at 20°C and 1013 hPa.
Melting / freezing point	1145°C at 101.3 kPa The melting range of Calcium cyanamide, technical grade (Kalkstickstoff) was measured by Differential Scanning Calorimetry (DTA) with simultaneous Micro Balance (TG, DTG). The melting range according DIN 51004 was determined to be 1145°C to 1217°C. Two endothermic thermal decompositions and continuous loss of mass were observed. Significant	The melting range according DIN 51004 was determined to be 1145°C to 1217°C.

	increase of mass loss at a temperature above 1040°C and 1124°C was measured.	
Boiling point		Waiving of study: In accordance with column 2 of REACH Annex VII, the test on boiling point (required in section 7.3) does not need to be conducted for solids which melt above 300°C.
Relative density	2.3 at 20°C The density of pure and technical grade ('Kalkstickstoff') calcium cyanamide were determined to be in the same range as shown by different handbook data. Thus, it is concluded that the impurities of technical grade calcium cyanamide have no influence on the density of the substance.	The density of Calcium cyanamide, technical grade (Kalkstickstoff) and Calcium cyanamide, purum was determined to be 2.36 g/cm3 and 2.3 g/cm3 at 25°C, respectively.
Granulometry	Calcium cyanamide, technical grade The mass mean diameter of the test item was determined using dry sieve analysis. Therefore about 80 g of the test item was partitioned using a sample splitter. After the defined sieving time the residues on each sieve was determined and the mass median diameter was calculated to be 40 µm. Calcium cyanamide, PERLKA® formulation A study was conducted equivalent to CIPAC MT 170. The mass mean diameter of the test item was determined using dry sieve analysis. Therefore the about 80 g of the test item PERLKA® was partitioned using a sample	The mass median diameter of Calcium cyanamide, technical grade (Kalkstickstoff) was determined to be 40 µm as measured by dry sieve analysis. The mass median diameter of PERLKA® (Formulation of Calcium cyanamide) was determined to be 2.142 mm as measured by dry sieve analysis.

	splitter. After the defined sieving time the residues on each sieve was determined and the mass median diameter was calculated to be 2.142 mm. Conclusion In a technical process, the powder calcium cyanamide will be formulated into commercial product PERLKA®. Due to this formulation process the particle size of calcium cyanamide will changed. The form of the substance changed from powder to granulate. It was shown that in the commercial product PERLKA® the mass median diameter is greater than in the technical product calcium cyanamide. Thus, for industrial application the particle size of calcium cyanamide, technical grade (Kalkstickstoff) and for professional and consumer application the particle size of PERLKA® will be used in risk assessment.	
Vapour pressure	0.51Pa at 20°C The vapour pressure of Cyanamid F1000 was measured by the vapour measure balance method according to the EU method A.4, in 4 different temperatures between 21 and 25.2 °C. Available experimental vapour pressure data for cyanamide are used in a read-across approach for the assessment of calcium cyanamide: Upon dissolution in water calcium cyanamide is fast transformed to hydrogen cyanamide. Thus, upon release of calcium cyanamide to water the environmental	In accordance with column 2 of REACH Annex VII, the test on vapour pressure (required in section 7.5) does not need to be conducted as the melting point of calcium cyanamide is above 300 °C. However, a numerical value for vapour pressure is required for environmental exposure calculations. Therefore, available experimental results for the structural analogue cyanamide are used in a read-across approach: Cyanamid F1000 vapour pressure: - T = 20°C: VP = 0.51 Pa (68 mm Hg) - T = 25°C: VP = 1.0 Pa (133

	distribution and exposure is driven by the physico-chemical/fate properties of cyanamide.	mm Hg The value of 0.51 Pa at 20 °C is carried forward as key value for environmental risk assessment.
Partition coefficient n-octanol/water (log value)	Log Kow (Log Pow): -0.72 at 20°C Available experimental data for cyanamide are used in a read-across approach for the assessment of calcium cyanamide: Upon dissolution in water calcium cyanamide is fast transformed to hydrogen cyanamide. Thus, upon release of calcium cyanamide to water the environmental distribution and exposure is driven by the physico-chemical/fate properties of hydrogen cyanamide.	The partition coefficient of calcium cyanamide is evaluated by means of data on its corresponding acid (cyanamide, CAS # 420-04-2) by read-across. Both measured data and a QSAR calculation are available for cyanamide. The QSAR-predicted partition coefficient is log Pow = –0.81, the measured result is log Pow = –0.72. For the calcium salt the value is expected to be even lower due to its ionic nature. By weight-of-evidence, in view of the good agreement between theoretically estimated and experimentally determined values, the latter (log Pow = –0.72) is adopted as a worst-case figure (potentially highest bioaccumulation and/or adsorption probability). Nevertheless, the worst-case figure for the partition coefficient indicates negligible bioaccumulation and adsorption potential of the substance.
Water solubility	15450 mg/L at 20°C For determination of the water solubility of Calcium cyanamide, technical grade (Kalkstickstoff), 25 g of the sample were weighed in a 250 mL flask, dissolved in water and the suspension was stirred for 24 h at 20 ± 0.5 °C. After 24 h, the suspension was filtered and the calcium concentration in the solution was determined	The water solubility of Calcium cyanamide, technical grade (Kalkstickstoff) was determined to be 29.4 g/L calcium cyanamide or 15.45 g/L cyanamide at 20 °C. The elemental carbon remains undissolved. The numerical value for cyanamide is used in the chemical safety assessment, as calcium cyanamide is instantaneously transformed

	by ICP-OES. The calcium concentration was measured to be 14.7 g/L equivalent to 29.4 g/L calcium cyanamide or 15.45 g/L cyanamide. The elemental carbon remains undissolved.	to hydrogen cyanamide upon dissolution in water. These two substances are similar in both chemical structure and fate in the environment. Cyanamide is the environmentally relevant transformation product.
Surface tension	64.4 mN/m at 20°C and mg/L The surface tension of Calcium cyanamide, technical grade (Kalkstickstoff) was determined with the OECD ring method with an interfacial tensiometer. The surface tension is determined by measurement of the maximum force (exerted vertically) necessary to separate a ring being in contact with the surface of an aqueous solution of the test substance. The water solubility of the main component calcium cyanamide is 29.4 g/L, but due to the component graphite the 'whole test substance' is not soluble in water in a concentration of 1 g/L at 20°C. According to the guidelines the surface tension was therefore determined with a solution of 90% saturation in water. The surface tension of the Calcium cyanamide, technical grade (Kalkstickstoff) was 64.38 mN/m, standard deviation 0.173, at a temperature of 20.0 °C.	The surface tension of Calcium cyanamide, technical grade (Kalkstickstoff) was 64.38 mN/m, standard deviation 0.173, at a temperature of 20.0 °C.
Flash point		Waiving of study: In accordance with REACH Annex VII, the determination of the flash point (required in section 7.9) does not to be conducted as the substance is solid.

Autoflammability / self-ignition temperature	The self-ignition temperature ('Zündtemperatur') of Calcium cyanamide, technical grade (Kalkstickstoff) was measured by bringing a dust cloud of the substance to a heated surface in an oven. The amount of dust varied from 0.1 to 3 g. The maximum measured temperature was 850°C. The self-ignition temperature of Calcium cyanamide, technical grade (Kalkstickstoff) was determined to be > 850°C at 1.1 -1.6 bar.	Calcium cyanamide, technical grade (Kalkstickstoff) did not ignite up to a temperature of 850°C.
Flammability	non flammable In the key study, Calcium cyanamide, technical grade (Kalkstickstoff) was tested for flammability according to UN N.1 (33.2.1.4 of BAM). A Brennwertzahl (BWZ) of 1 (max. 6) was determined in the pre-test. The substance only showed glowing combustion for a short time after removal of the flame. Thus, the substance is considered to be non-flammable. No further test is required. This is supported in a supporting study where the lower explosion limit of a sample of powdered Calcium cyanamide, technical grade (Kalkstickstoff) in air was determined to be 125 g/m3.	In the key study Calcium cyanamide, technical grade (Kalkstickstoff) was categorized in category 1 of 6 regarding flammability. Local burning or glowing without further extension. Thus, the substance is not regarded highly flammable. The lower explosive level in a dust explosion test was determined to be 125 g/m^3. In addition, no flammability in contact with water and no pyrophoric abilities are expected. These studies are thus been waived.
Explosive properties	non explosive	Waiving of Study: In accordance with column 2 of REACH Annex VII, the determination of explosiveness (required in section 7.11) does not need to be conducted as there are no chemical groups associated with explosive properties present in Calcium

		cyanamide and its impurities above 1% (refer to Guidance on information requirements and chemical safety assessment, Chapter R.7a). In addition, in a supporting study it was shown that Calcium cyanamide, technical grade (Kalkstickstoff) was not dust explosive using a chemical ignition energy of 30000 J.
Oxidising properties	no	Waiving of Study: The test on oxidising properties (required in section 7.13) does not need to be conducted as there are no chemical groups associated with oxidising properties present in Calcium cyanamide and its impurities above 1% (refer to Guidance on information requirements and chemical safety assessment, Chapter R.7a).
Stability in organic solvents and identity of relevant degradation products		In accordance with column 2 of REACH Annex IX, the test on stability in organic solvents and identity of relevant degradation products (required in section 7.15) does not need to be conducted as stability of Calcium cyanamide in organic solvents is not considered to be critical.

Dissociation constant	The titration method, one of the possible experimental methods for determination of the dissociation constant (pKa), described in the OECD test guideline 112, was used in this study for pKa determination of the test item, Cyanamid F1000. The pKa of Cyanamid F1000 could not be calculated because a dissociation reaction was not observed. Aqueous solutions (approx. 0.005 mol/L) of Cyanamid F1000 have a pH value of 6.3. They were titrated with 0.01 mol/L NaOH solution to test its acidic properties. There was no turning point in the titration curve, as it would be observed when an acid is titrated with a base. This result confirms the expectation that Cyanamid F1000 does not dissociate in aqueous solutions with pH values of 6 to 9. pH values > 9 were not tested since it is known from the literature that Cyanamid F1000 dimerises to cyanoguanidine at pH values of 8 to 9.5. Conclusion: Cyanamid F1000 does not dissociate in aqueous solutions with pH values of environmental relevance.	Upon dissolution in water calcium cyanamide is fast transformed to hydrogen cyanamide. Therefore, the dissociation behaviour is independent from the test material (calcium cyanamide vs. hydrogen cyanamide). Test data on hydrogen cyanamide can thus be used by way of read-across. The pKa of hydrogen cyanamide (Cyanamid F1000) could not be calculated because a dissociation reaction was not observed (in aqueous solutions with relevant pH values of 6 to 9). Accordingly, in the environmentally relevant pH range of 6–9 the acid-base equilibrium of the cyanamide system is entirely shifted towards the protonated form (hydrogen cyanamide).
Viscosity		Waiving of Study: In accordance with column 2 of REACH Annex IX, the test on viscosity (required in section 7.17) does not need to be conducted as Calcium cyanamide is solid at room temperature.

(Source: Alzchem, 2019a)

A.1.4. Justification for grouping

Not relevant for this substance.

A.2. Manufacture and uses (summary)

See report

A.3. Classification and labelling

A.3.1. Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

See report.

A.3.2. Classification and labelling in classification and labelling inventory/ Industry's self-classification(s) and labelling

Table 31. Self-classifications notified to the Classification and Labelling Inventory

Substance EC No CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Number of Notifiers
Calcium cyanamide 205-861-8 156-62-7	Acute Tox. 4	H302	65
	Skin Irrit. 2	H315	8
	Skin Sens.1	H317	29
	Eye Dam. 1	H318	65
	STOT SE 2	H371	2
	STOT SE 3	H335 (lung inhalation)	63
	Aquatic Chronic 2	H411	2
	Aquatic Chronic 3	H412	5
	Water-react 3.	H261	2
Cyanamide 206-992-3 420-04-2	Acute Tox.3	H301, H311	200
	Acute Tox.4	H312	126
	Skin Corr. 1	H314	49
	Skin Corr. 1B	H314	2

	Skin Sens. 1	H317	196
	Skin Sens. 1B	H317	2
	Skin Irrit. 2	H315	149
	Eye Dam. 1.	H318	51
	Eye Irrit. 2	H319	149
	Repr. 2	H361	51
	Carc. 2	H351	49
	STOT RE 2	H373 (thyroid)	51
	Aquatic Chronic 3	H412	51
Urea 200-315-5 57-13-6	Skin Irrit. 2	H315	109
	Skin Sens. 1	H317	1
	Acute Tox. 4	H302	4
	Eye Irrit. 2	H319	141
	Resp. Sens. 1.	H334	1
	STOT SE 2	H371 (resp. tract)	32
	STOT SE 3	H335	6
	Carc.2	H351	37
	Aquatic Chronic 4	H413	5
	Not classified		2868
Cyanoguanidine 207-312-8 461-58-5	Acute Tox. 4	H302	97
	Skin Irrit. 2	H315	13
	Eye Irrit. 2	H319	4
	Not classified		587

(Source: ECHA website)

A.4. Environmental fate properties

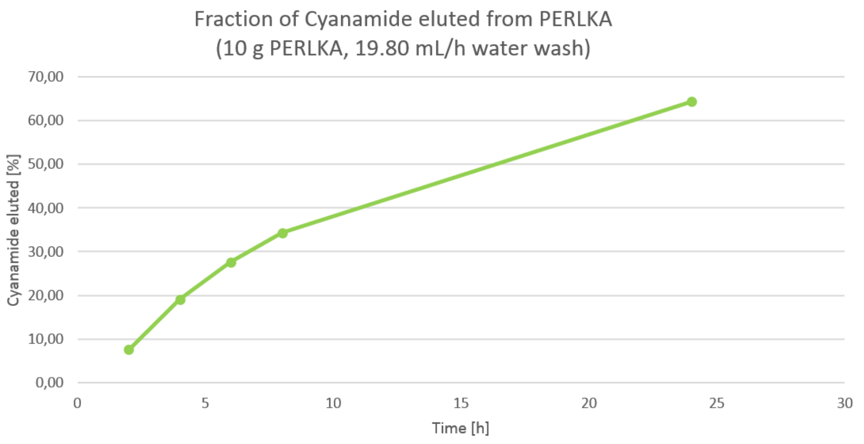
A.4.1. Degradation

A.4.1.1. The transformation of PERLKA® and calcium cyanamide in the environment

In its REACH registration dossier, the Registrant has not covered the transformation of PERLKA® granules in the environment to a significant degree. Instead an assumption is made that calcium cyanamide in PERLKA® rapidly hydrolyses to cyanamide, but the release of cyanamide from PERLKA® granules is slowed down by the granulated form.

On account of this rapid hydrolysis, in many cases the Registrant presents environmental studies with the test substance cyanamide and then applies these results for calcium cyanamide. The Dossier Submitter agrees with the Registrant that study results from cyanamide as a test substance can be used as a surrogate for calcium cyanamide in environmental studies. This approach is supported by ECHA guidance for REACH which states: 'where a substance rapidly breaks down to degradation products, test results from these degradation substances are normally used to derive PNECs[98]'. The Dossier Submitter therefore considers data from studies carried out using cyanamide as the test substance, as well as calcium cyanamide, in its risk characterisation, using a weight of evidence approach.

The delayed release of cyanamide because of the granulated form of PERLKA® is supported by a study by Becher & Winkler, 2018 carried out by the Registrant in which PERLKA® granules were continually washed with tap water. After 24 hours ~65% of the calcium cyanamide had dissolved as determined by cyanamide release. The results are shown graphically in Figure 3. The Dossier Submitter accepts these results and because of the rudimentary nature of this study an approximate half-life (DT50 value) for PERLKA® in surface water is assumed by the Dossier Submitter to be 1 day at 12ºC, the same value used by the Registrant for its exposure modelling in surface water. The Dossier Submitter has used this value in its exposure modelling.



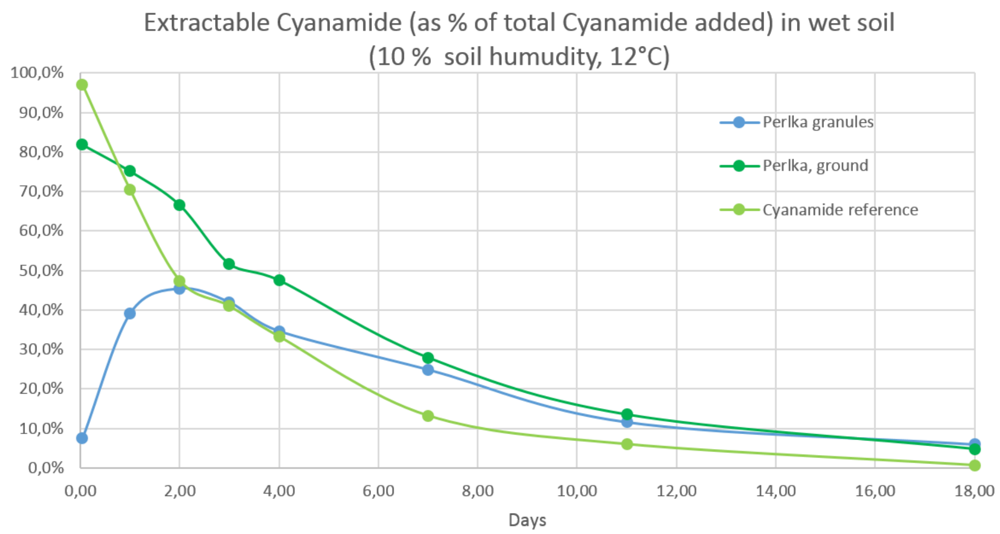
[98] IR & CSA guidance, Chapter 7b, Table R7.8 – 2, degradation, p74 June 2017 version: 'OECD recommends testing parent compound if disappearance time 50 (DT 50) >3 days; breakdown products for DT 50<1 hour and a case-by-case basis for anything in between. https://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf/1a551efc-bd6a-4d1f-b719-16e0d3a01919

(Source: Becher & Winkler, 2018 (for the Registrant))

Figure 3. Amount of cyanamide eluted from 10g PERLKA® granules washed with water (19.80 mL/hour) plotted as a percentage of the original amount of calcium cyanamide in the sample

In aerobic soil PERLKA® dissolves in contact with soil moisture and releases cyanamide and calcium hydroxide. The release of cyanamide from PERLKA® in soil has been modelled in house by the Registrant (Güthner, 2018). In this study the DT50 PERLKA® value in aerobic soil was found to be 1.45 days at 12ºC. The Dossier Submitter accepts this DT50 aerobic soil value and has used it in its exposure modelling. The maximum amount of cyanamide is released after nearly 48 hours with 10% soil moisture and the resulting pH was strongly alkaline. The results are presented graphically in Figure 4.

Urea and cyanoguanidine (DCD) were also measured in the study by Güthner 2018, but according to the Registrant did not account for a significant portion of the released nitrogen. However, the results indicate maximum concentrations of urea and DCD as follows urea 959 ppm and DCD 342 ppm. These findings are supporting evidence to investigate the environmental relevance of urea and DCD.



(Source: the Registrant/Güthner, 2018)

Figure 4. The release of cyanamide from calcium cyanamide in damp soil as a function of physical form in comparison to soil application of cyanamide in solution

In its late 2018 dossier updates the Registrant has presented a preliminary results from a further degradation study (Fraunhofer, 2018a) in which soil types similar to those of used for surface water exposure modelling are used[99] to which PERLKA® was applied with varying soil moisture levels. The Registrant has assumed the release of cyanamide from PERLKA® follows first order kinetics and half-lives (DT50 values) for this release is between 0.6 at 20ºC – 1.63 days at 12ºC. These results are presented in Appendix 4.

Unfortunately, the Fraunhofer 2018a study was received too late for the results to be used in the exposure assessment carried out by the Dossier Submitter. Instead the Dossier Submitter has used a mean value of the results from the study by Güthner 2018 to derive a DT50 aerobic

[99] RefeSol 01-A, similar to soil type simulated in FOCUS scenario R2 – see section 3.2.10.

soil PERLKA® of 1.45 days at 12ºC. The Dossier Submitter considers that the difference in the values derived from the Fraunhofer 2018a and Güthner study would not result in a significant difference in the exposure modelling results.

Degradation of PERLKA® in anaerobic soil is not considered by the Dossier Submitter to be of particular significance for the agricultural use of calcium cyanamide as a fertiliser.

PERLKA® appears to be very stable in air and the Registrant reports calcium cyanamide has a melting point of 1145-1217°C and thus a negligible vapour pressure. Thus, any potential air exposure will be driven by cyanamide, not calcium cyanamide. SCHER 2016 concluded the air compartment is not relevant because PERLKA® is applied to soil as a granulated product and the vapour pressure of calcium cyanamide was very low (estimated with EpiSuite: 4.58E-19 Pa). On this basis the Dossier Submitter accepts PERLKA® is very stable in air.

A.4.1.2. The transformation of cyanamide in the environment

A.4.1.2.1. Transformation of cyanamide in surface water and sediment (aquatic compartment)

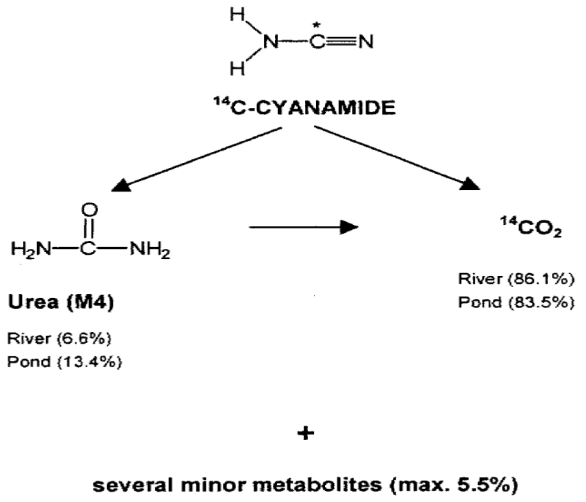
The Registrant has presented studies in which cyanamide is degraded with DT50 values ranging between 2-16 days for a whole river or pond system in aerobic aquatic degradation simulation studies using cyanamide as the parent substance and radioactively labelled [14C] (Völkl, 2000)[100]. A mean DT50 value was proposed by the Registrant for the water phase of 4.3 days at ~20ºC. From this evidence, the Dossier Submitter accepted the DT50 cyanamide in freshwater is 4.3 days at ~20ºC.

The Dossier Submitter notes the test temperature was rather high and 12ºC would have better reflected mean surface water temperatures in the EU. However, in the exposure modelling carried out by the Dossier Submitter the DT50 values are automatically adjusted by the FOCUS model to the temperature used.

From the (Völkl, 2000) study the Registrant also reported urea was the only significant metabolite detected, although five others were found in lower amounts. It appeared at a maximum amounts of 13.4% of applied radioactivity after 1 day in a pond system and up to 6.7% in a river system after 2 days. This was no longer detectable at day 21 of the study. PPP 2008-10 has derived a mean DT50 value for urea (river & pond) of 4.8 days at 20ºC which is consistent with the values used by BPR 2016. BPR 2016 proposed the breakdown pathway of cyanamide in the aquatic compartment shown in Figure 5. This was supported by the REACH registration for urea (RRD urea, 2017) in which urea was found to be readily biodegradable at temperatures between 2 and 20ºC, with 90-100% biodegradation after 21 days.

From the concentrations of urea observed and the potential longevity of urea in the aquatic compartment, the Dossier Submitter concluded the risk of urea should be considered in the environmental risk assessment of the aquatic compartment. A DT50 urea of 4.8 days at 20ºC has been used by the Dossier Submitter.

[100] Study carried out by RCC consultants on behalf of the Registrant.

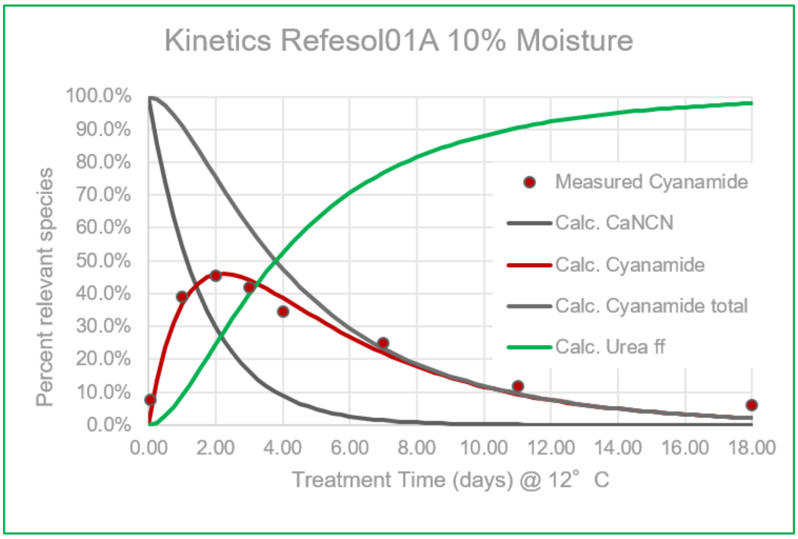


(Source: BPR, 2016)

Figure 5. Breakdown of cyanamide in aerobic water/sediment systems

A.4.1.2.2. The transformation of cyanamide in aerobic soil

Laboratory soil simulation studies of the degradation of cyanamide in soil were reported by the Registrant (Schmidt 1990 & 1991) using radioactively labelled cyanamide [14C]. From these, DT50 (aerobic soil) values for cyanamide were calculated to be in the range of 0.7 – 4.6 days, mean value 2.65 days at 20°C. These results were obtained using a sandy loam soil type with a high organic content. However, the aerobic DT 50 in sandy soil (low organic content) is lengthened to 12 days (Hess, 1978 and Rieder 1978). The Registrant concluded that the organic content of the soil influences the degradation of cyanamide and that biotic degradation likely plays an important role in this this process. The study by Güthner, 2018 resulted in similar DT50 values, with a mean value of 2.9 days at 12°C which are shown in Figure 6



(Source: the Registrant/Güthner 2018)

Figure 6. Release of cyanamide from PERLKA® in soil and modelling of degradation kinetics

Table notes: Soil: RefeSol 01-A = dystic cambisol (sandy loam); Water content: 10 %.

On the basis of these results the Registrant concluded the decomposition of free cyanamide as well as the release of cyanamide from the PERLKA® granules can be described by first order equations. From calculated rate constants (K1 and K2) the following half-lives were derived: hydrolysis of calcium cyanamide (K1): 1.1 days (10 % water), 1.8 days (5% water) decomposition of free cyanamide (K2): 3.2 days (10 % water), 2.6 days (5 % water).

The Dossier Submitter accepts these results and they are consistent with those accepted by BPR, 2016 and PPP 2008-10. The results from the study by Güthner, 2018 are used for the risk characterisation which was the most recent study available at the time of carrying out the exposure modelling. The DT50 cyanamide aerobic soil used by the Dossier Submitter was 2.9 days at 12ºC.

The Registrant's October 2018 REACH registration dossier update included a further study (Fraunhofer 2018a). This study predicted slightly shorter half-lives of cyanamide (DT50 0.77 at 20ºC – 0.95 days at 12ºC) but was received too late to take into account for the purposes of exposure modelling. The reason for the difference in these results from those of previous studies is unclear. Despite the difference in results, the Dossier Submitter does not expect the results of the exposure modelling to be affected significantly.

Some comments (#2755, 2759, 2777, 2769, 2770, 2929) received during consultation underlined the importance of the different DT50 values for cyanamide used by the DS and the Registrant in modelling PEC values. The DS underlines that such new data were not available when the modelling was conducted by the DS, therefore could not be taken into account in the exposure calculations presented in this report.[101]

In soil simulation tests by Schmidt 1990 & 1991[102], the Registrant reported that main transformation product of cyanamide was carbon dioxide, with several other transformation products detected at concentrations of less than 10%: DCD, guanylurea, guanidine and urea. However an overview of the breakdown pathway of calcium cyanamide in aerobic, moist soil has been presented by (Dixon, 2017) which appears to have been accepted by the Registrant (see Figure 1).

Quite late in the preparation of this report, the Registrant updated their REACH registration dossier (Alzchem, 2019a) to include a further study on the release and transformation of cyanamide from PERLKA® in aerobic soils with two test soil types (R1: high silt, low sand, 1.0% organic carbon[103]; and R2 as above) and varying moisture content (Fraunhofer, 2018a). The DT50 values put forward by the Registrant from this study is shown in Table 32.

Table 32. The transformation of PERLKA® in aerobic soil

	DT50 values from Güthner 2018 (days) R2 Soil type (% = H_2O content in soil)	DT50 values from Fraunhofer 2018a (days) R2 Soil type (% = H_2O content in soil)	DT50 values from Fraunhofer 2018a (days) R1 Soil type (% = H_2O content in soil)
Transformation of PERLKA® ($CaCN_2$) to cyanamide	1.1 (10%),	0.87 (21%)	0.6 (10%)

[101] The relevance of the different DT50 values used by the Dossier Submitter and by the Registrant in the modelling has been addressed by the RAC in the RAC opinion, concluding that the PEC values as predicted by the Registrant using the updated half-lives and the PECs predicted by the DS are within the same magnitude, resulting in RCRs > 1.

	1.8 (5 %)	1.63 (10.4%)	1.21 (5%)
Mean value	1.45	1.25	0.91
Degradation of cyanamide:	3.2 (10 %),	0.82 (10%)	0.95 (21%)
	2.6 (5%)	0.77 (5%)	0.79 (10.4%)
Mean value	2.9	0.80	0.87

(Source: The Registrant/Güthner, 2018 and Fraunhofer 2018a)

For PERLKA® degradation the results from the two studies for R2 soil type are difficult to directly compare because of the varying moisture content, although the results are broadly similar. The Fraunhofer 2018a study results are indicative that a higher concentration of silt in soil reduces the DT50, although again because of the varying moisture levels this effect is somewhat obscured. Comparing the results from Güthner, 2018 (R2 soil) with Fraunhofer 2018a (R1 soil) appears to confirm this effect.

The Dossier Submitter accepts these results but for the purposes of its risk characterisation in the terrestrial compartment has assumed at mean DT50 PERLKA® (aerobic soil) of 1.45 days at 12°C on the basis of the study by Güthner 2018 which was the most recent study available at the time of carrying out the exposure studies in soil.

Degradation of PERLKA® in anaerobic soil is not considered by the Dossier Submitter to be of particular significance in agricultural conditions.

A.4.1.2.3. The transformation of cyanamide in the atmospheric compartment

In the PPP 2008-10 Review cyanamide was reported to have the potential for volatilization when used in the formulation Dormex® for outdoor air-blast spraying for the stimulation of bud opening of grapes and kiwifruit. This assumption was based upon the vapour pressure of cyanamide of 0.51 Pa at 20°C.

Also in PPP 2008-10 the atmospheric half-life of cyanamide using Atkinson calculations[104] was reported as significantly longer than 2 days. Modelling was carried out and it was concluded that cyanamide is not expected to react with hydroxyl radicals or ozone and the proportion of cyanamide that is anticipated to be present in the air is small and the residence time in the air is short, therefore long-range transport through the atmosphere is not expected. Regarding the short-range transport, PPP 2008-10 reported the results from a field study which indicated that deposition of cyanamide after volatilisation is a relevant process for the aquatic and

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[102] By ABC laboratories in the US on behalf of the Registrant.

[103] RefeSol 02-A, corresponding to soil type in FOCUS scenario R1 – see section A.9.3.2.5.

[104] The Atkinson model is used in the PPP legislation to predict photochemical oxidative degradation in air.

terrestrial off-crop area.

In BPC 2016 in both the product types (PT) considered (PT 3 and 18) uses were in liquid form in indoor animal housings. On the basis of the vapour pressure of cyanamide, direct evaporation was not expected and no potential of volatility from water was considered. However, the BPC queried whether the Atkinson calculation allows for an adequate estimation of the photochemical degradation of cyanamide.

When considering these findings in the context of PERLKA® used as a fertiliser, it is clear that the application method (air blast spraying) of the formulation considered by the PPP 2008-10 Review is quite different from that of PERLKA® which is applied in solid granules. It is unlikely therefore that the 'potential for volatilization' observed will occur with the use of PERLKA®.

The consideration of a liquid formulation in the BPC 2016 review may be of some relevance for the use of PERLKA®, given that PERLKA® granules in some applications are applied to the soil surface and then release cyanamide in the presence of moisture. BPC 2016 concluded direct evaporation was not expected and no potential of volatility from water was considered in the indoor use considered by the BPC. However, given that some cyanamide may occur in liquid form on the soil surface and then be exposed to sunlight, volatility may well occur, albeit in limited amounts. For this reason, a limited volatilisation of cyanamide is assumed in the terrestrial exposure modelling carried out by the Dossier Submitter.

Because of very low vapour pressures of urea and DCD[105] and the low concentrations present compared to cyanamide, the Dossier Submitter did not investigate the possible fate of urea and DCD in the atmospheric compartment.

A.4.2. Environmental distribution

The adsorption coefficient (Koc[106]) for calcium cyanamide, has been estimated by the Registrant using an HPLC retention time method to be <1.25 at pH 5.5 and 7.5 (Seibersdorf Labor GmbH 2010). On this basis the Registrant explains calcium cyanamide is not expected to have a significant potential to adsorb to soil and instead be 'quite mobile' [in soil].

For cyanamide, the Registrant presented data using three soil types (Ruedel, H 1990). The derived Koc values for cyanamide were between 0 and <6.8. On this basis the Registrant noted cyanamide is likely to be 'very mobile' [in soil].

These findings are consistent with those of PPP 2008-10, SCHER 2016 and BPR 2016. Because of this high mobility potential and on the basis of FOCUS groundwater modelling results, in its review (PPP 2008-10) concluded there is a high potential for cyanamide to reach groundwater in a wide range of geoclimatic conditions. These findings were consistent with those of SCHER 2016, although SCHER concluded groundwater was unlikely to be at risk on the basis of results of lysimeter and column leaching studies presented by the Registrant (see below).

The REACH Registrants for urea reported a Koc urea of 0.037 – 0.0641 which indicates a high potential for mobility in soil. The REACH Registrants for DCD reported it to be 'reasonably mobile' based on its log Kow of -1 and reading across from the properties of nitroguanidine, a chemically similar substance.

The Dossier Submitter accepts the findings for potential mobility in soil based upon adsorption coefficients, i.e. calcium cyanamide is likely to be 'quite mobile', cyanamide and urea 'very

[105] Urea 0.002 Pa at 298K; DCD 0.0000085 Pa at 298K.

[106] Adsorption coefficient normalised for organic carbon content.

mobile' and DCD 'reasonably mobile'.

In the May 2018 REACH registration dossier update, the Registrant has presented results of lysimeter and column leaching studies in which calcium cyanamide was added to a lysimeter in two successive years and samples taken at 2-4 week intervals. In the initial leaching period trace amounts of cyanamide were detected. The mean cyanamide concentrations in the total percolate of the 1st and 2nd years were < 0.03 µg/l, the cyanamide concentrations in all soil samples investigated were below the detection limit of 0.05 mg/kg soil. The Registrant concluded from this study that calcium cyanamide will not leach into deeper soil layers and/or groundwater.

The conclusion reached by the Registrant is possibly correct for calcium cyanamide because it is likely to have been transformed to cyanamide before reaching deep soil or groundwater. However, from the reports of the studies it appears the sampling frequency was insufficient to detect a rapid elution of calcium cyanamide and/or its primary transformation substance cyanamide. From the information available therefore it appears a rapid leaching of calcium cyanamide and/or cyanamide may have been occurred but was not measured in the reported studies. The details of these studies had been removed from the October 2018 registration dossier update.

The likelihood of mobile substances reaching groundwater after application to soil is a balance between their rate of formation/application, their rate of transformation/removal and their rate of leaching. The high potential for mobility of cyanamide and urea in particular suggests leaching to groundwater could be important for the risk assessment. DCD is less mobile but significantly more persistent in aerobic soil than urea. On this basis the Dossier Submitter has carried out exposure modelling to predict the likelihood of cyanamide and DCD reaching groundwater following the application of PERLKA® to soil.

A.4.3. Bioaccumulation

Based on a low estimated log Kow of -0.72 and bioconcentration factor of -0.047 the Registrant concluded for calcium cyanamide there is no evidence of bioaccumulation potential. REACH states if the potential for bioaccumulation is low (e.g. a log Kow ≤ 3) and/or a low potential to cross biological membranes, further testing is not required[107].

The same conclusion was also reached for cyanamide by (BPR, 2016 and PPP, 2008-10) on the basis of a log Kow of -0.72 at 20°C (pH 6.8) and a calculated bioconcentration factor in fish of 0.049 $L/kg_{wet\ fish}$ and the estimation on terrestrial bioconcentration leads to a value of 0.84 $L/kg_{wet\ earthworm}$ for earthworm.

For urea the measured Log Kow was -1.73 at 20°C and for DCD it was -1 at 20 °C.

On the basis of the above the Dossier Submitter considers bioaccumulation is unlikely for calcium cyanamide, cyanamide, urea or DCD.

A.4.4. Secondary poisoning

Secondary poisoning from cyanamide released from PERLKA® is theoretically possible but has not been considered in detail in this report.

[107] REACH, Annex IX, column 2, paragraph 9.3.2.

A.5. Human health hazard assessment

Not relevant for this dossier.

A.6. Human health hazard assessment of physicochemical properties

Not relevant for this dossier.

A.7. Environmental hazard assessment

A.7.1. Aquatic compartment (including sediment)

A.7.1.1. Ecotoxicity to surface water and sediment-dwelling organisms

There are 16 studies available to the Dossier Submitter for this compartment – 11 acute or short-term and 5 chronic studies. One of the chronic studies is for sediment-dwelling organisms. These are summarised in Table 33 below.

Table 33. Ecotoxicity studies on aquatic compartment-dwelling organisms used for this report (test substance: calcium cyanamide/cyanamide**)

Species	Test substance	Test/duration	NOEC/NOAEL mg/L	Reference$
Surface water				
Anabaena flos-aquae (cyanobacteria)	cyanamide	acute (72 h) biomass	0.11	Hertl (2000a)
Pseudomonas putida (microorganism)	cyanamide	acute (19 h)	157	Hanstveit et al. (1988)
Scenedesmus capricornutum (algae)	cyanamide	chronic (90.5 h)	1.1	Schoot Uiterkamp, A.J.M. (1988)
Pseudokirchneriella subcapitata (algae)	calcium cyanamide	chronic (72 h)	6.64	Ipser 2010a
Pseudokirchneriella subcapitata (algae)	calcium cyanamide	chronic (72 h)	2.6	Seyfried, B. (2000)
Daphnia magna (invertebrates)	cyanamide	acute (48 h)	1.6	Adema, M. (1983)
Daphnia magna (invertebrates)	calcium cyanamide	acute (48 h)	1.8	Ipser (2010b)

Daphnia magna (invertebrates)	cyanamide	chronic (21 d)	0.1044	Murell et al. (1995)
Oncorhynchus mykiss (fish)	cyanamide	acute (96 h)	30.6	McAllister et al. (1985a)
Oncorhynchus mykiss (fish)	cyanamide	acute (96 h)	31.8	Barrows, B. (1985),
Danio rerio (fish)	calcium cyanamide	acute (96 h)	~100.0	Ipser 2010c
Lepomis macrochirus (fish)	calcium cyanamide	acute (96 h)	30.6	McAllister et al. (1985b)
Cyprinus carpio (fish)	cyanamide*	acute (96 h)	29.9	Bowmann and Herzig (1990a)
Oncorhynchus mykiss (fish)	cyanamide	chronic (21 d)	3.7	Bowmann and Herzig (1990b)
Lemna gibba (plant)	cyanamide	short-term (7 d)	0.5	Hertl (2000b)
Sediment				
Chironomus riparius (insects)	cyanamide	chronic (28 d)	6.64	Heintze, A. (2001)

Source: Alzchem, 2019a, RAC 2015, BPR 2016, PPP 2008-10 and SCHER 2016.

Table notes: * based on an aqueous solution of cyanamide (about 50%); ** pure unless stated otherwise; $ some studies included in Alzchem, 2019a by the Registrant do not have a reference source. These are not included in this table.

A.7.1.1.1. Derivation of the PNECfreshwater for calcium cyanamide/ cyanamide by the Dossier Submitter

Of all these studies the most sensitive organism in freshwater chronic studies is *Daphnia magna* using the test substance cyanamide. The Dossier submitter has chosen the key study to be a chronic 21d *D. magna* study (Murrel & Leak, 1995) using cyanamide as the test substance because this resulted in the lowest NOEC values for aquatic organisms. The 21-d

NOEC is reported as 0.1044 mg cyanamide/L. Chronic studies are available for three trophic levels so an assessment factor (AF) of 10 was used, in line with ECHA Guidance, to derive a PNEC. On this basis the PNECfreshwater cyanamide used by the Dossier Submitter was 0.01044 mg/l or 10.44 µg/L.

In this key study using cyanamide (50 % (w/w) aqueous solution) as a test substance, the growth and reproduction of *D. magna* were assessed in an non-aerated, flow-through 21-day test according to OECD test 202. The chronic effects for cyanamide are used as a surrogate for calcium cyanamide by the Registrant, in the absence of a specific chronic test for calcium cyanamide. Nominal concentrations of cyanamide were administered between 0.025 – 0.4 mg/L cyanamide. The pH ranged from 7.78 – 8.45. 40 daphnids (4 replicates containing 10 daphnids) were exposed to each test level. Mean measured concentrations ranged from 92 to 105 % of nominal concentrations. In the test medium the test item was sufficiently stable during the test period of 21 days. Nevertheless, the results are based on mean measured concentrations.

Survival of *D. magna* was not significantly affected in any test level when compared to the control. The 21-d-EC50 based on immobility was > 0.4 mg of a 50 % (w/w) aqueous solution of cyanamide/L. The mean weights were not significantly different from the control at any test concentration. The time to first brood was 7 days for the control and all test concentrations. For the endpoint: number of offspring the 0.21 and 0.41 mg of a 50 % (w/w) aqueous solution of cyanamide/L - test levels were significantly different when compared to the control and therefore the NOEC reproduction is 0.1 mg of a 50 % (w/w) aqueous solution of cyanamide/L. The parameter length was significantly affected in all concentrations compared to control and therefore NOEC length is < 0.023 of a 50 % (w/w) aqueous solution of cyanamide/L. As the mean weights were not significantly different to the control at any test concentration and as reproduction is regarded as most relevant parameter for the survival of a population, the appropriate effect value for assessment is the NOEC for reproduction of 0.1 mg cyanamide/L. This was adjusted by calculation in CLH 2015 to be 0.1044 mg/L and was used as the starting point for the derivation of the PNECfreshwater by the Dossier Submitter for the current risk assessment.

From Table 33 it can be seen that *A. flos-aquae* and *L. gibba* were also found to be very sensitive to cyanamide in acute studies. In chronic studies *O. mykiss and C. riparius* were found to be sensitive to cyanamide, although a PNECfreshwater derived from these studies would result in a value one order of magnitude less stringent than that from Murrel and Leak, 1995.

A.7.1.1.2. The Registrant's approach to deriving a PNECfreshwater

In its registration dossier (Alzchem, 2019a) the Registrant has derived three PNECfreshwater values and has used different studies as the point of departure and used different methodologies to derive the PNEC values. The three PNECs are: (1) PNECfreshwater for industrial manufacturing and use of the substance, associated with potential continuous release of calcium cyanamide/cyanamide to surface waters; (2) PNECfreshwater for intermittent release of calcium cyanamide/cyanamide; and (3) PNECfreshwater for fertiliser use. The Dossier Submitter considers the most appropriate point of departure for deriving the PNECfreshwater for fertiliser use is the Murrel & Leak, 1995 study. This is elaborated below.

For industrial manufacturing and use of the substance (1), the Registrant has used the same key study as the Dossier Submitter (Murrel & Leak, 1995) and derived the same PNECfreshwater as the Dossier Submitter (PNECfreshwater (industrial manufacturing) of 0.01 mg/L cyanamide). For intermittent releases (2) the Registrant derives the PNECfreshwater from an acute study with *Daphnia magna* (Ipser 2010), resulting in a 48-hr EC50 value of 4.2 mg calcium cyanamide/L or 2.2 mg cyanamide/L. An AF of 100 is applied (because it is a short-term study) resulting in a PNECfreshwater (intermittent) of 22 µg/L cyanamide. Releases from industrial manufacturing and intermittent releases are outside of the scope of this report.

. For fertiliser use (3), the Registrant draws upon the results of two studies conducted to specifically assess potential adverse effects of the transformation product cyanamide under exposure conditions that realistically reflect the actual exposure of ecosystems related to the typical agricultural use of the fertiliser product PERLKA®. These studies are an outdoor mesocosm study (Hommen, 2019) and a non-standard *D. magna* 21-d reproduction study (Brüggemann, 2019). The justification by the Registrant for these higher-tier studies is that the agricultural use of calcium cyanamide in the form of PERLKA® is invariably restricted to single application once a year[108], resulting in short-term exposure of adjacent surface waters to the transformation product hydrogen cyanamide. The Registrant argues the exposure regime in the mesocosm study (Hömmen, 2019) and the non-standard *D. magna* reproduction study (Brüggemann, 2019) match realistic agricultural use conditions. The aquatic outdoor mesocosm study (Hommen, 2019) is considered by the Registrant as the key study as lower effect values are reported for the most sensitive organism (*algae*) in comparison to the results for *D. magna* obtained by Brüggemann (2019). Although the Registrant decided not to take into account the *D. magna* study (Brüggemann, 2019) in the derivation of the PNECfreshwater for fertiliser use, ECHA conducted also an evaluation of the non-standard *D. magna* reproduction study (Brüggemann, 2019) observing that the test was based on OECD guideline 211 but with some notable deviations:

- a water-sediment system (using artificial sediment) was used instead of water,
- the test medium was not renewed (static exposure),
- the results were expressed in terms of initial measured test concentrations whereas most of the substance was lost by the end of the test,
- two different life stages were tested: *juvenile daphnids* aged less than 24 hours as recommended by the test guideline, but also adult *daphnids* with an age of c.a. 7 - 8 days.

The study report indicates the use of a water-sediment system with the aim of simulating the degradation of cyanamide for a typical run-off-situation. However, if the substance degrades during the test, then the intrinsic toxicity of the substance itself cannot be assessed.

In relation to the test medium renewal, OECD test guideline 211 recommends that the test medium should be renewed at least 3 times per week but more frequent medium renewal or the use of a flow-through test is necessary if the substance concentration in the test medium tends to drop rapidly. Furthermore, if the concentration of the substance has not been maintained within ± 20% of the nominal or measured initial concentration throughout the test, then OECD test guideline 211 requires that the results should be based on the time-weighted mean, not on the nominal or measured initial values. In order to assess the intrinsic toxicity of the substance, it is important to maintain as far as possible the test concentrations constant. If not possible, then the results must be expressed in terms of the actual concentrations to which the test organisms have been exposed.

The concentrations of cyanamide were measured throughout the test. Initial concentrations were between 104 – 118 % of nominal but decreased to 0 – 4.3% of nominal after 21 days without renewal of the test medium. This confirms that most of the substance was degraded,

[108] Two applications of PERLKA® per year are recommended for some crops.

transformed or dissipated by the end of the test. A 21-d NOEC ≥ 0.470 mg cyanamide/L was derived, but it was based on initial measured test concentrations. Since the substance was lost throughout the test and virtually absent from the test medium after 21 days, this NOEC of ≥ 0.470 mg cyanamide/L does not reflect the intrinsic toxicity of the substance.

The study report does not explain why adult *daphnids* (7-8 days old) were tested in addition to the *juveniles* (< 24 hours old). The age of the test organisms was standardised in the OECD test guideline for a better comparability of the test results as it can have a significant impact on the test results.

ECHA further noted that the authors claim that the modified test was done under more "*realistic conditions*" compared to a standard OECD 211 test and that it was as such suitable for a "*refined risk assessment*" of the substance. However, the conditions for this test were still very unrealistic compared to actual environmental conditions. For example, the test temperature (18 - 22°C) was not representative of temperate ecosystems. The authors claim that the test simulated the degradation of cyanamide for a typical run-off-situation. However, actual environmental exposure depends on many factors: not only degradation under environmental conditions, but also releases pattern, environmental transport and distribution. Therefore, the evolution of the substance concentrations measured during this test cannot be regarded as representative of the actual fate and behaviour of the substance under environmental conditions. The effects observed for the specific exposure conditions of this test cannot be extrapolated directly to the actual effects in the environment.

Therefore, ECHA concluded that the non-standard *D. magna* reproduction study (Brüggemann, 2019) does not provide definite data for risk assessment and shall not be used as a replacement for the chronic 21d *D. magna* study (Murrel & Leak, 1995) with cyanamide as the test substance to assess the intrinsic toxicity of the substance to *daphnids*.

In relation to the mesocosm study, the Dossier Submitter acknowledges that the Registrant considered the aquatic outdoor mesocosm study (Hommen, 2019) as the key study since it covers a large number of species, comprising a much wider taxonomic diversity than those represented by the base-set and the non-standard reproduction study with *D. magna* (Brüggemann, 2019). The Registrant further argues the high diversity of taxa in the mesocosm study significantly reduces the uncertainty in the evaluation of toxic effects. The results are presented in

Table 34.

The approach utilised by the Registrant to interpret the results is claimed to be that used in the PPP legislation109. The PPP tier approach includes four tiers within the acute and chronic effect assessment. The tier 1 and tier 2 effects assessments are based on single species laboratory toxicity tests, but to better address risks of time-variable exposures the tier 2 assessment may be complemented with toxicokinetic/toxicodynamic (TK/TD) models. 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 guidance (EFSA, 2013) were developed to allow the derivation of Regulatory Acceptable Concentrations (RACs) 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

[109] Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters'; EFSA Journal 2013;11(7):3290.

effects if ecological recovery takes place within an acceptable time period. The PPP approach classifies study effects as follows: 1 = no effect, 2 = slight effect, 3A = effect duration shorter than 8 weeks, 4A = effect at the end of the study, duration could not be assessed, 5A = effect over more than 8 weeks but recovery within the study, 5B = effect longer than 8 weeks without recovery within the study. Using this effect classification the Registrant concluded acceptable short-term effects are observed at a nominal test concentration of 0.32 mg/L (ERO-RAC; effect class 3A).

Table 34. Results of the mesocosm study (Hömmen, 2019) using cyanamide as a test substance

Group/sampling strategy	Taxon	0.032 mg/L	0.1 mg/L	0.32 mg/L	1 mg/L	3.2 mg/L
Zooplankton	Cladocera			[red/blue]	[blue]	
	Copepoda				[red]	[blue]
	Cyclopidae			[red]	[blue]	
	Ostracoda			[red/blue]		
	Insecta[1]				[red/blue]	
	Rotifera			[red]	[blue]	
	Community	[red]		[blue]		
Macroinvertebrates	Diptera[1]		[red/blue]			
	Other insecta				[red/blue]	
	Asellus aquaticus			[red/blue]		
	Others					[red/blue]
	Community			[red/blue]		
Phyoplankton	Total				[red/blue]	
	Cyanophyceae	Not assignable				
	Cryptophyceae		[red]		[blue]	
	Dinophyceae	Not assignable				
	Bacillariophyceae[2]			[red/blue]		
	Chrysophyceae			[red]		[blue]
	Zygnematophyceae	Not assignable				
	Euglenophyceae	Not assignable				
	Chlorophyceae[3]				[red/blue]	
	Community		[red/blue]			
Whole mesocosm		[red]	[blue]			

Legend
- [red] Lowest NOEC-ETO[110] within the group
- [blue] Lowest NOEAC-ERO within the group

(Source: Alzchem, 2019a)

The Registrant evaluated the effect values considering the ecological recovery option (ERO). To derive the PNECfreshwater (fertiliser use) the Registrant argues that because of the high diversity of taxa in the mesocosm study assessment factors (AF) can be reduced to three or four, as required under the PPP legislation. The Registrant claims that due to the large species diversity covered by the mesocosm study, in combination with a realistic exposure pattern, the results of the mesocosm study are associated with only little uncertainty. Additionally, the observed shift within the *algae* biocoenosis at 0.32 mg/L did not have adverse effects on organisms of higher trophic levels, i.e. the food chain and the structure and functionality of the entire ecosystem was unaffected by the transient alteration of the species composition of primary producers, which represent keystone species in aquatic ecosystems. Thus, the Registrant concluded that it is justified to further reduce the AF to 3 specifically for the fertiliser use of PERLKA. Considering the effect class 3A concentration of 0.32 mg cyanamide/L at which *acceptable short-term effects* are observed derived from the results of the outdoor

[110] ETO: Ecological Threshold Option

mesocosm study, the PNECfreshwater (fertiliser use) derived by the Registrant is therefore 0.107 mg cyanamide/L (107 µg cyanamide/L).

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Under REACH well conducted mesocosm studies can be used in a weight of evidence approach to refine the PNEC derived from chronic aquatic toxicity data. However there are a number of methodological difficulties with the study performed that lead the Dossier Submitter to conclude the study results cannot be used to refine the PNEC. These are described below.

The Dossier Submitter has received input from EFSA (EFSA, 2018) on this study and EFSA has pointed out a number of methodological difficulties with the mesocosm study.

- The study offers a good representation of a mid-European lotic community, but any extrapolation to other conditions (e.g. other EU zones and other water bodies) remains to be addressed.
- *Chaoborus* larvae and pupae were sampled with two different techniques, one used for zooplankton (depth integrated sampler) and another used for macroinvertebrates (netting). The two sampling techniques have been assessed in isolation. While the natural dynamics for the taxon is rather similar in the control, results of treatment-related effects for the two sampling techniques are quite different.
- For zooplankton, it should be flagged that the abundance of most Cladocera species was generally very low. As cladocerans included the most sensitive taxa at lower tiers (i.e. *Daphnia*), this should be considered as a general source of uncertainty in the final outcome. Finally, a marked decrease of *Chaoborus* was seen before the exposure phase, indicating that most phantom midges were not exposed or were only exposed at a later developmental stage. Despite for specific taxa only transient effects were seen only up to 0.32 mg/L, pronounced effects on the zooplanktonic community composition were seen at all but the lowest concentration (0.032 mg/L). Overall, a NOEC for the ETO option for zooplankton could be set at 0.032 mg/L, while the NOEAEC for the ERO option can be set at 0.32 mg/L.
- Among macroinvertebrates, dipterans (and specifically *Chaoborus sp.*) were the most sensitive order. The same uncertainty reflected above regarding this taxon still applies here. Overall, both the NOEC (ETO option) and the NOEAEC (ERO option) for macroinvertebrates could be set at 0.1 mg/L. In this case the two options overlap because at 0.32 mg/L recovery for dipterans cannot be properly demonstrated.
- Phytoplankton seemed to be mainly impacted in an indirect way, i.e. most taxa presented an increased cells density when compared to the control levels, likely due to the treatment-related removal of grazers feeding on algae. However, this was not true for all taxa. The endpoint derivation was particularly uncertain for Chlorophyceae, due to a significant increase (compared to the control) of the cell density seen at all but the lowest tested concentration and at the end of the study. Apart from this, taxa-specific analysis showed only transient effects up to 0.1 mg/L (i.e. Cryptophyceae) and complete recovery up to 1 mg/L. Nevertheless, when the community structure was assessed as a whole, significant long-lasting effects were seen for all concentrations ≥ 0.32 mg/L. Overall, both the NOEC (ETO option) and the NOEAEC (ERO option) for phytoplankton could be set at 0.1 mg/L.

EFSA has concluded that an assessment factor of 2 is suitable or the ETO option, while an assessment factor of 4 is chosen for the ERO option. Therefore, the PNECs derived by the Dossier Submitter are: PNEC for ecological threshold option (based on zooplankton PRCs, 0.032

mg/L/2) = 0.016 mg/L and PNEC for the ecological recovery option (based on Diptera/Chaoborus sp. and phytoplankton PRCs, 0.1 mg/L/4) = 0.025 mg/L. Due to the methodological difficulties explained in relation to the mesocosm study, the Dossier Submitter decided to use as key study for the PNECfreshwater derivation the chronic 21d *D. magna* (Murrel & Leak, 1995) with cyanamide as the test substance (PNECfreshwater of 0.01 mg cyanamide/L).

Additionally The PNECfreshwater values 0.016 mg/L based on ETO-RAC was used for comparison with the PNECfreshwater value of 0.0104 mg/l derived from the chronic endpoint for Daphnia (NOEC=0.104 mg/L). The ETO-RAC was considered for deriving PNECfreshwater from the mesocosm data because (1) it's more conservative than the PNEC derived using the ERO value, (2) in order for the ERO value to be used according to the EFSA guidance (2013) "all relevant processes that determine population viability and the propagation of effects to the community-, ecosystem- and landscape-level are to be considered" and these processes are don't described in the study report and (3) as mentioned in the guidance (EFSA, 2013) by selecting ETO were are "not accepting population-level effects on representative sensitive populations in edge-of-field surface waters, these populations will be protected and propagation of effects to the community-, ecosystem- and landscape-level will not occur". This falls within the specific protection goals of REACH of no significant adverse effects on ecological populations, food chains, and communities. As the PNECfreshwater value derived from the chronic daphnia study is more conservative, but very close to the PNECfreshwater derived from the mesocosm study, it strengthens the conclusion that this value is appropriate for use in risk assessment to the aquatic environment.

The Dossier Submitter has conducted a sensitivity analysis exploring the significance of the size of the assessment factor used to derive the relevant PNEC value. The results of this sensitivity analysis show that applying the assessment factors that would be used if the substance were being assessed under the PPP legislation still results in risks to surface water and soil that are not adequately controlled. For surface water the PPP risk characterisation results are identical to those derived from an assessment under REACH. For further details please refer to Annex A.10.4.

Overall, based on the reasoning above and the uncertainty underlined, the mesocosm study is considered by the Dossier Submitter not to be adequate and reliable enough to be used to refine or replace the PNECfreshwater derived from chronic aquatic toxicity data. In addition, Annex I to REACH only requires a single PNEC to be derived rather than three. Further details are provided in Annex A.7.1.

A.7.1.1.3. Ecotoxicity to sediment-dwelling organisms

The Dossier Submitter has derived a PNECsed cyanamide to be used as supporting information in the risk assessment. A PNECsed has been derived on the basis of one chronic study (Heintze 2001). An assessment factor of 100 has been used according to ECHA Guidance on Information Requirements, Chapter R10, May 2008. The resulting PNECsed cyanamide is 66.4 µg/L.

In BPR, 2016 a PNECsed cyanamide was derived on the basis of the equilibrium partitioning coefficient to be 9.16 µg/L cyanamide. That there is a difference by an order of magnitude between the experimental value and the calculated value may indicate the inaccuracy of the calculated value, or that the experimental value based on one study underestimates the toxicity to sediment-dwelling organisms.

On the basis of the ECHA Guidance (ECHA, 2017) it is not necessary for the Registrant to derive an PNECsed. It states: substances that are potentially capable of depositing on or sorbing to sediments to a significant extent have to be assessed for toxicity to sediment-dwelling organisms. In addition, marine sediment effects assessment is necessary for substances that are known to be persistent in marine waters and may accumulate in sediments over time. In general, substances with a Koc< 500–1000 L/kg are not likely sorbed to sediment. According to this, a log Koc or log Kow of ≥ 3 is used as a trigger value for sediment effects assessment. As cyanamide, the relevant transformation product of calcium cyanamide, has a log Kow of -0.72 and is not persistent in water/sediment systems, no hazard is identified. Sediment effects assessment is not required.

A.7.1.1.4. Ecotoxicity of urea and cyanoguanidine (DCD) to surface water and sediment-dwelling organisms

For urea the PNECfreshwater was derived from the chronic study using *M. aeruginosa* by Bringmann, G. & Kuhn, R. 1978. An assessment factor of 100 was applied.

For DCD the PNECfreshwater was derived from the *D. magna* study reported by the Environment Agency Japan (1998b). An assessment factor of 10.

Table 35. Ecotoxicity studies on aquatic compartment-dwelling organisms used for this report (test substance: urea and cyanoguanidine)

Species	Test substance	Test/duration	NOEC/NOAEL mg/L	Reference
Surface water				
Microcystis aeruginosa (algae)	urea	toxicity threshold (192h) Chronic	NOEC: 47 mg/L based on biomass	Bringmann, G. & Kuhn, R. 1978
Daphnia magna freshwater invertebrate	urea	acute test (24h)	EC50: >10000 mg/L based on mobility	Bringmann, G. & Kuhn, R. 1982
Gambusia affinis freshwater adult fish	urea	short-term (1 wk)	NOEC: 200 mg/L based on mortality	Oster, et al. 2011
Pseudokirchnerella subcapitata (algae)	DCD	short-term (4 d)	EC50: 2.04 g/L based on cell number	Oldersma, H.; Hanstveit, A. O.; Pullens, M. A. H.L. (1985)
D. magna	DCD	chronic (21 d)	NOEC: 25.0 mg/L based on reproduction	Environment Agency Japan (1998b)

Oryzias latipes freshwater adult fish:	DCD	short-term (14 d)	NOEC: >= 100.0 mg/L Based on mortality	Environment Agency Japan (1998a)
Sediment				
No data	urea	No data available		
No data	DCD	No data available		

(Source: RJRD DCD, 2015 and RRD urea, 2017).

A.7.2. Terrestrial compartment

A.7.2.1. Ecotoxicity to soil-dwelling organisms

There are 17 studies available to the Dossier Submitter for soil-dwelling organisms – 8 acute or short-term – 9 chronic. The source of the studies is mainly the Registrant's REACH registration dossier (Alzchem, 2019a), but also cross-referenced with BPR 2016, CLH 2015, PPP 2008-10, SCHER 2016. These are summarised in Table 36 below.

Table 36. Ecotoxicity studies on terrestrial compartment-dwelling organisms used for this report (test substance: PERLKA®/calcium cyanamide or cyanamide)

Species/ material	Test substance	Test/duration	NOEC/NOAEL mg/kg soil$$	Reference**,$
Soil dwelling organisms				
Innoculum soil microorgansims	PERLKA®	chronic (90 d)	1.3 g/kg soil dw derived NOEC cyanamide$$$: 295.1	Schönborn 1990
Innoculum soil microorgansims	cyanamide	chronic (28 d)	27.2	Reis, 2002 (BPR 2016)
E.fetida (annelid)	PERLKA®	chronic (56 d) reproduction	82.0 derived NOEC cyanamide$$$: 18.9	Scheffczyk, 2016a
E.fetida & L.terrestris (annelids)	calcium cyanamide/ PERLKA®	short term (14 d)	LC 50: 261.4	Haque and Ebing, 1983

E.fetida & L.terrestris (annelids)	calcium cyanamide	short term (14 d)	LC 50: 115.0	Heimbach, 1984
E.fetida (annelid)	cyanamide	short term (14 d)	LC50 111.3	Lührs, 2001
E.fetida (annelid)	cyanamide	chronic (56 d)	>/=1.05*	Scheffczyk, 2016b
8 species of annelids	calcium cyanamide (40-45%)	chronic (52 wks)	>/= 213.2 – </= 239.9 No statistical difference between earthworm populations	Bauchhenβ, 1992
Bembidion lampros (coleopteran)	calcium cyanamide	short term (5 d)	264	Mead-Briggs, 1990
Poecilus cupreus (coleopteran)	cyanamide	short term (14 d)	</=20 kg cyanamide/ha application rate	Schmitzer and Stork, 2000
Pardosa species (soil-dwelling spider)	cyanamide	short term (14 d)	LR50: <20 kg cyanamide/ha application rate	Schmitzer, 2000
Pardosa species (soil-dwelling spider)	cyanamide	short term (14 d)	0.9 kg cyanamide/ha application rate Derived concentration***: 1.2 mg/kg soil dw	Röhlig, 2006b

A. bilineata (Coleopteran – soil-dwelling beetle)	cyanamide	chronic (28 d) reproduction	</= 0.3 kg cyanamide/ha application rate Derived concentration***: 0.4 mg/kg soil dw	Röhlig, 2006a
A. bilineata	cyanamide (51.1%)	chronic (4 wks)	LOEC: <20 kg cyanamide/ha application rate	Drexler, 2000
F. candida (Arthropod – springtail)		chronic (28 d)	EC10: 1.515	Moser and Scheffczyk, 2009
Terrestrial plants				
Z.mays, A. sativa, A.cepa, L.perenne (monocots.) B.oleracea, D.carota, C. sativus, L. sativa, L, esculentum (dicots.)	cyanamide	Short term (14 d)	<0.02 (*A.cepa*) shoot dry weight	Meister, 2001 (BPR 2016)
A. sativa, (monocot.) *B. rapa* (dicot.)	cyanamide	chronic (28-39 d)	50.0 (both)	Förster, 2009

(Source: Alzchem, 2019a, PPP 2008-10, BPR 2016)

Table note: *highest concentration of 50% cyanamide solution used in the study; $ some studies included in Alzchem, 2019a by the Registrant do not have a reference source. These are not included in this table; $$ unless indicated otherwise. ***In order to use in the risk assessment carried out by the Dossier Submitter, where a threshold value in the table above is given as kg per hectare, for the most sensitive organisms a soil concentration (dry weight) has been calculated using the method described by The Australian Agricultural Production Systems Simulator (APSIM)[111]. The method is as follows: concentration of substance in soil (mg/kg) =

[111] The Agricultural Production Systems Simulator (APSIM) https://www.apsim.info/Portals/0/APSoil/SoilMatters/Mod1/3_07.htm

(concentration (kg/ha) x 2)/BD (g/cc). Assuming a soil bulk density (BD) of 1.5 g/cc and test substance distributed in a 5cm layer of soil. For example, in the Röhlig study 2007 on *A. rhopalosiphi* using cyanamide as a test substance the NOEC (14-d) is 0.58 kg/ha. The concentration of cyanamide in soil equivalent to this is 0.8 mg/kg soil dw. $$$ concentration of cyanamide derived from PERLKA® as follows: NOEC PERLKA® = 82.0 mg/kg soil, NOEC cyanamide = 82 x 0.44 x 42.04/80.11 = 18.9 mg/kg soil dw (assuming average concentration of calcium cyanamide in PERLKA®=44%, molecular weight of calcium cyanamide = 80.11 g/mole & molecular weight of cyanamide = 42.04 g/mole).

A.7.2.1.1. Derivation of the PNECsoil for calcium cyanamide/ cyanamide by the Dossier Submitter

Table 36 show the ecotoxicity studies on soil-dwelling organisms and terrestrial plants that are available to the Dossier Submitter. It can be seen that the most sensitive organism in short-term studies is *A. cepa* with a NOEC of <0.02 mg/kg soil dw based upon shoot dry weight. This study result was taken from BPR 2016. The key study used by the Dossier Submitter for its risk assessment was the chronic 28 day study with F*. candida* by Moser and Scheffczyk, 2009 which resulted in a NOEC 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 can be used. The PNECsoil cyanamide used by the Dossier Submitter was 0.15 mg cyanamide/kg soil w/w.

The Moser and Scheffczyk, 2009 study was actually performed two times in 2009 – in the first run with three test concentrations of cyanamide and not to good laboratory practice (GLP) - and in the second run to GLP using eight concentrations of cyanamide (0.4 – 100 mg/kg soil dw). In the second test *F. candida* were introduced into test vessels containing standard soil according to OECD guideline 207 mixed with cyanamide at a temperature of 18 ± 22 ºC and constant moisture content. Five replicates per concentration and control (ten collembolans per replicate) were tested. Adult mortality and effects on reproduction were compared against the control after 28 days. From this study it was found that reproduction effects were observed at lower concentrations of cyanamide than mortality. NOECMortality was determined to be 40.00 mg cyanamide/kg soil (dw) and NOECReproduction was determined to be 0.40 mg cyanamide/kg soil (dw).

According to ECHA guidance (ECHA, 2008) an EC10[112] for a long-term test which is obtained using an appropriate statistical method (usually regression analysis) will be used preferentially [to derive a PNEC]. However, in this case only eight test concentrations were used instead of the 12 concentrations as proposed in ISO 11267:1999(E)[113] for an ECx approach. In this study, an EC50 value has been calculated, rather than an EC10 value.

During its assessment of cyanamide for use in plant protection products (PPP 2008-10) the German Competent Authority has derived an EC10 value from the results of the second Moser and Scheffczyk, 2009 study. It calculated the EC10 value to be 1.515 mg/kg soil dw (95% confidence limits: 0.229 and 3.555 mg/kg). The Dossier Submitter has used this EC10 value as the point of departure for its terrestrial risk assessment. An alternative approach was

[112] The concentration at which 10% effect was observed or derived statistically when compared to the control group.

[113] https://www.iso.org/standard/19245.html

considered by the Dossier Submitter, namely to use the NOECreproduction value of 0.40 mg/kg obtained directly from the Moser and Scheffczyk, 2009 study. However, it was decided to use the less stringent derived value.

Reference to Table 36 shows there are other studies with NOEC values lower than the EC10 value from the Moser and Scheffczyk, 2009 study *with F. candida.* For example, the chronic 56 day study with E.fetida by Scheffczyk, 2016b resulting in a NOEC of >/=1.05 mg/kg soil dw; and a chronic study by Röhlig, 2006 with A. bilineata resulting in a NOEC value of </= 0.3 kg/ha cyanamide application rate (calculated to be equivalent to 0.4 mg/kg soil dw).

The study with *E.fetida* by Scheffczyk, 2016b was reported by the Registrant (Alzchem, 2019a), but the Dossier Submitter has been unable to obtain this study. The Registrant states: the study was carried out according to OECD test guideline 222 (earthworm reproduction test) and *E.fetida* biomass, mortality and reproduction were not affected by the treatment of cyanamide. Therefore the NOEC for biomass, mortality and reproduction is >/= 1.05 mg/kg soil dw. From this report the Dossier Submitter understands 1.05 mg/kg soil was the highest concentration of test substance used in the study. Due to the absence of verifiable experimental data this study has not been used as the point of departure for the risk assessment.

The results of the chronic study by Röhlig, 2006 with *A. bilineata* were presented as an application rate. From this the Dossier Submitter calculated an equivalent concentration of cyanamide in soil assuming it is uniformly distributed in a soil depth from the surface (0 cm) to 5 cm and the bulk density of soil is 1.5 g/cc. However, because the NOEC was calculated, rather than directly based upon experimental evidence, the Dossier Submitter has taken a conservative approach and used this study result as supporting evidence, rather than the point of departure for the risk assessment for soil-dwelling organisms.

In a further chronic 56 day study (Scheffczyk, 2016a) a NOEC was derived based upon the reproduction of *E.fetida* using PERLKA® as the test substance. The Dossier Submitter and the Registrant have estimated the NOEC cyanamide by stoichiometric calculation to be 18.9 mg/kg soil dw.

A.7.2.1.2. The Registrant’s field study on the effects of calcium cyanamide on soil-dwelling organisms

During the preparation of this report, the Registrant initiated a seven year field study (Ebke, 2018) of the effects of PERLKA® application on soil-dwelling organisms known to be sensitive to cyanamide. PERLKA® has been applied to an agricultural plot of land and to serve as a control an adjacent plot has been treated with what is described as a ‘standard nitrogen fertiliser’ containing urease and a nitrification inhibitor (presumably to mimic the slow release function of PERLKA®). The preliminary results were provided to the Dossier Submitter in October 2018 and then an update was provided on 21 December 2018.

The study was carried out in Germany using an application rate of 400 kg/ha PERLKA® and the effects over time on collembolans e.g. *F. candida*, earthworms and nematodes. Sampling was carried out in May/June and October 2018. Sampling was done at pre-determined sampling points as follows: earthworms by hand; collembolans by soil cores and pitfall traps and nematodes by soil cores. The fields were sown with silage maize at the same time as PERLKA® and the standard fertiliser. The field with the standard ‘comparison fertiliser’ had an enhanced loading of urea, reportedly to be comparable with PERLKA® which was expected to have a higher yield of crops than the standard fertiliser.

For collembolans, the sampling results from soil cores are reported below and are illustrated in Figure 7, which compares the number collembolans between the PERLKA® and standard fertiliser-treated plots:

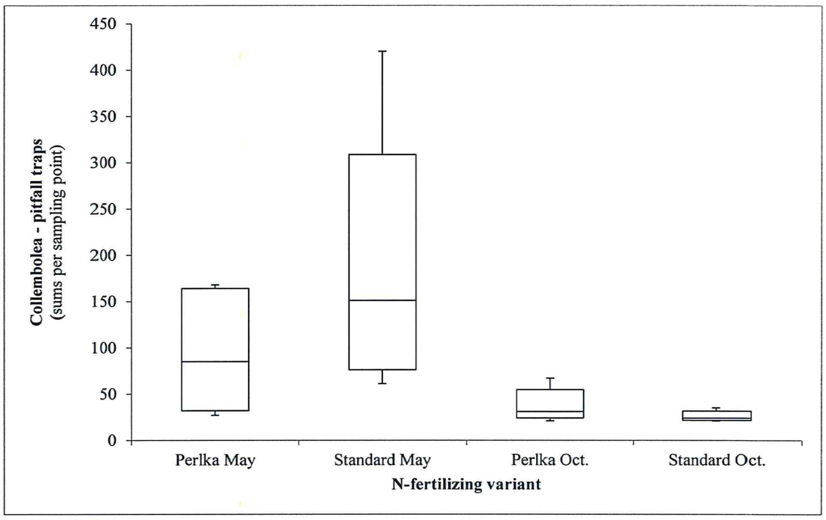
May 2018: PERLKA® 117 individuals; standard fertiliser 104 individuals

Oct 2018: PERLKA® 37 individuals; standard fertiliser 40 individuals.

The numbers of collembolans collected from the pitfall traps are as below and are illustrated in Figure 7

May 2018: PERLKA® 477 individuals (average per sampling point: 95 +/- 59 individuals); standard fertiliser 920 individuals (average per sampling point: 184 +/- 127 individuals)

Oct 2018: PERLKA® 188 individuals (average per sampling point: 38 +/- 16 individuals); standard fertiliser 130 individuals (average per sampling point: 26 +/- 5 individuals).



Source: the Registrant (Ebke, 2018).

Figure 7. Results for collembolan sampling from field study (May and October 2018)

The Registrant has carried out a t test statistical analysis on the significance of the difference in results between the PERLKA®-treated field compared to the field fertilised with the standard fertiliser field. For collembolans, earthworms and nematodes no significant statistical difference was reported between the PERLKA® and standard fertiliser plots by the Registrant.

The Dossier Submitter, together with assistance from EFSA has identified a number of methodological difficulties with this study which are described below.

Firstly, the control used for the study usually would be the absence of the test substance, in this case PERLKA®. Instead the Registrant has used a 'standard nitrogen fertiliser' that is poorly defined in the study results. As a result a comparison cannot be made between unfertilised soil and PERLKA®-treated soil. Additionally, a positive control is missing e.g. the use of a substance known to be toxic to species of interest e.g. carbendazim for earthworms.

A second difficulty is that the application rate of PERLKA® used in the field study was 400 kg/ha. This is lower than the maximum application of PERLKA® recommended by the Registrant of 500 kg/ha, meaning the full extent of the possible risk posed by PERLKA® in normal use has not been considered.

The soil concentration of PERLKA® was also not measured during the study, normal practice in such field studies. In addition, pre-treatment sampling was not carried out and this should have been done to assess the species composition and density prior to treatment. The absence of such pre-sampling makes it difficult to interpret the results of this study.

Considering the organisms studies themselves, collembolans are not presented at the species level which is a shortcoming in the study because some species may be more sensitive that others e.g. F. candida, the test organism in the Moser and Scheffczyk, 2009 study. Furthermore, the number of individuals found at the sampling/trapping points appear to be mixed. Focusing upon the results for collembolans, from the soil core samples the results appear to be approximately the same for the PERLKA® and standard fertilised fields. However, looking at the soil trap results there were considerably more collembolans in the standard field (May sampling) compared to the PERLKA®-treated field. At the October 2018 sampling, this situation is reversed although the difference is marginally less pronounced. There is clearly a significant degree of variability of the results which over time may possibly become less pronounced. The usual duration of such studies is one year.

To fully analyse these results further work is required on the behaviour and life-cycle of the test organisms studied. For example, it is known for example that *F. Candida* has a typical life span of 136 days at 21°C (Sneider and Butcher, 1973), hence will have probably only undergone one life cycle between the May and October 2018 sampling periods. Conversely *F. Candida* has a reproductive cycle of 28 days so this would be expected to occur during the sampling points. Also *F. Candida* is known to be very mobile in the top soil layers (Pommeresche and Løes, 2014) which may explain the apparent difference between the soil core and soil trap results.

In addition to the points above, EFSA (EFSA, 2018) has made a number of detailed comments which question the validity of the study:

- There has only been a short sampling period reported so far
- The second sampling in October 2018 was hampered by the dry summer and it is unclear whether irrigation was carried out. Usually irrigation is foreseen on field studies with earthworms[114]
- The time between the sampling points (May-Oct) is not sufficient to address potential effects on earthworms and possibly on other organisms.
- Only an interim study report is available and it was not conducted according to GLP.
- The quantity of calcium cyanamide applied as well as its variability were not verified.
- An herbicide treatment (S-metolachlor, Terbuthylazine and Sulcotrione) occurred on 7 May 2018, i.e. less than 1 month before the first sampling. Even though it was applied on the entire trial field (i.e. both the area treated with calcium cyanamide and the reference area treated with a conventional nitrogen fertiliser) in the same way, this complicates the interpretation of the results.

  The depth and volume of soil samples are not specified for earthworms and for collembolans.

Overall because of the methodological difficulties the Dossier Submitter considers the field study results (Ebke, 2018) are not a sufficiently reliable basis to derive a PNECsoil value.

The Registrant initiated a Field Study to Evaluate the Effects of granulated calcium cyanamide fertiliser (PERLKA®) on Collembola in Central Europe (Stegger, 2019). The aim of the study was to investigate the possible side-effects of calcium cyanamide (as formulated commercial product Perlka®) on populations of collembolans in the field. A randomised design with 5 treatments and 4 replicates each (20 plots in total) was used:

- Treatment 1: application rate of 200 kg Perlka® / ha
- Treatment 2: application rate of 400 kg Perlka® / ha
- Untreated control
- Fertiliser control with a conventional nitrogen fertiliser. The amount of nitrogen supplied

[114] ISO 11268-3:2014.

was equivalent to the nitrogen amount provided by treatment 2 (i.e. 400 kg Perlka®/ha)

- Reference item (positive control) with Chlorpyrifos. Chlorpyrifos is known as a substance harmful to collembolans. It was used to verify the sensitivity of the test system.

A distance of at least 3 m was kept between the adjacent plots. The quantity of substance applied as well as its variability were verified. The experiment lasted approximately one year with 2 application times with an interval of 6 months, in September 2018 and April 2019. The field used for the test was used as hay meadow without use of fertilisers and pesticides since 2010. Soil cores were used to sample collembolans living in the soil. Six cores were sampled per plot. Core samplers of 5 cm depth and 5 cm diameter were used. Pitfall traps were used to sample those living on the soil surface. Four funnel pitfall traps were used per plot, opened for 4 days on each sampling occasion. The abundance and activity of total collembolans and of the most abundant collembolan species were measured. Two interim reports were provided to the Dossier Submitter in June 2019 and in November 2019 while the final report was received in March 2020.

ECHA assessed the Field Study to evaluate the effects of granulated calcium cyanamide fertiliser (PERLKA®) on collembola in central Europe (Stegger, 2019) and observed that fertilisation by nitrogen seems to have an influence, generally beneficial, on the abundance of collembolans: the comparison of untreated control and fertiliser control samples revealed several statistically significant differences for both pitfall traps and soil cores samples. Therefore, the evaluation of the effects from the test item was done in comparison to the untreated control and to the fertiliser control separately.

ECHA underlined some uncertainties related to the Field Study on collembola (Stegger, 2019). Firstly, it evaluates the effect of calcium cyanamide on collembola only, no other terrestrial specie is evaluated at the same time. Field studies normally evaluate the effect of a substance on the whole population present in standard conditions in the soil. Additionally, it is a non guideline study. Finally, due to the likely endocrine disruption properties of cyanamide, the risk to soil might not be removed.

Overall, on the basis of the methodological difficulties described above for the field study (Ebke, 2019) and of the uncertainties on the field study on collembola (Stegger, 2019), the Dossier Submitter does not consider the field studies and results to be appropriate to be used as the point of departure to derive the PNECsoil values. The approach taken by the Registrant to derive the PNECsoil by comparing exposure data with the field study results is not supported under REACH. Concerning the relative stringency of the environmental protection goals under REACH and PPPs, the Dossier Submitter understands that the protection objective during a PPP assessment is to maintain populations of soil-dwelling organisms, which is not considered to be different from the protection objective under a REACH-based assessment. A sensitivity analysis has been carried out by the Dossier Submitter which supports this – see Annex A.10.4.

A.7.2.1.3. Terrestrial ecotoxicity studies (except soil-dwelling organisms) with PERLKA®/ calcium cyanamide/cyanamide

There are 15 studies available to the Dossier Submitter for non-soil-dwelling terrestrial organisms – 12 acute or short-term – 3 chronic. The source of the studies is mainly the Registrant's REACH registration dossier (Alzchem, 2019a), but also from BPR 2016, PPP 2008-10, SCHER 2016. This set of studies includes a study on rats which have been used in previous regulatory reviews as a surrogate for small terrestrial mammals (PPP 2008-10). These are summarised in Table 37.

Table 37. Terrestrial ecotoxicity studies (except soil-dwelling organisms)

Species/ material	Test substance	Test/duration.	NOEC/NOAEL mg/kg soil**	Reference*
T. pyri (Acari, leaf-dwelling predatory mite).	cyanamide	short term (7 d)	100 g/ha	Goβmann, 2000
C.carnea (Homoptera – leaf-dwelling lacewing - predator)	cyanamide	short term (18 d)	2.5 kg/ha	Röhlig, 2006c
T. pyri	cyanamide	short term (7 d)	1.02 Kg/ha	Röhlig, 2007a
A. rhopalosiphi (leaf-dwelling parasitic wasp)	cyanamide	acute (48 h)	313.0 g/ha	Moll, 2001
A. rhopalosiphi	cyanamide	acute (48 h)	LR50: <39.14 Kg/ha	Moll and Groer 2000a
C. carnea	cyanamide	chronic (21 d)	LR50: <39.14 Kg/ha	Moll and Groer 2000b
A. rhopalosiphi	cyanamide	Acute (48 h)	0.34 Kg/ha	Röhlig, 2007b

A. rhopalosiphi	cyanamide	short term (14 d)	>=0.58 Kg/ha Derived concentration***: 0.8 mg/kg soil dw	Röhlig, 2007b
A. mellifera (Hymenoptera – honeybee)	cyanamide	Acute (72 h)	LC50: <51.6 µg/bee	Kleiner, 1991
C. virginianus Virginia Quail	cyanamide	chronic (22 weeks)	13.3 mg/kg body weight (bw)/day	Johnson, 2001 PPP 2008-10
Camellia japonica Japanese Quail	calcium cyanamide/ PERLKA®	short term (14 d)	LD50 1665.0 mg/kg bw/day	Spanjers and Til, 1984
C. virginianus	cyanamide	short term (14d)	62 mg/kg bw based on behaviour	Robaidek, 1985
Anus platyrhynchos (Mallard)	cyanamide	short term (5 d)	NOEC: <312.5 mg/kg bw/d reduction of body weight gain	Lynn, 1991
C. virginianus	cyanamide	short term (5 d)	NOEL: 625 ppm	Lynn, 1991
Rat (Sherman Rat)	calcium cyanamide purum	chronic (17-50 weeks)	NOAEL: 1.3 mg/kg bw/d (oral in feed)	Benitz and Salamandra, 1960 Cavallo, 1960

(Source: Alzchem, 2019a, PPP 2008-10, BPR 2016)

Table notes: General note: *some studies included in Alzchem 2019a do not have a reference source and are not included in this table; ** unless stated otherwise.

A.7.2.1.4. Terrestrial ecotoxicity studies with DCD and urea

The studies available to the Dossier Submitter from the joint REACH registration dossier for DCD (RJRD DCD, 2015) are shown below in Table 38.

Table 38. Terrestrial ecotoxicity studies for DCD and urea

Species/ material	Test substance	Test/duration.	NOEC/NOAEL mg/kg soil**	Reference*
Soil	DCD	chronic 28 days OECD tests 216 & 217	2.5 based on: nitrate formation rate 316 based on: respiration rate	Foerster, B. (2014b)
Nitrosomonas sp. (soil)	DCD	chronic 28 days	NOEC: > 100 mg/l	Rodgers, G.A.; Ashworth, J. (1982)
Eisenia fetida (annelids)	DCD	short-term (14d)	1800 based on: body weight	Adema, D.M.M. (1985)
Avena sativa (Monocot.) Brassica rapa (Dicot.)	DCD	short-term (14d)	31.6 Avena sativa based on growth (shoot length)	Foerster, B. (2014a)
Oligochaeta and Lumbricidae (grassland worm)	Urea fertiliser	Chronic 1040 weeks	Urea fertiliser reduced worm numbers and biomass and lowered pH at <60 kg nitrogen /ha	Wei-Chun Ma., Brussaard, L. & de Ridder, J.A. 1990

(Source: RRJD DCD, 2015 and RRD urea, 2017).

Table notes: General note: *some studies included in Alzchem 2019a do not have a reference source and are not included in this table; ** unless stated otherwise.

The Dossier Submitter derived the PNECsoil DCD from the nitrate formation rate study by

Foerster, B. (2014b). In the joint REACH registration dossier for DCD (RJRD DCD, 2015) it is argued that DCD has been known as a nitrification inhibitor for decades and this is a desired property in agricultural applications and for this reason it is used as an additive to fertilisers. Hence the results from nitrification study are not considered appropriate to derive a PNECsoil. Instead, the PNECsoil is derived from the respiration rate (carbon transformation) study by Foerster, B. (2014b). The Registrant for calcium cyanamide also argues the formation of DCD from PERLKA® provides a positive delayed nitrogen effect.

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 DS acknowledges potential difficulties in risk management of substances that have active function under REACH.

Some consultation comments #2750, 2759, 2773, 2776, 2919 criticised the Dossier Submitter approach in identifying a risk for soil microorganisms based on the PNECsoil for DCD derived from the nitrate formation rate study by Foerster, B. 2014b and concluded that, according to this logic, ECHA would have to ban all nitrification inhibitors. DCD is known to be used as a nitrification inhibitor. The Dossier Submitter underlines that when DCD is used in the production of industrial slow-release fertilizers, it is mainly used in relatively small amounts, and thus in the case of such alternatives the amount of DCD in the final product is limited.

A.7.3. Atmospheric compartment

No further information to add.

A.7.4. Microbiological activity in sewage treatment systems

Not relevant for this report.

A.7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

No further information to add.

A.8. PBT and vPvB assessment

No further information to add.

A.9. Exposure assessment

A.9.1. General discussion on releases and exposure

In the absence of significant monitoring data, the Dossier Submitter, the Registrant and indeed previous regulatory reviews have relied upon exposure modelling to predict the concentrations of calcium cyanamide and its transformation products that may be present in the environment after its use as a fertiliser or plant protection product (PPP). The absence of monitoring data is perhaps not surprising given the short-half-life of calcium cyanamide and relatively short half-lives of its transformation substances. It is likely assessing the possible environmental risk of calcium cyanamide may have been a low priority in the past due to its possible health risks and the focus on the environmental risk of plant protection products.

A.9.1.1. Summary of the existing legal requirements

See report.

A.9.1.2. Summary of the effectiveness of the implemented operational conditions and risk management measures

No further information to add.

A.9.2. Manufacturing

Outside of the scope of this report.

A.9.3. Use 1: Use of calcium cyanamide as a fertiliser

A.9.3.1. General information

No further information to add.

A.9.3.2. Exposure estimation

A.9.3.2.1. Workers exposure

No further information to add.

A.9.3.2.2. Consumer exposure

No further information to add.

A.9.3.2.3. Indirect exposure of humans via the environment

The Dossier Submitter has derived limit values for cyanamide and DCD in drinking water and thereby considered the potential risk to human health by indirect exposure. The methodology for this is that established in the WHO Guidelines for Drinking Water Quality[115]. 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. It is therefore applicable to the general population. The derivation is detailed below.

$$\text{Guideline value (GV)} = \frac{\text{TDI x bw x P}}{\text{C}}$$

TDI = tolerable daily intake

bw = bodyweight of an average person (kg)

P = fraction of TDI allocated to drinking water (%)

C = daily drinking water consumption litres/day

For cyanamide:

Assuming TDI=DNEL (oral route)[116]= 0.017 mg/kg bw/d; assuming fraction of TDI allocated to drinking water =100% i.e. drinking water is the only source of cyanamide.

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[115] WHO Guidelines for drinking water quality, 4th edition (2017) https://www.who.int/water_sanitation_health/publications/drinking-water-quality-guidelines-4-including-1st-addendum/en/.

[116] See ECHA, 2018.

» $GV_{general\ population} = \frac{0.017\ mg/kg\ bw/d \times 60 \times 1}{2} = 0.51\ mg/l = 510\ \mu g/l$

For DCD:

Assuming TDI=DNEL (oral route)[117]= 6.5 mg/kg bw/d; assuming fraction of TDI allocated to drinking water =100% i.e. drinking water is the only source of cyanamide.

» $GV_{general\ population} = \frac{6.5\ mg/kg\ bw/d \times 60 \times 1}{2} = 195.0\ mg/l = 19\ 500\ \mu g/L$

A.9.3.2.4. Environmental exposureby the Dossier Submitter

A.9.3.2.5. Surface water and sediment modelling by the Dossier Submitter

EUSES modelling is commonly used by REACH Registrants to model environmental exposure. However it is not yet considered appropriate for predicting the environmental concentrations following direct release of a substance which is intentionally added to the environment, such as calcium cyanamide when used as a fertiliser. Instead, FOCUS modelling has been used by both the Registrant and the Dossier Submitter to derive predicted environmental concentrations (PECs) of calcium cyanamide and its transformation substances in surface water and sediment. FOCUS modelling is the recommended modelling in the EU to assess whether active substances in PPPs, directly applied to crops, meet the requirements of the PPP legislation. Because FOCUS modelling is for intentionally added substances to the environment, this was the preferred choice of model for the Dossier Submitter, the Registrant and in previous regulatory reviews of calcium cyanamide/cyanamide as a fertiliser and a PPP.

FOCUS DG SANTE stands for FOrum for the Co-ordination of pesticide fate models and their USe and was an initiative of the European Commission to harmonise the calculation of predicted environmental concentrations of active substances of PPPs in the framework of the EU Directive 91/414/EEC, which meanwhile has been repealed and replaced by the new Regulation (EU) No 1107/2009. The work of FOCUS was based on a close co-operation between scientists of regulatory agencies, academia and industry, under the auspices of the Commission's DG SANTE, and subject to the opinion of EFSA, or in the case of the surface water guidance and tools the Commissions Scientific Committee on plants.

The work started in 1993 via the FOCUS Leaching Modelling Workgroup and the installation of the FOCUS Steering Committee. Subsequently several other working groups were installed covering all environmental compartments. Today, it can be observed that all important fate issues have been duly covered by high quality reports and guidance documents which provide the necessary assessment tools, not only for the evaluators and the manufacturers, but also for the designated competent authorities for product authorisations. This vast work was concluded in 2014, with the finalisation of the Groundwater II Report. Amendments to these guidance documents may still be necessary, while especially the underpinning mathematical models need systematically update and improvement, as to keep pace with scientific progress. Further information on the background and operation of FOCUS models is provided on the Commission, JRC's website[118]. For the purposes of understanding the exposure modelling

[117] Based upon long term systemic effects found in oral repeat dose toxicity studies (RJRD DCD, 2015).

[118] https://esdac.jrc.ec.europa.eu/projects/focus-dg-sante.

carried out by the Dossier Submitter, key aspects are explained below.

The FOCUS surface water (FOCUSsw) scenarios are used to assess the potential contamination of active substances and metabolites of plant protection products to surface water. They form a part of the review process for active substances in the EU. The FOCUS concentration estimation methodology was developed as a tiered approach with four levels of assessment. The Step 1 has been defined as a relatively simple calculation based on a maximal loading and a fixed scenario, while the Step 2 allowed multiple applications and regional variation across Europe.

Step 3 focuses on more detailed modelling taking into account the realistic[119] 'worst case' amounts entering surface water via relevant routes (run-off, spray drift, drainage, atmospheric deposition). Step 4 allows a detailed site-specific approach in case all other Steps fail. Step 4 also allows a simulation of the effect of introducing risk management methods (RMMs) such as vegetated buffer strips and no spray zones (for PPPs) to the PEC surface water values predicted at step 3. FOCUSsw steps 3 and 4 surface water modelling was carried out by the Dossier Submitter.

The FOCUSsw scenarios are a set of ten standard combinations of weather, soil and cropping data and water bodies, which collectively represent agriculture in the EU for the purposes of a Step 3 EU-level assessment of concentration estimation. The scenarios and their derivation are described in detail in a published report[120] but in summary are: drainage of the test substance through soil to nearby surface water (D1 – D6) and four surface runoff (R1 – R4) scenarios. The ten scenarios are further differentiated into water body types: e.g. lower case 's' which denotes stream variant, 'p' pond variant and 'd' denotes ditch variant. The water bodies are assumed to have fixed dimensions, fixed organic and sediment components and fixed catchment areas.

The exposure of sediment in the FOCUS modelling is based upon a fixed sediment depth (5 cm). A relatively vulnerable sediment layer is used with a low organic carbon content for small surface waters in agricultural areas.

Some specific notes regarding the interpretation of FOCUSsw results are given below.

The scenarios have been implemented as sets of input files for three simulation models estimating the influence of drainage, run-off and fate on the final concentration estimations. The model MACRO is used to estimate the drainage (D scenarios) as a sub-surface loading to surface waters, the model PRZM accounts for run-off (R scenarios) as a superficial loading to surface water and finally the model TOXSWA, which takes into account the dissipation processes in surface waters itself. The results of the MACRO-model or the PRZM-model are used as input into the model TOXSWA in addition to the drift input. The resulting concentrations from TOXSWA are used in the risk assessment process and provide both predicted surface water and sediment concentrations of test substance for the ten FOCUSsw scenarios. There is a limitation with MACRO in that secondary transformation substances such as DCD cannot be modelled, meaning D scenarios were not able to be modelled.

Pesticide and fertiliser losses in both surface runoff and subsurface drainage flow are 'event-driven' and therefore very strongly dependent on the weather conditions immediately following

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[119] In REACH, the *reasonable worst case* is used.

[120] https://esdac.jrc.ec.europa.eu/public_path/projects_data/focus/sw/docs/Generic%20FOCUS_SWS_vc1.4.pdf

application, in particular the rainfall pattern. The FOCUS model has been designed to help minimise the influence of the user choice of application date on the results of FOCUS surface water scenario calculations, whilst at the same time as retaining some degree of flexibility in simulated application timings to allow realistic use patterns. A Pesticide Application Timing calculator (PAT) was developed to achieve this dual purpose. The PAT calculator eliminates a significant number of potential application dates due to the requirement that at least 10 mm of precipitation be received within ten days following application. This criteria in the PAT calculator results in selection of application dates which are the 60th to 70th percentile wettest days for non-irrigated crops and the 50th to 60th percentile wettest days for irrigated crops (based on analysis of maize met files). The slightly lower percentile values for irrigated crops are due to the additional number of wet days created by irrigation events for these crops.

The results obtained by the Registrant and the Dossier Submitter indicated surface water adjacent to fields fertiliser with calcium cyanamide were at most risk from cyanamide from run off. However, grassland and Winter Oilseed Rape fertilised appear to be at risk from drainage through soil, in particular as simulated in the D2 scenario. D2 is a scenario considered to simulate rather conservative, instead of representative conditions. The soil conditions are classified by FOCUS as ‘extreme worst case’ and the weather conditions are classified as ‘worst case’. The slope is rather moderate but it is an strongly drained (mole drains, closely spaced in ca. 0.5m depth) clay soil over an impermeable substrate, waterlogged for part of the year, so that drainage is an especially important route within the water balance. In addition, the abundance of this soil is limited to the southern UK and small areas in France, although this soil type is found in other parts of the EU.

The FOCUSsw Step 4 modelling carried out by the Dossier Submitter in most cases does not reduce the PECsw values to below the PNECfreshwater values. However, the effects of the vegetated buffer strips appears to be approximately linear, with increasing diameter. The Dossier Submitter has therefore explored with an expert in this area whether the effects of the width of the buffer strips on the PECsw of cyanamide could be extrapolated to wider diameters from the results obtained already? The expert has confirmed in the evaluation of plant protection actives interpolation of the run-off mitigation factors has been criticised during review procedures in recent years. The argument is that the experiments are based on distances of 10 and 20m and interpolation even to 5 or 15 m may have uncertainties. EFSA has also confirmed (EFSA, 2018) that it is not possible to extrapolate to wider buffer strip widths from the results obtained with 20 m buffer strips.

From the information provided by the Registrant it is know the principal markets for PERLKA® are Germany, Italy, Belgium and France. The expert was asked whether it is possible to link some of the ten FOCUS scenarios to the geoclimatic conditions found in these specific EU Member States or are the scenarios representative of different geoclimatic conditions across the whole EU?

The expert confirmed: the FOCUS scenarios were intended to provide a representative range of agricultural, geographic and meteorological situations of the EU early in the last decade (before east-extension). However, in the PPP context, it is indeed discussed which scenarios should be considered as relevant for national/zonal evaluations. Among the countries specified, France covers the broadest range and considers all FOCUS SW scenarios as relevant except D1. Germany has its own national models aside from FOCUS. Belgium considers D3, D4 and R1 as relevant, Italy focuses on D4, D6, R3 and R4. This suggests France would be susceptible to D & R scenarios failing the surface water modelling, whilst Italy would only be susceptible in a more limited number of failing scenarios. Sweden has also adapted the results of FOCUS [by the Dossier Submitter] modelling for PPP actives to be more representative of the geoclimatic and soil conditions experienced there. Specifically, Sweden (KEMI 2016) has excluded surface run off as a route of exposure of PPPs to surface water on the grounds that run off only occurs in a minor fraction of arable land particularly vulnerable to erosion and then driven by short and heavy storm events. Furthermore, pesticide transport in surface runoff during snowmelt is considered of minor importance. There may well therefore be arguments to vary the interpretation of exposure modelling results for particular local conditions in the EU, but since the restriction proposed must protect the entire EU all the geoclimatic conditions modelled by FOCUSsw are considered relevant by the Dossier Submitter.

The Dossier Submitter has explored the reliability of the results it has obtained from the FOCUS modelling with the expert in this area. In particular whether two known aspects which may cause reliability issues for FOCUS would apply to the modelling the Dossier Submitter has carried out: 1) the particularly high application rates compared to PPPs; and 2) the ionic nature of calcium cyanamide.

The expert has confirmed the following. (1) The FOCUS leaching and surface water models were evaluated by the FOCUS working group in the context of PPP actives with typical use rates of up to a few kg/ha. An aspect with respect to the suitability of the simulations for the use of PERLKA® is the flux of water in the soil scenario compared to the abundance of the compounds assessed. For the fertiliser product PERLKA®, which is applied at rates of up to 500 kg/ha, it is assumed that the granular formulation remains immobile at the soil surface/the defined soil depth while constantly releasing its very mobile component Cyanamide at an high rate corresponding to the DT50 of 1.45 days (at 12 °C). The calculations conducted for calcium cyanamide by the Dossier Submitter show that the use rate of up to several hundred kilogrammes per hectare leads to temporal numerical conditions, under which only a part of the amount of substance present in the system can be transported with the water flux at a given time step. However, this is a realistic condition for soil scenarios which do not contain an excess of water (e.g. due to significant rainfalls at the time around application, which is excluded by the models to reflect good agricultural practice for PPPs) and with respect to the formulation type and use rate. The calculations can therefore be considered appropriate for substances with the use rate as considered for PERLKA®. In this context, it can be noted that FOCUS surface model calculations are also used for other product types like soil fumigants, which are applied at similar rates. The evaluator has also conducted additional calculations starting from use rates as common for plant protection actives and confirmed that the results were qualitatively consistent among the different scenarios.

(2) After release from the formulation, calcium cyanamide as well as cyanamide may be solved at least partly in an ionic form. For the soluble ionic fraction, a higher mobility in soil can be assumed. While the FOCUS surface water models do not consider the (pH-dependent) behaviour of dissociated substances, the FOCUS workgroup made respective considerations in the context of the leaching model PEARL. The assumption is that the ionic form of a compound could exhibit adsorption by a factor of 1000 lower compared to the non-ionic form. However, calcium cyanamide is converted rapidly into cyanamide when in contact with (soil) moisture and will therefore be very transient once resolved from the granules. Both compounds can be considered to be very mobile in their dissolved form, regardless if dissociated or not. The tests leading to the EU agreed adsorption endpoint for cyanamide as peer reviewed according to requirements for plant protection actives are expected to cover also the dissociated form of this compound. In addition, a pH-dependent behaviour was not detected for Cyanamide. All in all, given the high solubility and the low persistence of both compounds in addition to their high mobility in soil make it very unlikely that dissociation has a significant impact on the reliability of the simulations.

Some consultation comments (#2763, 2769, 2770) were highlighting that FOCUSsw scenarios may not necessarily represent realistic worst-case situations for the different member states of the EU and the suitability of these scenarios for risk assessments for the national PPP authorisation procedures is not known. Consequently, for Germany, statistically based run-off and drainage scenarios for PPPs were developed (Bach et al., 2017). The same comments referred to the use of the Exposit model which is required for the national authorisation of PPPs in Germany. The Dossier Submitter underlines that FOCUS modelling has been used by both the Registrant and the Dossier Submitter to derive predicted environmental concentrations (PEC) of calcium cyanamide and its transformation substances in surface water and sediment. In the modelling tier 3 and 4 of FOCUS modelling are based on reasonable and realistic worst-case scenarios, which collectively represent agriculture in the EU; different ways of fertiliser application have been taken account and modelled; different applications methods and rates depending on the crops were modelled. FOCUS modelling is the recommended modelling approach in the EU to assess the potential contamination of active substances and metabolites of plant protection products to surface water and sediment. For the purposes of an EU-level assessment of calcium cyanamide used as a fertilizer in Europe the Dossier Submitter could not use a country specific model for exposure assessment but had to chose a model having standard combinations of weather, soil and cropping data and water bodies, which collectively represent agriculture in the EU. Finally, as the most of the $CaCN_2$ fertiliser use is concentrated in small number of member states in the central Europe, the DS considers that the Focus model can give quite a good representation of the real world fertiliser use in this case.

A.9.3.2.6. Groundwater modelling by the Dossier Submitter

The Dossier Submitter has carried out first level (Tier 1) simulations of the concentrations of cyanamide and DCD that could leach to groundwater after the use of calcium cyanamide as a fertiliser. To do this a specialised form of FOCUS modelling was carried out for groundwater kwon as FOCUS PEARL. FOCUS groundwater modelling is based upon a set of nine standard scenarios: combinations of weather, soil and cropping data which collectively represent agriculture in the EU for the purposes of a Tier 1 EU-level assessment of leaching potential. The scenarios with names such as Hamburg, Chateaudun and their derivation are described in detail in a published report[121]. The scenarios have been implemented as sets of input files for four simulation models - MACRO, PEARL, PELMO & PRZM.

In its groundwater modelling the Dossier Submitter used the PEARL simulation model which can simulate leaching for all nine scenarios. PEARL is an acronym of Pesticide Emission Assessment at Regional and Local scales. It is a one-dimensional numerical model of pesticide behaviour in the soil-plant system which has been developed by two Dutch institutes (Alterra and RIVM) in close co-operation. Further details of the PEARL model are provided by the Commission/JRC[122].

A.9.3.2.7. Soil modelling by the Dossier Submitter

The modelling of the soil concentrations following application of PERLKA® have been carried out based on the approach outlined in Boesten et al. (1997). The approach given in Boesten et al. (1997) is the standard approach used to assess the soil concentrations of PPPs after their application to soil/crops.

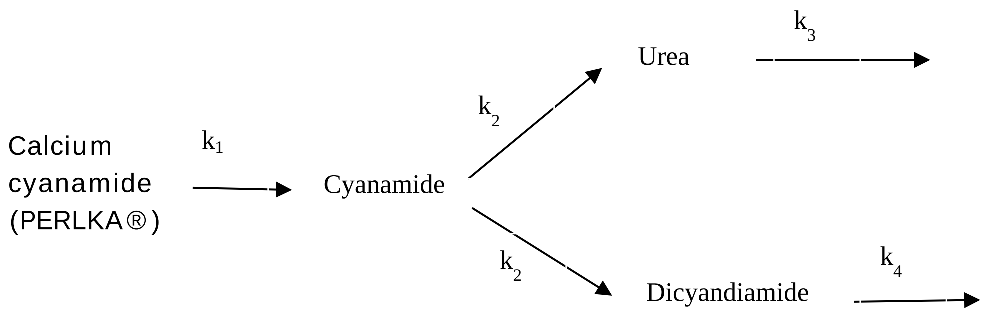
The Boesten approach assumes first order degradation kinetics following the application of the

[121] https://esdac.jrc.ec.europa.eu/public_path/projects_data/focus/gw/NewDocs/GenericGuidance2_2.pdf

[122] https://esdac.jrc.ec.europa.eu/projects/pearl

parent substance to soil, and concentrations in soil are averaged over certain time periods following application. In order to model the conversion of calcium cyanamide (PERLKA®) into cyanamide and then the subsequent degradation into urea and cyanoguanidine the model in Boesten et al. (1997) has been extended to incorporate formation of the subsequent degradation products assuming first order kinetics as outlined below.

Reaction scheme



It is important to note that the above scheme may be an oversimplification of the actual situation, particularly that the same rate constant applies for the formation of both urea and cyanoguanidine. Indeed, it is possible that the formation of cyanoguanidine does not follow first order kinetics (Dixon, 2017). By necessity, the formation of urea and, in particular, cyanoguanidine, has been treated in a very simplistic way in the model, which will lead to uncertainties in the concentrations predicted for these degradation products. However, it is noteworthy the Registrant also considers the breakdown of cyanamide to be based on first order kinetics (Güthner, 2018).

Some consultation comments (e.g. #2755, 2769, 2777, 2786) were underlying that the Dossier Submitter described the decomposition product cyanoguanidine under the assumption that the formation of cyanoguanidine from cyanamide is a first order reaction but such comments noted that dimerisation reactions are of second order. However, in relation to cyanamide degradation in soil both under aerobic and anaerobic conditions, the DS concludes that it can be assumed that first order degradation kinetics are sufficient for the purposes of modelling taking into account all other uncertainties[123]. This can be expressed kinetically in terms of the rate of formation and degradation[124] of each substance as follows.

$$\frac{d[Calcium\ cyanamide]}{dt} = -k_1 \times [Calcium\ cyanamide]$$

$$\frac{d[Cyanamide]}{dt} = k_1 \times a \times [Calcium\ cyanamide] - k_2 \times [Cynamide]$$

[123] The significance of these kinetics are also discussed in more detail by RAC both in the RCOM and in the RAC opinion.

[124] The rate of change in concentration of calcium cyanamide in soil.

$$\frac{d[Urea]}{dt} = k_2 \times b \times [Cyanamide] - k_3 \times [Urea]$$

$$\frac{d[Dicyandiamide]}{dt} = k_2 \times c \times [Cyanamide] - k_4 \times [Dicyanamide]$$

where [Calcium cyanamide] = concentration of calcium cyanamide in soil.

[Cyanamide] = concentration of cyanamide in soil.

[Urea] = concentration of urea in soil.

[Cyanoguanidine] = concentration of cyanoguanidine in soil.

k_1 = first order rate constant for degradation of calcium cyanamide to cyanamide.

k_2 = first order rate constant for degradation of cyanamide in soil. This is assumed to be equal to the rate constant for formation of both urea and cyanoguanidine from cyanamide.

k_3 = first order rate constant for degradation of urea in soil.

k_4 = first order rate constant for degradation of cyanoguanidine in soil.

a = molar fraction of calcium cyanamide converted to cyanamide. This is assumed to be 1.

b = molar fraction of cyanamide converted to urea. This is uncertain - see text.

c = molar fraction of cyanamide converted to cyanoguanidine. This is uncertain – see text.

In Boesten et al. (1997) the concentration of the parent substance (in this case calcium cyanamide) at different times is calculated by means of the integrated form of the above rate equation. However, for the subsequent steps, integration of the rate equations is difficult and so an approximation approach has been used whereby the change in concentration over small time steps is calculated directly from the rate equations. Although an approximation, such approaches give acceptable results provided the time step chosen is small compared with the half-lives for the various kinetic processes. This has been implemented in a spread sheet using a time step of 0.1 days. In order to verify that the approach taken is consistent with that given in Boesten et al. (1997) the concentrations of calcium cyanamide in soil following a single application have been estimated using both the spread sheet developed for this modelling work and the approach given in Boesten et al. (1997); the results are shown in Table 39.

The calculations assumed an application of 220 kg ha^{-1} as calcium cyanamide [500 kg ha^{-1} as PERLKA®], a degradation rate constant of 0.478 d^{-1} (a half-life of 1.45 days at 12°C) and a bulk density of dry soil[125] of 1500 kg m^{-3}. Similarly, the averaging times for the predicted concentrations follow the recommendations in Boesten et al. (1997) for pesticides (1, 2, 4, 7, 28, 50 and 100 days after application).

The application rates to soil are given in kg ha^{-1} (i.e. a mass per unit area). In order to estimate a concentration in mg kg^{-1} soil it is necessary to assume a depth of soil in which the substance is applied (known as the mixing depth; used to convert the area over which the substance is applied into the equivalent soil mass). For surface application Boesten et al.

[125] Value recommended in Boesten et al. (1997). ECHA REACH Guidance R.16 (ECHA, 2016) uses a bulk density of wet soil of 1,700 kg m^{-3}; this is also equivalent to a bulk density of dry soil of 1,500 kg m^{-3}.

(1997) recommends a default mixing depth of 5 cm and this has been assumed in the modelling carried out by the Dossier Submitter. Thus the predicted concentrations effectively represent the average concentration in the top 5 cm depth of the soil. The input parameters used are summarised in Appendix 1.

Table 39. Comparison on the results from the spread sheet model developed for this study and Boesten et al. (1997) for calcium cyanamide developed by the Dossier Submitter.

Time following application (averaging time)	Time weighted average Predicted concentration in soil (mg kg^{-1} dry wt.)	
	Boesten et al. (1997)	Spreadsheet model developed for this study
1	233.2	232.4
2	188.9	187.7
4	130.7	129.6
7	84.6	83.8
14	43.8	43.4
21	29.2	29.1
28	21.9	21.8
42	14.6	14.6
50	12.3	12.2

(Source: Dossier Submitter)

The Boesten et al. (1997) model takes into account loss of the substances through degradation only. However, loss from soil via leaching is also likely to be significant, particularly for cyanamide, urea and cyanoguanidine, and loss from soil via volatilisation may also occur. In order to take this into account, first order rate constants for leaching and volatilisation have also been included into the model. These have been estimated using the EUSES program (version 2.1.2) which implements the estimation methods given in the ECHA REACH Guidance R.16. These rate constants are dependent upon the soil depth, and values have been estimated for 5 cm, 7.5 cm and 15 cm.

For each exposure scenario, the model has been run both without including leaching and volatilisation (i.e. degradation only) and including leaching and volatilisation along with degradation. The estimates including leaching and volatilisation are considered to be more relevant for a risk assessment in the REACH context.

It is important to note that the predicted soil concentration is sensitive to a number of the assumptions made in the model, notably the averaging time, application rate, mixing depth and also assumptions made in the substance properties, notably the degradation/removal rate constants and molar conversion fractions. The Dossier Submitter has therefore carefully considered the molar conversion fraction for cyanamide to both urea and DCD as this determines the relative amounts of these two degradation products formed.

For the FOCUS surface water modelling, PPP 2008-10 assumed a cyanamide to urea conversion amount of 13.4%. Taking into account the molecular weight difference between cyanamide (molecular weight 42.04 g mol^{-1}) and urea (molecular weight 60.06 g mol^{-1}) this is equivalent to a fractional molar conversion amount of 0.094. For DCD, the formation for cyanamide in soil is uncertain but the key soil degradation study reported in section 3.2.7.2 by Dixon (2017) indicates that the amount of DCD formed from cyanamide in moist soil is around 6-11% and assuming that the maximum amount of DCD formed is around 10% of the mass of cyanamide the molar conversion fraction from cyanamide can be estimated as around 0.05, assuming a molecular weight of 42.04 for cyanamide and 84.08 for DCD. For urea assuming that urea is the only other degradation product from cyanamide, the molar conversion to urea would be 1-0.0425 = 0.957. In order to take into account of the uncertainty in the molar conversion fraction for urea and DCD both a low conversion to urea (molar conversion of 0.094 for urea and 0.05 for DCD) and a high conversion to urea (molar conversion of 0.957 for urea and 0.0425 for DCD) are considered in the calculations.

The application rates and soil depths assumed by the Dossier Submitter in its soil modelling are summarised in Table 40Table 40. The simulations have been carried out assuming both a low molar conversion to urea and a high molar conversion to urea. Based on Dixon (2017), and also the reaction scheme provided by the Registrant in the registration dossier, a high assumed conversion to urea would appear to be more realistic[126].

Table 40. Application rates and soil depths modelled

Application Scenario	Calcium cyanamide (PERLKA®) application rate	Assumed mixing depth[127]	Comment
Surface application - high	220 kg ha^{-1} as calcium cyanamide [500 kg ha^{-1} as PERLKA®]	5 cm	Assumes PERLKA® contains 44% w/w calcium cyanamide. A mixing depth of 5 cm is recommended in Boesten et al. (1997) for surface application.

[126] Although the available experimental data given in PPP 2008-10 suggest a lower conversion to urea, such studies effectively give a snap-shot of the amount of urea present at a given sampling time; this amount is a result of its rate of formation and rate of degradation.

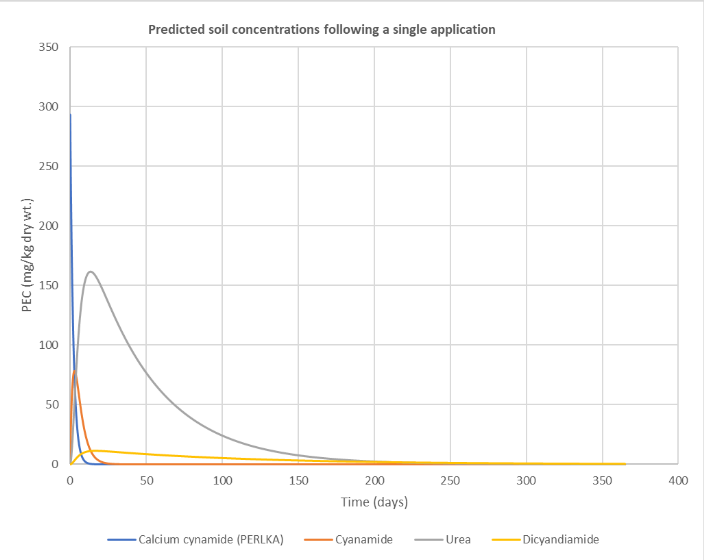
[127] The mixing depth is used to convert the area over which the substance is applied into the equivalent soil mass. For surface application Boesten et al. (1997) recommends a default mixing depth of 5 cm and this has been assumed for surface application. For applications at a given depth, the mixing depth has been assumed to be the depth to which the substance is applied. The predicted concentrations effectively represent the average concentration in the soil from the surface down to the given mixing depth.

Surface application - mid	132 kg ha^{-1} as calcium cyanamide [300 kg ha^{-1} as PERLKA®]	5 cm	Assumes PERLKA® contains 44% w/w calcium cyanamide. A mixing depth of 5 cm is recommended in Boesten et al. (1997) for surface application.
Surface application - low	66 kg ha^{-1} as calcium cyanamide [150 kg ha^{-1} as PERLKA®]	5 cm	Assumes PERLKA® contains 44% w/w calcium cyanamide. A mixing depth of 5 cm is recommended in Boesten et al. (1997) for surface application.
Application at 7.5 cm depth – high	220 kg ha^{-1} as calcium cyanamide [500 kg ha^{-1} as PERLKA®]	7.5 cm	Assumes PERLKA® contains 44% w/w calcium cyanamide. Assumes mixing to a depth of 7.5 cm.
Application at 7.5 cm depth – mid	132 kg ha^{-1} as calcium cyanamide [300 kg/ha as PERLKA®]	7.5 cm	Assumes PERLKA® contains 44% w/w calcium cyanamide. Assumes mixing to a depth of 7.5 cm.
Application at 7.5 cm depth – low	66 kg ha^{-1} as calcium cyanamide [150 kg ha^{-1} as PERLKA®]	7.5 cm	Assumes PERLKA® contains 44% w/w calcium cyanamide. Assumes mixing to a depth of 7.5 cm.
Application at 15 cm depth – high	220 kg ha^{-1} as calcium cyanamide [500 kg ha^{-1} as PERLKA®]	15 cm	Assumes PERLKA® contains 44% w/w calcium cyanamide. Assumes mixing to a depth of 15 cm.
Application at 15 cm depth – mid	132 kg ha^{-1} as calcium cyanamide [300 kg ha^{-1} as PERLKA®]	15 cm	Assumes PERLKA® contains 44% w/w calcium cyanamide. Assumes mixing to a depth of 15 cm.

Application at 15 cm depth - low	66 kg ha^{-1} as calcium cyanamide [150 kg ha^{-1} as PERLKA®]	15 cm	Assumes PERLKA® contains 44% w/w calcium cyanamide. Assumes mixing to a depth of 15 cm.

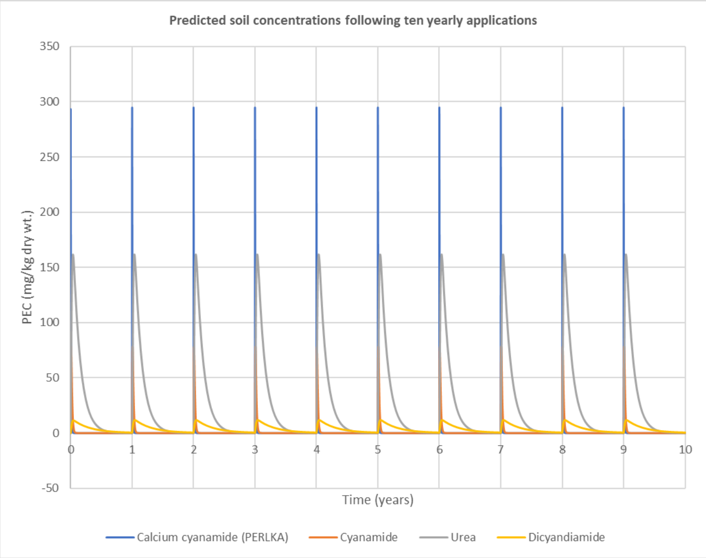
(Source: Dossier Submitter)

The averaging times correspond to the averaging times given in Boesten et al. (1987). Calculations are given following 10 once-yearly applications; this corresponds to the approach normally taken within REACH. As can be seen from Figure 8 and Figure 9 there is little year-on-year build-up of parent or any of the degradation products predicted by the model (i.e. the single application concentrations (Figure 8) are similar to the concentrations obtained following 10 once-yearly applications (Figure 9).



(Source: Dossier Submitter)

Figure 8. Variation in concentration with time following a single application (for the scenario surface application – high; using the higher conversion to urea and considering loss only by degradation)



(Source: Dossier Submitter)

Figure 9. Variation in concentration with time following 10 once-yearly applications (for the scenario surface application – high; using the higher conversion to urea and considering loss only by degradation).

In terms of averaging times, the normal approach in REACH is to take the 30-day average value following the last application. Therefore the 28-day average value calculated in Boesten et al. (1987) corresponds closest to this value and is the soil concentration used for the risk assessment. From the above the Dossier Submitter chose a high molar conversion to urea and incorporating moderate loss from leaching and volatilisation alongside degradation.

A.9.4. Other sources

No further information to add.

A.9.5. Overall environmental exposure assessment

No further information to add.

A.9.6. Combined human exposure assessment[1]

Not relevant.

A.10. Risk characterisation

A.10.1. Manufacturing

No relevant for this report.

A.10.2. Environment

No further information except the two sections below.

A.10.3. Estimation of the application rate of calcium cyanamide needed to ensure no adverse environmental effects occur in soil

EC10 cyanamide in soil = 1.515 mg/kg soil (see section 3.2.9.5.1)

In order to convert the EC10soil (i.e. lowest concentration allowed before an adverse effect occurs) to an application rate the method described by The Australian Agricultural Production

Systems Simulator (APSIM)[128] has been used.

The method is as follows:

Maximum allowable application rate of cyanamide (kg/ha) =

(maximum allowable concentration of cyanamide in soil (mg/kg) x bulk density of soil (g/cc)) /2

= (1.515 x 1.5)/2 = 1.14 kg/ha cyanamide

By stoichiometry this is equivalent to:

»1.14 x RMM $CaCN_2$ / RMM CN_2 = (1.14 x 80.11)/42.04 = 2.2 kg/ha calcium cyanamide

» (1.14 x RMM $CaCN_2$) / (RMM CN_2 x % $CaCN_2$ in PERLKA®) = (1.14 x 80.11)/(42.04 x 0.44) = 4.9 kg/ha PERLKA®

Assuming a soil bulk density (BD) of 1.5 g/cc and cyanamide is distributed in a 5cm layer of soil, the relative molecular mass (RMM) of $CaCN_2$ is 80.11 g/mol and the RMM of CN_2 is 42.04 g/mol.

However because an assessment factor (AF) is normally built into the allowable dose to provide a safety margin and in the PNECsoil derivation the AF was 10 the maximum application rate on this basis is 0.49 kg/ha PERLKA® or 0.2 kg/ha calcium cyanamide.

For surface water, a direct comparison of the NOEC cyanamide in surface water and the application rate has not been carried out, because the risk to surface water is mainly via run off across the soil surface/top soil layer. Hence, the amount of cyanamide applied as a fertiliser is not the same as the cyanamide reaching surface water.

128 The Agricultural Production Systems Simulator (APSIM) https://www.apsim.info/Portals/0/APSoil/SoilMatters/Mod1/3_07.htm

A.10.4. Sensitivity analysis to compare the results of the risk characterisation (surface water and soil) using the approaches in REACH and the Plant Protection Products legislation

The applicability of the REACH approach to the protection of the environment has been questioned as regards agricultural land. Therefore the assessment factors used in the PPP to derive a PNECfreshwater and PNECsoil has been used as a sensitivity analysis to assess if this makes a significant difference in the risks to the aquatic or terrestrial environment. The major difference between the two assessment regimes is that when a chronic hazard laboratory study is used to derive a PNECsoil value, an assessment factor of 5 is used as opposed to an assessment factor of 10 in REACH. For PNECfreshwater, the assessment factor is the same for PPP and REACH for chronic studies. The tables below illustrate the sensitivity analysis.

Table 41. Surface water sensitivity analysis - comparison of risk characterisations derived using the approach in REACH and the Plant Protection

Crop	Application rate (kg/ha)		Application method	PNEC, PEC and RCR values based on cyanamide							Buffer strip:		Buffer (ECHA/PPP PNEC)	
	PERLKA®	$CaCN_2$		Depth in soil (cm)	FOCUS Scenario	PNEC (PPP) (µg/L)	PNEC (REACH) (µg/L)	PEC (µg/L)	RCR* (PPP PNEC)	RCR* (REACH PNEC)	PEC 10m	PEC 20m	RCR 10m	RCR 20m
Winter oilseed rape	500	220	Top dressing	0	R1,s	10.4	10.4	1030.1	98.7	98.7	No results		No results	
Winter oilseed rape	300	132	Top dressing	0	D2,d	10.4	10.4	5161.8	494.4	494.4	5161.8	5161.8	494.4	494.4
Winter oilseed rape	300	132	Top dressing	0	D2,s	10.4	10.4	3651.3	349.7	349.7	3651.3	3651.3	349.7	349.7
Winter oilseed rape	300	132	Top dressing	0	R1,s	10.4	10.4	618.0	59.2	59.2	260.0	132.3	24.9	12.7

Winter oilseed rape	100	44	Top dressing	0	R1,s	10.4	10.4	206.0	19.7	19.7	No results		No results	
Maize	300	132	Soil surface	0	R4,s	10.4	10.4	2052.1	196.6	196.6	No results		No results	
Potatoes	300	132	Soil surface	0	R3,s	10.4	10.4	15704.0	1504.2	1504.2	No results		No results	
Maize	500	220	Uniform incorporation	10	R4,s	10.4	10.4	246.7	23.6	23.6	No results		No results	
Leafy veg	500	220	Uniform incorporation	15	R4,s	10.4	10.4	310.5	29.7	29.7	140.6	73.6	13.5	7.0
Potatoes	400	176	Uniform incorporation	15	R3,s	10.4	10.4	503.9	48.3	48.3	207.1	104.5	19.8	10.0
Winter oilseed rape	200	88	Uniform incorporation	10	D2,d	10.4	10.4	19.8	1.9	1.9	19.8	19.8	1.9	1.9
Winter oilseed rape	200	88	Uniform incorporation	10	R3,s	10.4	10.4	41.3	4.0	4.0	18.9	9.9	1.8	0.9
Winter oilseed rape	100	44	Uniform incorporation	10	R3,s	10.4	10.4	20.7	2.0	2.0	No results		No results	
Leafy veg	200	88	Deep placement	15	All	10.4	10.4	<1.0	<<1.0	<<1.0	No results		No results	
Potatoes	250	110	Deep placement	15	All	10.4	10.4	<1.0	<<1.0	<<1.0	No results		No results	
All	Up to 700	Up to 308	All	N/A	D1, D3,D4, D5,D6	10.4	10.4	<3.0	<<1.0	<<1.0	No results		No results	

Note: the PNEC (PPP) has been derived as follows: using the chronic *D. magna* study by Murell et al (1995) and using an assessment factor of

10 as confirmed by EFSA. The PEC values used are those derived from modelling by ECHA. The RCR results using either the approach under REACH or the PPP legislation are identical, including when the use of a vegetated buffer strip is considered.

Table 42. Soil sensitivity analysis - comparison of risk charcterisations derived using the approach in REACH and the Plant Protection Products (PPP) legislation

Application rate (kg/ha)		Application method		PNEC, PEC and RCR values based on cyanamide				
PERLKA®	$CaCN_2$		EC10 *F. candida* mg/kg	PNEC soil (PPP) mg/kg	PNEC soil (REACH) mg/kg	PEC soil (28-d)	RCRsoil (PNEC PPP)	RCRsoil (PNEC REACH)
500	220	Surface application	1.51	0.30	0.15	20.3	67.2	135.3
300	132	Surface application	1.51	0.30	0.15	12.2	40.4	81.3
150	66	Surface application	1.51	0.30	0.15	6.1	20.2	40.7
500	220	Uniform incorporation to 7.5 cm	1.51	0.30	0.15	14.1	46.7	94.0
300	132	Uniform incorporation to 7.5 cm	1.51	0.30	0.15	8.45	28.0	56.3
150	66	Uniform incorporation to 7.5 cm	1.51	0.30	0.15	4.22	14.0	28.1
500	220	Uniform incorporation to 15 cm	1.51	0.30	0.15	7.32	24.2	48.8

300	132	Uniform incorporation to 15 cm	1.51	0.30	0.15	4.39	14.5	29.3
150	66	Uniform incorporation to 15 cm	1.51	0.30	0.15	2.2	7.3	14.7

Note: the PNEC (PPP) has been derived as follows: the EC10 derived from the NOECReproduction in the chronic study by Moser and Scheffczyk, 2009 using *F. candida* was 1.515 mg/kg soil. With a chronic study in the PPP legislation, an assessment factor of 5 is used as confirmed by EFSA. The RCR results using either the approach under REACH or the PPP legislation result in a risk to soil-dwelling organisms that is not adequately controlled.

From the above results it is evident that applying the assessment factors that would be used if the substance were being assessed under the PPP legislation still results in risks to surface water and soil that are not adequately controlled. For surface water the PPP risk characterisation results are identical to those derived from an assessment under REACH; for soil the risk characterisation results are lower than those under REACH, but remain significantly above the threshold values of 1.

Annex B. Baseline.

According to the risk assessment done in this report, a risk is found to both the aquatic and terrestrial compartments, primarily from cyanamide, one of the primary transformation products of calcium cyanamide in the environment. There is also a risk in some circumstances from the secondary transformation products: leaching of urea and cyanoguanidine (DCD).

The risk to waterways adjacent to a field is primarily from the run off of fertiliser from the surface of the field or from the top layers of soil. For the terrestrial compartment there is a clear risk to beneficial soil macro organisms from using calcium cyanamide. There is also evidence that significant quantities of cyanamide and DCD reach groundwater via leaching through soil when used in apple cultivation. The quantities found in groundwater may breach the Groundwater Directive, however from modelling carried out by the Dossier Submitter do not appear to pose a risk to human health via the consumption of drinking water from contaminated groundwater.

From the risk characterisation work reported here, risk management measures (RMMs) modelled (vegetated buffer strips) were mostly insufficient to reduce the risk to adjacent surface water. Similarly, if calcium cyanamide is continued to be used it will pose a clear risk to beneficial soil macro organisms.

To describe the scale of the issue, it can be assumed that the terrestrial organisms are negatively impacted on the total area in the EU in which PERLKA® is currently used – assumed to be 230 000 hectares. For waterways adjacent to PERLKA®-treated fields there will be a negative environmental impact, however, this applies to smaller area as not all treated fields are expected to be adjacent to waterways.

As a baseline for the benefit assessment in this report the negative environmental impact is assumed to occur on the total of 230 000 hectares on the basis of the impact on the terrestrial environment. The Dossier Submitter notes that in its REACH registration dossier (Alzchem, 2019a) the Registrant makes a case that the risk to agricultural soil and terrestrial organisms cannot be judged with the same environmental ambition level as soil in a pristine environment, with uncultivated soil. The same issue was brought up in the consultation comments, e.g. #2773, #2923. The Dossier Submitter agrees with the basic idea that often the main principle in the agricultural field production is simplification of the local ecosystem or a creation of a monoculture, however, the Registrant's argument is not valid as the current assessment is being carried out under REACH and REACH does not differentiate protection goals for agricultural versus other soil types, but strives for a high level of protection of human health and the environment..

PPP 2008-10 in its review has also reported on the basis of short and long term studies with a cyanamide-based formulation[129] used to promote bud opening of kiwi and grape crops at the end of the winter. Cyanamide was found to have properties that are highly hazardous to birds and small mammals from dietary exposure and are highly hazardous to bees. Exposure and hence risk to these species was considered unlikely in practice because the application of the cyanamide formulation is carried out at the end of the winter when the species were expected to be largely absent. The Dossier Submitter has not quantitatively assessed this risk for these species, however it is noted that exposure of these organisms to cyanamide is theoretically possible from the use of calcium cyanamide in moist conditions because calcium cyanamide is used as a fertiliser from February through to September.

[129] Dormex.

Annex C. Impact Assessment

C.1. Risk Management Options

The following two sections detail the other evaluated restriction options and the non-restriction risk management options identified and assessed. There is no further information to add beyond what is in the report.

C.1.1. Other evaluated restriction options (ROs)

A number of restriction options were identified and analysed prior to the Dossier Submitter selecting its preferred option. This section sets out the reasons for discarding the other restriction options which were assessed against the main criteria for proposing a restriction identified in Annex XV of REACH: effectiveness, practicality and monitorability.

RO1 bans placing on the market of the calcium cyanamide as a fertiliser in powder form. The ban is seen to mainly protect users applying fertilisers, however, the potential effect would be minor as most of the fertilisers used in recent years have already been in the granulated form. Furthermore, the real effect in the future would be insignificant as the registrant has already informed it has ceased the sales of the powder form by January 2017. In practise, such a restriction would only ensure that the sales of the powder form cannot be reintroduced by the registrant (or another party) in the future.

RO2 - Detailed regulation of acceptable agricultural production methods – could in theory provide a detailed measure offering a differentiated and effective regulatory approach capable of reducing the environmental risk to adjacent surface water from the use of calcium cyanamide. The risk to soil-dwelling organisms would remain however. In practise, for the approach to properly function this would require very careful differentiation according to crop, soil type, agricultural technology chosen, environmental conditions (e.g. length of the growing season, slope of the land, temperature, level of precipitation), etc. As such, the RO would need to be carefully adjusted to variety of conditions throughout Europe and its design would require extremely detailed sector specific expertise and differentiation. Furthermore, similar requirements would apply to the enforcement and monitoring.

For instance, a potential requirement for a buffer strip would need to be adjusted according to the closeness of the field to the waterways, soil type and crop and agricultural technology chosen. Still, alone it may not sufficiently reduce the risk to ensure safe use. In a similar manner, maximum application rates and features of restrictions concerning agricultural technologies would need to be designed for different crops and different environmental conditions. This would result in a RO, which could be in principle effective to reduce the risk to surface water and case specific, however, at the same time be very complex, difficult to administer and expensive to enforce. The risk to soil-dwelling organisms would nevertheless remain unaffected by this RO. To reach the same effect, in practise, it could be preferable to design and implement the restriction as part of the agricultural legislation/policy as the sectoral expertise lays there and the enforcement could be aligned with CAP enforcement mechanisms. Developing such a detailed restriction as part of the REACH regulation appears inefficient.

RO3 - Utilisation of existing CAP measures (e.g. cross-compliance) – appears a tempting way to regulate and manage environmental effects of the fertiliser use. The cross-compliance measures create a link between farm-relevant support and farm-relevant legislation (for more information: https://ec.europa.eu/agriculture/envir/cross-compliance_en). The cross-compliance measures, although centrally agreed on the European union level are member-state specific and in such a way adjusted to specific conditions of the each member state. This

RO – to use existing measures from the agricultural sector - would solve some of the implementation problems listed above concerning the RO2. At the same time, as designed to generally improve environmental effects of agriculture, it is unclear whether these measures would be exact and effective enough in removing the risk due to fertiliser use of the calcium cyanamide e.g. the modelling by the Dossier Submitter indicated the introduction of vegetated buffer strips up to 20 m in width are only effective in a few scenarios considered.

RO2 and RO3 can be seen as opposite reflections of the difficulties concerning the restriction design: where the RO2 concentrates on effectiveness and in so doing causes complex regulation and expensive implementation, the RO3 emphasises ease and simplicity of regulation with the expense of effectiveness. In summary, the proposed restriction RO4 – even if potentially rigid and very restrictive - is expected to be both effective and implementable in practise and as such it is found to overall better meet the criteria for restriction in comparison to the other evaluated restriction options. The proposed restriction is described in the dossier.

A consultation comment #2764 criticised the choice of the restriction options, however, the Dossier Submitter has to follow REACH regulation and the restriction option was chosen based on that. Another consultation comment (#2926) proposed an alternative restriction option, “RO5”, which would allow sales of calcium cyanamide as a fertiliser only to professional users. The Dossier Submitter notes the restriction option, however, from the outset it appears as such an option would not be able to remove the risk, and as a whole would only have a minor significance.

C.1.2. Other Union-wide risk management options (RMOs) than restriction

As a first step, the possibility to address the risks posed by the use of calcium cyanamide under other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined. Whilst it was recognised, and taken into account when developing the scope of the proposed restriction, that some existing or proposed EU legislation or other measures could have an impact on the risk management of certain sectors, such as the recast of the fertilising products regulation (FPR), these were assessed as inappropriate to address *all* of the sectors and products contributing to risk.

Possible Union-wide risk management measures other than a restriction are outlined in Table 43 below. However, it is concluded that none of these are realistic, effective and balanced means of solving the problem. As such, none of these other risk management options have been analysed further.

Table 43. Possible other Union-wide options discarded at this stage

Option	Reasons for discarding this option
Non-legislative measures	
Voluntary industry agreement to restrict the use of calcium cyanamide as a fertiliser.	The manufacture and placing on the market of calcium cyanamide is by one company in the EU and there in principle could be other importers. The use of the substance is by numerous farmers. This situation does not seem tenable for a voluntary agreement.
Voluntary agreement for industry to label.	• ‘Use only with deep placement and vegetative strips of at least 20 meters’. The agreement to use this label would be a voluntary measure to implement the option to use certain risk management as discussed in the dossier. This RMO will also share many of the disadvantages of the voluntary agreement to restrict substances such as enforcement and coverage (as above).
Legislation other than REACH	
Taxation on calcium cyanamide content	Taxation in general is not a harmonised measure across the EU. Therefore, whilst it might be effective in encouraging substitution, it is not likely that all Member States would introduce relevant taxes and thereby, not all EU environmental risk would be removed. This is likely to lead to a non-harmonised situation where different Member States apply different tax rates (if at all).
Fertilisers Regulation Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down the rules on making available on the market fertilising products	The Fertiliser regulation (2019) harmonises the requirements for fertilisers in the EU. According to the regulation, EU fertilising products bearing the "CE marking" will have to fulfil certain requirements to benefit from free circulation in the EU's internal market. Environmental controls in this Regulation are largely delegated to REACH.

Biocidal Products Regulation (BPR) 528/2012	The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. All biocidal active substances and products require an approval/authorisation before they can be placed on the market, and the active substances contained in that biocidal product must be previously approved. Cyanamide is already approved under the Biocidal Products Regulation for use as a biocide and its use as a fertiliser is not within scope. In June 2019, the 14th Endocrine Disruptors Expert Group discussed the substance cyanamide and concluded that "*there was broad agreement by the experts from Member States that the information available is sufficient to identify the substance as 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. The Biocidal Products Committee provided an opinion in December 2019 that cyanamide is an endocrine disruptor for human health and non-target organisms. Following the adoption of the BPC opinion, the European Commission may proceed to decision making within a few months.
Plant Protection Products Regulation (PPP) 1107/2009.	Plant protection products are 'pesticides' that protect crops or desirable or useful plants primarily used in the agricultural sector but also in forestry, horticulture, amenity areas and in home gardens. They contain at least one active substance - before an active substance can be used within a plant protection product in the EU, it must be approved by the European Commission. They have one of the following functions: protect plants or plant products against pests/diseases, before or after harvest; influence the life processes of plants (such as substances influencing their growth, excluding nutrients); preserve plant products; destroy or prevent growth of undesired plants or parts of plants. They may also contain other components including safeners and synergists. EU countries authorise plant protection products on their territory and ensure compliance with EU rules. Fertilisers are not within the scope of the PPP Regulation, but because calcium cyanamide has 'secondary properties' that are usually associated with PPPs, it may be considered for authorisation for use as a PPP. If so, this could be a useful way of managing the risks from the use of the substance.
Other REACH processes	

REACH Authorisation process	Calcium cyanamide is not classified as CMR category 1A or 1B, nor has it been identified as an SVHC. Therefore, authorisation cannot be used as a Risk Management Measure for them.
REACH Art. 68.2	REACH Article 68(2) stipulates that substances that are CMR categories 1 or 2 can be subject to a proposal from the Commission to inclusion in Annex XVII for consumer uses without using the procedures in article 69-73 in the REACH Regulation. calcium cyanamide is not so classified and this measure is not applicable to them.

C.2. Alternatives

In this assessment it has been assumed that in case calcium cyanamide was not available, potential alternative could be other industrial nitrogen fertilisers, e.g. urea, ammonium nitrate or ammonium sulphate, or alternatively, if the slow-release characteristics were indispensable, advanced industrially designed slow-release fertiliser (SRF) or controlled-release fertiliser (CRF).

C.2.2. Identification of potential alternative substances and techniques fulfilling the function

In practice the choice of fertiliser is made based on a soil type, crop grown and environmental conditions facing a farmer. When assessing alternatives to calcium cyanamide, one of the main issues is whether to use one of the simple, traditional, inexpensive nitrogen sources like urea or ammonium nitrate or whether to choose a slow/controlled-release fertiliser. There are a few products available, where the slow/controlled-release characteristics is built-in into the fertiliser by adding a nitrogen inhibitor to a product or by coating a fertiliser material, mostly urea with sulphur or water resistant polymers to diminish its solubility in the soil[130]. For instance, Entec 26 and Agrocote/Agromaster are examples of slow/controlled-release fertilisers.

C.2.2.1. Non-slow release fertilisers

Urea and ammonium nitrate as well as ammonium sulphate are widely used and therefore clearly technically feasible. Similarly, commonly available, N-P-K products offer an alternative to calcium cyanamide, especially if supplemented with additional liming. None of these alternatives have a slow-release character. Furthermore, they tend to be also lower in price (see e.g. Landor, 2017), however, potentially affecting some of the agricultural practices or input use in general (e.g. requiring more labour input). Based on information available (Chohura & Kolotai (2014)) they also may have (negative) effect on the harvest quality and quantity. Based on the information available, it appears that use of alternatives tend to require more nitrogen per kilogram harvested and therefore per hectare amount of nitrogen leaching may end up being higher (assuming similar nitrogen content in the harvest).

C.2.2.2. Slow release fertilisers

Industrially engineered slow- and controlled-release fertilisers (SRFs and CRFs) could provide another suitable alternative (see e.g. (Trenkel, 2010)). Such fertilisers have the slow/controlled release characteristics built-in into the product for instance by coating a fertiliser material, mostly urea with sulphur or water resistant polymers to diminish its solubility in the soil[131] or by adding nitrogen inhibitor to a product to slow down the release. The objective is to have the nutrients (optimally) available throughout the whole growing season in order to increase use-efficiency of the nutrients and thus improve crop growth and in the same time to reduce nitrogen leaching from the production process.

Based on Terlingen, et.al. (2016) the use of controlled-release fertilisers has increased within high-value production like horticulture, turf and landscaping applications in recent decades. However, farmers producing traditional agricultural products have not widely adopted their use because of their higher prices compared to conventional fertiliser. The use of the controlled-release fertilisers has also been mentioned in the context of reducing fertiliser run-offs and mitigation of agricultural greenhouse gas emissions (e.g. Eory, et.al. 2018), however, broad economic comparisons between controlled-release and traditional fertilisers are scarce.

An alternative technique is using nitrification inhibitors to delay the oxidation of ammonium to nitrate in the soil e.g. in a fertiliser Entec 26, where DMPP (3,4-dimethyl-pyrazole phosphate) is used as a nitrification inhibitor. In field studies its addition to fertilisers containing ammonium form of nitrogen appeared to be effective in increasing yield as well as in reduction of nitrates accumulation in vegetables as shown by Kołota & Adamczewska-Sowinska (2009).

The Registrant has provided some information where the effects of using alternative fertilisers on the size of the harvest are compared. Additionally, there are scientific reports on trial results available comparing the effects of using alternative fertilisers to the size of harvest. These data and information is used as basis in the impact analysis later in this report.

Other more recent controlled release nitrogen products on the market based on a so called E-Max Release Technology marketed under the brand names Agromaster© and Agrocote Max©. The technology is said to be specifically designed for use in agriculture. The manufacturer informs that a recently installed production line in The Netherlands has a capacity of 25 thousand tonnes per year (see Appendix 11). This is mentioned here as a potential alternative, however, no broad information on the products is available. One comparison of Agrocote and PERLKA® in sugar cane production in Costa Rica was found (Araya et.al. 2015), however, its applicability to EU is unclear. These products are not pursued further here at this point, as the availability of the fertiliser as well as availability of information on the fertiliser appears limited.

C.2.3. Risk reduction, technical and economic feasibility, and availability of alternatives

C.2.3.1. Availability

Urea and ammonium nitrate are both available in the EU and internationally. There are several suppliers of such products where products differ for instance by nitrogen contents and/or by other ingredients added to the mix. These basic products are familiar to farmers and have

[131] It is to be mentioned here, that such products have been encountered in preparation of another restriction proposal concerning microplastics, as coating materials contain polymers.

been on the market for decades.

Entec 26 has also been available in the EU for some years and as mentioned above tested for different uses over the years. It is sold by different merchandises and information on price and availability can be found from suppliers websites e.g. from Landor (2017).

C.2.3.2. Technical feasibility

There are several alternatives to a farmer to choose in which form he adds nitrogen to an agricultural production process. A farmer makes his choice based on multiple criteria including the crop, soil type, length of the growing season, machinery available, labour available, farmer's knowledge and habits, farmer's attitude towards risk, regulation affecting the production, etc. A change in the use of one input, say fertiliser, normally affects the uses of other inputs e.g. labour or herbicides and as a result the whole input combination is affected. Consequently, the quantity and the quality of the harvest as well as production risk may be affected.

For instance articles by Chohura & Kołota (2014) trials where use of PERLKA®, Entec 26 and ammonium nitrate have been used as alternative nitrogen sources in cabbage production. According to the trials, the all three fertilisers are suitable to be used in production. Another, confidential calculation provided by the Registrant describes economic comparison of PERLKA® and urea as alternative fertiliser source in potato production, and still another comparison by the Registrant shows an effect of the use of PERLKA® and ammonium sulphate on potato harvest. As a conclusion, there appears to be several technically feasible alternatives with slightly different characteristics available for nitrogen addition, some also including slow-/controlled release characteristics.

C.2.3.3. Economic feasibility

Based on our assumptions, as discussed above calcium cyanamide as a fertiliser is used on 0.2% of agricultural land within EU, which means, that although widely used, the most of the farmers in the EU do not use calcium cyanamide as a fertiliser. Therefore, it must be that most of the farmers prefer not to use calcium cyanamide for some reason. The limited share of calcium cyanamide on the fertiliser markets alone shows that alternatives must clearly be economically feasible. Calcium cyanamide is thought to be especially suitable for high value crops with a long growing time requiring large amount of nitrogen (like cabbage, potatoes), grown in the areas with a long growing season (like central, southern Europe).

There are a few clear reasons why farmers may choose alternatives instead of calcium cyanamide. First, the timing of fertiliser application in case of calcium cyanamide tends to be limited, as it cannot be applied too close to a seeding/planting timing. Timing requirements may cause rigidities, lags in production process, which may be important and costly to a farmer during a busy season. Secondly, the use of calcium cyanamide fertilisers requires some human health precautions to be taken that farmers are not used to when using other fertilisers. Although the health effects may only apply to the powdered form, such characteristics are expected reduce the desirability of the product.

Pricewise calcium cyanamide tends to be more expensive than the other nitrogen sources, based on the price information available (Landor, 2017). The price of a fertiliser is an important concern to a farmer – even if connected with high profitability. To farmers, who are used to consider a host of production risks in their decision making, the high price of an input has negative connotations. In case of a difficult summer and low yield e.g. during challenging weather conditions, the high-priced input may bring no difference to the yield and income in the end of the season.

Chohura and Kołota (2014) found that three fertilisers - calcium cyanamide, ammonium nitrate, and Entec 26 - produced a somewhat comparable marketable yield in cabbage production. However, out of the three calcium cyanamide produced the highest marketable yield of cabbage heads (~4% increase vs. others) with significantly lower mean content of nitrates (13-15%) in edible parts. Furthermore, it had a high efficiency in reducing weed infestation during the whole vegetation period. In the high value crops like cabbage the four percent difference in marketable yield becomes important. Furthermore, if a quality premium exists (on level of nitrates), the economic effect may be sizable. In the aforementioned report the economic issues were not assessed.

The price information available by Landor (2017) shows that nitrogen addition in form of PERLKA® is clearly more expensive than by using more common urea or ammonium nitrate and is also more expensive than Entec 26. Based on this information the price is €4.33 per kilogram of nitrogen in PERLKA®. The difference is significant, as the price of nitrogen in Entec 26 appers to be about €2.5/kg and in Ammonsalpeter (ammonium nitrate) about €1.8/kg when calculated according to nitrogen content in the fertiliser.

C.3. Economic impacts

No further information to add except in the following sections.

C.3.1. Environmental impacts of uses of alternatives and net risk reduction

The use of alternatives although technically feasible, may have environmental risks of their own. These risks have to be accounted for when assessing the net environmental risks of the restriction. At least two potential impacts are evident given the information available. First, in case calcium cyanamide is substituted with non-slow or non-controlled release fertilisers, like urea or ammonium nitrate, the fertiliser use-efficiency of the crop may change (reduce) and as a result nitrogen leaching may increase. This is based upon the assumption that typical nitrogen-based fertilisers release their nitrogen quickly compared to PERLKA® and this may not be used by crops at the same rate as its release and therefore more nitrogen is left in soil available for leaching. Whether this poses a risk in practice will depend upon a number of factors which have not been studied in detail here e.g. rate of release, rate of uptake by plants, the likelihood of leaching and the proximity to adjacent waterways.

Secondly, the urea as a transformation product of calcium cyanamide has been shown in the risk assessment above to pose its own risk to surface water–dwelling organisms the environment, albeit in fewer modelling simulations than calcium cyanamide. The use of urea as a fertiliser instead of calcium cyanamide therefore could represent a regrettable substitution.

Calcium cyanamide has been shown to have positive secondary effects controlling weeds and fungi, replacing it with another type of fertiliser without such effects may result in a farmer needing to use an additional herbicide or fungicide. The Dossier Submitter expects the use of additional pesticides to have a neutral, or possibly marginally positive impact on the environment comparing to a case where calcium cyanamide is used. In both cases there appears to be a toxic effect, however, in case of PPP-authorised pesticides, the products have been tested and considered safe to use and provide the farmer with reassurance that they are using an authorised product.

The literature cited above (Chohura & Kołota, 2014), recognises expected changes in nitrogen (nutrient) balance and clear increase in amount of weeds due to substitution. Namely, it shows that after applying the same amount of nitrogen in different forms (PERLKA®, Entec 26, Ammonium nitrate) to a field during the agricultural production process, the resulting harvest is smaller in case of alternatives. Therefore, it is clear, that more nitrogen is left to the field/environment assuming the nitrogen content in the harvested crop is similar. The study does not articulate whether the larger harvest in that case is due to higher use-efficiency of the nitrogen itself when in calcium cyanamide form or whether reason is the beneficial secondary effects – less weeds competing for the nitrogen (and space, sun, etc.). The study only gives the difference in yield (and amount of weeds) related to the specific fertiliser choice. The direction of the effect (on leaching) appears quite clear, however, no specific studies concerning use of calcium cyanamide as a fertiliser have been found, where the consequent leaching and/or environmental impacts would have been further quantified.

C.3.2. Impacts of Calcium cyanamide on harvest

The assessment of economic impacts of substitution is in large parts based on the effect of alternative fertilisers on profitability. For comparison purposes the Registrant provided the Dossier Submitter with (confidential) information about user costs and benefits in potato production. More recently the Registrant also provided the Dossier Submitter with profitability comparisons of PERLKA® and ammonium nitrate for several other crops including oilseed rape, cabbage, lettuce, maize, sugar beet and rice. Separately, the Registrant provided confidential information on the current use (in terms of acreage) of calcium cyanamide to grow different crops. This information was used by the Dossier Submitter to construct a monetary estimate of the value of calcium cyanamide as a fertiliser. In the estimation, the profit contribution of PERLKA® has been compared to the profit contribution of an alternative.

For potatoes, the costs are affected only by a different price of the fertilisers used, whereas in case of several crops the alternative fertiliser is also complemented by additional liming adding to the costs. In both cases the effectiveness of the fertilisers are assumed to differ, where the effectiveness may show either through different quality and/or quantity. Other things are assumed to be constant, for instance labour use and use of plant protection products are assumed to remain the same.

There are two other comparisons constructed by the Dossier Submitter. The first one is based on effectiveness information available from a fertilisation trial and the second uses promotional information published on the Registrant’s webpage. Observed market prices are used to monetise the comparisons. The resulting information is used for the added transparency and to validate the confidential information provided by the Registrant.

The comparison of the potato production is described in a confidential appendix 12: *Profitability difference calculated in case of potatoes and several „other“ crops* below. The fertilisers used are calcium cyanamide (PERLKA®) and urea ammonium nitrate (UAN) solutions. The ‘Profit contribution’ is calculated by deducting ‘Sum of variable costs’ from ‘Total returns’ (price * quantity).

It is to be underlined, that the comparison assumes all other things equal, i.e. there are no differences in labour/machinery costs neither in plant protection costs, thus the comparison should only reflect the impact of the fertiliser itself. It is to be expected, that the inclusion of labour/machinery costs as well as the plant protection costs would further increase the difference, as UAN may require more than one application compared to slow-release calcium cyanamide. Similarly, if aforementioned beneficial secondary effects of the calcium cyanamide allow a farmer to use less plant protection products, the profitability difference may be even larger.

A comparison consisting of several other crops (rice, sugar beet, maize and oilseed rape, processed cabbage, fresh cabbage and lettuce) has also been undertaken. This shows profit differences i.e. a potential loss due to a substitution with an alternative fertilisers to vary widely. In this case, alternative fertiliser was complemented with lime. Potential higher needs e.g. for labour or PPPs were not accounted for.

The crop specific profitability losses calculated in the confidential annex are weighted with the use-area information to further calculate the weighted average per-hectare profitability loss. Resulting from the calculation these per-hectare profitability losses range from €270/ha to €343/ha, and describe the value loss from substitution of calcium cyanamide with an alternative. When summed together, the total value loss of substitution of calcium cyanamide as a fertiliser ranges from €62M to €79M annually.

In another context, a trial reported by the Registrant claims over a 2-digit% yield increase in potato production due to a calcium cyanamide use (vs. ammonium sulfate as a nitrogen source). However, no further reasoning is provided to support this claim, so the information is not used in the analysis.

Besides the comparisons provided by the Registrant, there is trial evidence available by Chohura & **Kołota** (2014), which, in case of cabbage production, found about a 4% increase in marketable yield when calcium cyanamide was used (PERLKA®) vs. alternatives (ammonium nitrate, Entec26). According to the report, the use of calcium cyanamide also improved the quality of the product by decreasing the content of nitrates in the cabbage. Furthermore, the authors reported the amount of weeds as a function of the fertiliser used, showing that calcium cyanamide has a clear impact reducing weeds on the area where it is used. This in turn decreases the need for and costs of plant protection costs. No economic information was provided in this report.

Table 44. Added value of CaCN2 (PERLKA®)) for cabbage crops based on the trial information by Chohura & Kołota (2014).

Chemical used	N added	Unit cost	Amount	Ha-Cost	Cost diff	Yield difference	Yield diff.	Avg. yield	Price (output)	Revenue	Added revenue	Added value
	kg/ha	€/ tonne	kg/ha	€/ha	€/ha	kg/ha	%	kg/ha	€/kg	€/ha	€/ha	€/ha
PERLKA®	150	520	750	390				94400	0.15	14160		
Entec(26)	150	388	577	224	166	3600	4	90800	0.15	13620	540	374
Am.nitr(27)/Salpeter	150	288	556	160	230	3800	4	90600	0.15	13590	570	340
A discount of 40% of the Landor (2017) list price assumed												
PERLKA®	150	693	750	520				94400	0.15	14160		
Entec(26)	150	517	577	298	221	3600	4	90800	0.15	13620	540	319
Am.nitr(27)/Salpeter	150	384	556	213	306	3800	4	90600	0.15	13590	570	264
A discount of 20% of the Landor (2017) list price assumed												

Using price information[132] available by Landor (2017), the aforementioned profitability loss shown by Chohura & Kołota (2014) monetised (see the table). Based on this, the estimate for a value loss ranges from €264/ha to €374/ha when substituting calcium cyanamide in cabbage production.

It is to be noted here that there is no assessment about an optimum application rate in the trial. The amount used per hectare appears quite high compared to the recommendations given by the registrant. Given the relatively high price of the fertiliser, unnecessary high amounts of fertilisers may quickly reduce the cost-effectiveness of the application. Secondly, the revenue estimate is only partial, as it is simply based on the increased quantity and does not take into account the higher quality. Furthermore, in practise substitution by alternatives often increases labour and materials needs in plant protection. In case of ammonium nitrate (non-slow-release fertiliser) more labour and machinery inputs may also be needed due to increased tasks related to fertilisation. There may be for instance, needs to add calcium (lime), which has not been accounted for. Such costs could increase the profitability difference. This is case specific and there is no estimate available for such additional costs.

When comparing different crops, the cabbage is seen as a high value crop. Therefore, it can be concluded, that the range above can be used to represent losses due to the substitution of calcium cyanamide as a fertiliser in high value production, and given the discussion above, the cost range may be somewhat underestimated.

Promotional information provided by the Registrant is the fourth piece of information used to assess the potential profitability loss due to substitution. This is included in the report in order to transparently show, what type of calculations are used by the Dossier Submitter. It is acknowledged that the quality of this information is not comparable to trial information presented above. Based on an insert from registrant's (AlzChem) webpage 20 Nov 2018 (see the appendix 12: *Promotional information by the registrant used in the Impact analysis*) 40kg/ha addition of nitrogen in the form of calcium cyanamide (PERLKA®) increases the oilseed rape harvest on average 350kg/ha. As PERLKA® contains about 20% of nitrogen, this means the use of 200 kg of Pelka per hectare. This is compared to an alternative, where 40 kg nitrogen addition would be done by using ammonium nitrate (here Ammonsalpeter). Using the same price information as above in case of Chohura & Kołota (2014) and assuming a price of 360€/tonne for rape seed oil, the increase in profit contribution would range from €44 to €65 per hectare. As in the previous case, the additional costs due to the potential increases in labour needs, plant protection activities are potentially in liming are not taken into account and therefore the estimates given here may be somewhat underestimated.

[132] When calculating the range for the cabbage profitability loss the fertiliser prices by Landor (2017) are used, however, with a discount of 20% and 40% as farmers are expected to receive discount prices when buying large amounts of fertilisers.

Table 45. Added value of $CaCN_2$ (PERLKA®) (no lime added) of oilseed rape as published on the registrant's webpage.

Chemical used	N added	Unit cost	Amount	Ha-Cost	Cost diff	Yield increase	Price(output)	Added revenue	Added value
	kg/ha	€/tonne	kg/ha	€/ha	€/ha	kg/ha	€/kg	€/ha	€/ha
*PERLKA® (19.8)	40	693	200	139	82	350	0.36	126	44
*Amm.Nitr(27)(Salpeter)	40	384	148	57					
**PERLKA® (19.8)	40	520	200	104	61	350	0.36	126	65
**Amm.Nitr(27)(Salpeter)	40	288	148	43					
*A discount of 20% of the Landor (2017) list price assumed									
**A discount of 40% of the Landor (2017) list price assumed									

Compared to the cabbage production the oilseed rape production can be taken to represent the low value crop here. Therefore, the range given here may be used to represent the losses due to the substitution in low value production, and due to the omission of some potential costs, the resulting estimate may be somewhat underestimated.

The above calculated per-hectare values are further used to estimate the total value loss due to the substitution. Assuming calcium cyanamide is used 50/50 in high-value and low-value production and assuming again the total use-area to be 230 000 hectares, this would reveal the total value loss of substitution to range from €35M to €50M annually.

It is to be noted here, that the total value losses reported above are quite very sensitive to the product price changes. It was calculated as a sensitivity analysis that in case the price of the high value crop – here cabbage – would double from €0.15/kg to €0.3/kg (still in a possible range) the resulting per-hectare losses would more than double and the total value loss estimates would end up being over €100M. Besides the sensitivity, this gives an idea of the profitability risk farmers are faced with when making their production decisions.

Compared to the estimates given above based on the confidential information by the Registrant, the values listed here are – although clearly less – well in the same ballpark. The result appears as expected as the higher values are based on the Registrant's own estimates, which may have a tendency to rather overestimate than underestimate the value of calcium cyanamide in the production process. On the other hand, it is to remember, that the lower estimates do not take into account some omissions in the input costs related to e.g. potential liming needs.

None of the calculations takes into account potential savings in plant protection costs (materials and labour). Looking at the analysis by Chohura & Kołota (2014), the fertiliser type clearly affects the amount of weeds, and thus it is expected that accounting for the change (reduction) in the weed control costs would show a larger difference in the profitability.

C.3.2.1. Principles for assessing costs of RO2

The RO2 appears less suitable than the proposed RO4 for regulating calcium cyanamide as it would not adequately control risks in both the aquatic and terrestrial compartments. Economic impacts of RO2 have not been assessed, however, a rudimentary plan is described below on how an assessment could be undertaken.

In section 4.10 the RO2 was described to consist of a requirement: i) for deep placement of fertiliser to the soil (stricter than an instant incorporation requirement in case of surface application), ii) to use of vegetated buffer strips on the fields adjacent to waterways, and iii) of a ban of the use of the calcium cyanamide on sensitive areas and/or specific soil types.

Requirement for deep placement

Currently calcium cyanamide application is often done using a traditional disk spreader as a surface application. The fertiliser is in some cases left on the soil surface to find its way to the soil and to plants, in some cases it is incorporated to the soil within a few days. In some cases the fertiliser is already now directly placed to the optimal depth in the soil. The new measure is expected to require the farmers to use machinery equipped with direct placement technology.

For assessing the extra costs due to the adoption of the measure, one needs to assess how many hectares would be affected by the measure on average. Secondly, the size of the additional investments needed (per ha) have to be identified. Third, one needs to assess the increased labour costs. After summing these costs up, they have to be balanced with income increase due to potential increases in quality and/or quantity in harvest. Currently, no data is available allowing such a calculation.

Costs of the vegetated buffer strips

A vegetated buffer strip has at least two main cost elements – it decreases hectares available for agricultural production and its maintenance normally requires labour input e.g. weeding, etc. The vegetated buffer strip may also offer a breeding ground for useful as well as harmful weeds and insects and alike. A farmer may view them as an additional source for weeds requiring higher use of plant protection inputs. However, in the same time they may provide public goods as they offer place for insects and even mammals to breed.

The cost calculation needs to assess the number of hectares used for a buffer strip. For instance, assuming 20% of the 230 000 hectares in question are adjacent to waterways, this would mean 46 000 hectares. Assuming fields are generally square and of a size of 10 hectares, this would mean that we would have 4 600 of such fields with the length of a field (adjacent to a waterway) being about 316 meters. Thus, the total length of fields adjacent to waterways would be 316m*4 600 equalling to 1 456 600 m (or around 1 500 km). Assuming a buffer strip width of 10 m, there would be about 1 454 hectares left under vegetated buffer strips. If the average profit made per hectare was €100, this would mean total losses of at least €150 000; assuming the average profit made per hectare was €1 000 the losses would be at least €1 500 000. Realistically, the average profit from the remaining area could be expected to decrease as the parcel size decreases and the total cost could increase due to additional input needs to take care of the vegetated buffers themselves. However, the data availability would hinder the calculations also in this case. For a 20-meter buffer strip the area, and the costs, would about double. However, as found out in the modelling done as part of the risk assessment, even the 20-meter buffer strip would not be large enough in all cases.

Ban of the use of calcium cyanamide on certain soils/areas

This calculation also requires the knowledge of which (and how many) hectares would be affected and what would be a loss per each hectare and/or an average loss per hectare on the area affected. Again, such data is not readily available. If one assumes 15% of the area to be affected, the total area affected would be 34 500 hectares. Assuming an average loss of €100 due to substitution of calcium cyanamide with another fertiliser and/or due to a crop change, the total cost would be €3 450 000, in case the loss was €500 per hectare, the total lost would increased up to € 17 250 000.

Above text sketches out how to approach calculating costs due to certain measures limiting agricultural technologies used and requiring e.g. use of buffer strips. It is clear, that in each case there are severe data limitations hindering the calculations, and therefore they mainly point out a way to address the costs. In each case the loss is due to a different reason. The first measure decreases the profitability of the CaCN2 for certain number of hectares. The second measure decreases the agricultural production area and increases the total costs and the third measure decreases profits from number of hectares. However, when looking at the numerical results in this section, one needs to note, that they are based on ad hoc assumptions, and may not be realistic.

Annex D. Assumptions, uncertainties and sensitivities

Several uncertainties and assumptions have been maintained when assessing the impact and proportionality of the proposed restriction. The main uncertainty is the net environmental benefit of replacing calcium cyanamide with other alternative. It does appear self-evident that restrictions on the placing on the market and use of the calcium cyanamide may provide environmental benefits in principle. However, if environmental impacts of potential alternatives are assessed the comparison becomes more difficult. In practise, both main effects of the calcium cyanamide need to be accounted for – slow-release fertilisation and so called secondary benefits. Furthermore, the costs of using alternatives is instrumental from a farmer point of view – even if alternatives with no environmental effects exist, they are not feasible if they are prohibitively expensive.

The impact analysis concentrates on assessing potential profitability losses end users of the calcium cyanamide encounter due to substitution to another fertiliser and potentially complementary plant protection products. These calculations are largely based on information provided by information received from the registrant. These calculations were compared to calculations based on scientific fertiliser trial information in order to improve transparency. The profitability calculations largely depend on the input and output prices. The calculations appear quite sensitive to input and output prices used.

Annex E. Stakeholder information

The work on calcium cyanamide in ECHA has continued already over two years as first, during 2017, ECHA prepared a preliminary assessment on the use of calcium cyanamide as a fertiliser[133]. Based on that assessment Commission asked ECHA in the autumn 2017 to prepare an Annex XV restriction report on the matter. During the preparation of the preliminary assessment report, only the single Registrant, AlzChem was consulted. During the preliminary analysis work AlzChem provided further information as requested. There was no separate call for evidence on the use of calcium cyanamide as a fertiliser during the work on the preliminary assessment report. The restriction proposal here basis its analysis also on the information and experience gathered during the preliminary analysis work.

E.1. Call for evidence

The Call for evidence on calcium cyanamide as a fertiliser was held between 21 March–17 May 2018. The Call resulted in 26 comments mainly supportive to the use of calcium cyanamide as a fertiliser underlining its effectiveness and suitability for the use for crops with a long growing season, secondary effects helping to manage weeds and potential increased nitrogen leakages in case it was substituted with a non-slow-release alternatives. Positive effects of calcium cyanamide on quality of the output were also promoted, on the other hand a high price of the calcium cyanamide fertilisers was also brought up. The comments came from 7 different European countries and were sent by companies, individuals, authorities, industry/trade associations, research institutes and ‘others’. More information on the Call for evidence itself is available on ECHA webpage[134].

E.2. Discussions with industry

In the case of calcium cyanamide there is one registrant in the EU which manufactures and sells calcium cyanamide fertilisers. The Dossier Submitter was in contact with the Registrant first during the preparation of the preliminary assessment report 2017. This information was also applicable for the restriction report itself.

The Dossier Submitter has also contacted the Registrant several times for information during the restriction dossier preparation and representatives of the registrant took part in a meeting in ECHA in June 2018. The purpose of the meeting was to receive first-hand information about the product, it production and characteristics. The Registrant also shared information about quantities used and acreages applied. In the meeting, the Registrant also provided information about the economic comparison of potato production with calcium cyanamide compared to an alternative. After the meeting the dossier submitter has contacted the Registrant a few times for clarifications and/or for additional information e.g. on risk assessment issues, on application rates as well as on profitability comparisons covering more crops.

E.3. Consultations with authorities/EU Agencies

As a dossier submitter ECHA has made close cooperation with EFSA on the topic. EFSA has provided very useful information especially on risk assessment issues related to plant protection products regulations as we as otherwise. The EEA has also assisted ECHA in

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[133] https://echa.europa.eu/documents/10162/13641/calcium_cyanamide_review_report_en.pdf/e0b43a34-1a52-b6a9-8d96-bd8183c7beb4

[134] Specific information and the background note related to Call for evidence can be found here: https://echa.europa.eu/fi/previous-calls-for-comments-and-evidence/-/substance-rev/19401/term

searching for monitoring data.

Appendix 1: Input parameters for the exposure modelling (Source: Dossier Submitter)

Table 46. Input parameters used by the Dossier Submitter for exposure modelling

Parameter	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine (DCD)	Comment
Molecular weight (g/mol)	80.11	42.04	60.06	84.08	
Parent/ Transformation product	Parent	Transformation product of calcium cyanamide	Transformation product of cyanamide	Transformation product of cyanamide	
Assumed molar conversion	Not application	1	0.097 (Based on EFSA (2010) which assumed a 13.4% cyanamide-to-urea conversion rate in water/sediment – corrected for the relative molecular weight of cyanamide and urea)	0.053 (Based on EFSA (2010) actual conversion is not known – assumes a cyanamide-to-DCD conversion rate of ≤10% in soil and sediment – corrected for the relative molecular weight of cyanamide and DCD)	
Sorption constant (Koc) in soil (L/kg)	172400 (Based on Fraunhofer 2018b)	4 (Based on EFSA (2010))	5.3 to 9.1 Mean=7.2 Calculated from Hongprayoon C et al 1991	Registration dossier: Koc=5.25; log Koc=0.72	
Sorption constant (Koc) in water body (L/kg)	0 (Based on Fraunhofer 2018b)	4 (Based on EFSA (2010))	5.3 to 9.1 Mean=7.2 Calculated from Hongprayoon C et al 1991	Registration dossier: Koc=5.25; log Koc=0.72	
Freundlich exponent	1	1	1	1	default
Reference concentration (mg/l)	1	1	1	1	default

Coefficient of linear sorption on macrophytes (l/kg)	0	0	0	0	default
Vapour pressure	0 Pa at 20°C	0.51 at 20°C	0.0016 Pa at 25°C	<0.004 Pa at 100°C (assumed to be 0 at 20°C)	
Water solubility (g/l) at 20°C	29.4 at (taken from SCHER, 2016)	560 at 20°C (taken from EFSA, 2010)	624	32	
Molar enthalpy of vaporisation (kJ/mole)	95	95	95	95	default
Molar enthalpy of dissolution (kJ/mole)	27	27	27	27	default
Diffusion coefficient in water (m^2/d)	4.3×10^{-5}	4.3×10^{-5}	4.3×10^{-5}	4.3×10^{-5}	default
Diffusion coefficient in air (m^2/d)	0.43	0.43	0.43	0.43	default
Half-life in aerobic soil	1.45 days at 12°C	2. 9 days at 12°C	30 days at 12°C (default for a readily biodegradable substance).	Not readily biodegradable 72 days at <10°C Kelliher et al 2008.	
Exponent for the effect of liquid - Walker	0.7	0.7	0.7	0.7	default
Exponent for the effect of liquid – Calibrated value	0.49	0.49	0.49	0.49	default
Moisture content at which the half-life is measured	100% relative to field capacity	100% relative to field capacity	100% relative to field capacity	100% relative to field capacity	
Q10 Factor for the effect of temperature on transformation	2.58	2.58	2.58	2.58	default

pF at which half-life is measured (log(cm))	2	2	2	2	default
Effect of temperature (K^{-1})	0.079	0.079	0.079	0.079	default
Half-life in surface water	1 day at 12°C Fraunhofer 2018b	4.3 days at 20°C Registration CaCN2	4.8 days at 20°C (geometric mean value from EFSA, 2010)	Not readily biodegradable. Simulation study DT50 pond >1000 days at 20°C.	
Half-life in sediment	1 day at 12°C Fraunhofer 2018b	1000 days at 20°C	1000 days at 20°C (to be comparable with the approach used for cyanamide)	Not readily biodegradable Simulation study DT50 pond >1000 days at 20°C	
Molar activation energy (kJ/mole)	65.4	65.4	65.4	65.4	default
Canopy wash-off factor (m^{-1})	50	50	50	50	default
Canopy process option	Lumped	Lumped	Lumped	Lumped	default
Half-life on crop canopy (d)	10	10	10	10	default
Coefficient for uptake by plant (TSCF)	0	0	0	0	
Molar enthalpy of sorption (kJ/mole)	0	0	0	0	default

Appendix 2: Secondary effects of calcium cyanamide (as described by the Registrant 2018)

1. Preamble

Calcium cyanamide is known as a fertiliser with secondary side effects for more than 100 years. Although its beneficial secondary effects are highly appreciated by the farmers, there has not been much scientific research on the possible modes of action leading to these effects. Farmers as well as researchers were more interested in understanding *how* to achieve the intended beneficial secondary effects than in investigating *why* those secondary effects can be achieved. Thus, over the last century the application of this fertiliser has continuously been adapted to the technical progress in arable farming. Observations concerning lower disease incidence or lower disease severity were described as 'fungicidal side effects' regardless whether the effect was really based on fungicidal or fungistatic action, on improved crop resistance or enhanced natural antagonism due to increased bacterial activity in the soil. This example shows that for calcium cyanamide – in contrast to most pesticides – the observed effect cannot be explained by a single specific mode of action. When applied to the soil as fertiliser, calcium cyanamide always causes numerous changes simultaneously, which cannot be separated and quantified individually. Depending on the varying environmental conditions, one or the other property of the fertiliser contributes more or less to the overall effect. Thus, there is no single or typical mode of action for the various secondary effects of calcium cyanamide. The use of calcium cyanamide as fertiliser always involves a number of different effects and thus has to be evaluated in a holistic approach.

Nevertheless, in the following we will try to describe the most important secondary effects as they are known from literature. Most of them have already been described in our paper 'socio-economic advantages of calcium cyanamide fertiliser'.

2. Secondary herbicidal effect

The use of calcium cyanamide as fertiliser can lead to phytotoxic effects, which have to be considered in order to avoid crop damage. On the other hand, by applying this fertiliser deliberately, i.e. at the right time and rate, its phytotoxic potential or secondary herbicidal effect can be utilised to affect weeds without harming the crop. There are two explanations for the 'herbicidal' mode of action:

a) Scorching of plant leaves and germinating plant seeds due to the high alkalinity
   In contact with water calcium cyanamide reacts highly alkaline, resulting in a pH of 12.5. Thus, in the first half of the 20th century powdered calcium cyanamide was used to burn down broad-leaved weeds due to its scorching properties. Today only granulated calcium cyanamide fertiliser is used and thus the leaf-scorch effect is limited to grassland: Plants with leaf rosettes such as dandelion (*Taraxacum officinale*) or the highly toxic common ragwort (*Senecio jacobea*) can be pushed back in the plant community by fertilisation with calcium cyanamide. As the granules of the fertiliser roll into the middle of the rosettes like into a funnel they will scorch the "heart" of the plant. In a two-year trial fertilisation with granulated calcium cyanamide (400 kg/ha PERLKA® in early spring and 400 kg/ha PERLKA® in summer) reduced common ragwort on pasture between 97 and 100 % compared to unfertilised control (Dienstleistungszentrum Ländlicher Raum, 2015). However, in the same trial urea-ammonium-nitrate fertiliser solution reduced ragwort by 83 %. This indicates that not only the leaf-scorch of calcium cyanamide but also the improved nitrogen supply contributes to the herbicidal effect. Thus, this example supports the common

experience that the secondary side effects of calcium cyanamide cannot be separated from its fertilising effects. Comments received during consultation (e.g. #2748, 2762, 2768) stated that, according to farmer-experience, calcium cyanamide fertiliser also accelerates the biological degradation of leave-residues on the soil, which otherwise serve as a reservoir for the apple scab disease (*Venturia inaequalis*). The Dossier Submitter ackowledges this information as another crop-specific secondary benefit.

b) Phytotoxicity by cyanamide uptake
Cyanamide is a secondary plant compound which is produced naturally by plants such as Robinia and hairy vetch (Kamo et al. 2008). Cyanamide taken up in small quantities by the roots will be metabolised in plants within a few hours (Wünsch and Amberger, 1974). However, taken up at higher rates, cyanamide inhibits the plant enzyme catalase, responsible in plant cells for the breakdown of H2O2 (produced e.g. by photosynthesis) into non-hazardous compounds. Thus, higher cyanamide uptake leads to self-intoxication of plant cells with H2O2 (Amberger, 1961). The resulting symptoms are wilting, white leaf tips, necrosis and dying-off. These symptoms become visible within a few hours after the cyanamide uptake. This secondary herbicidal effect depends on the cyanamide concentration in the water taken up by the plants. Thus, it depends the application rate of calcium cyanamide and the rooting depth of the plants. Deeper rooting plants such as trees, shrubs, but also well-established arable crops such as brassicas, cereals are not very sensitive whereas shallow-rooted plants such as germinating weeds or seedlings are highly sensitive to fertilisation with calcium cyanamide. This effect is often utilised to reduce weed pressure in orchards and some vegetable crops such as asparagus, brassicas, onions and leek. In those minor crops fertilisation with calcium cyanamide in combination with mechanical weeding helps to keep the crops free of weeds. Using this secondary effect of calcium cyanamide is considered essential for minor crops as suitable and approved herbicides are often no longer available. In major arable crops such as cereals, oilseed rape, sugar beet and maize timing as well as rate of application of calcium cyanamide usually does not permit economically viable reduction of weeds.

3. Secondary fungicidal effect
In the literature a multitude of examples can be found, where the use of calcium cyanamide as fertiliser reduces the incidence and severity of fungal diseases. Usually, these observations are simplistically described as ‘fungicidal side effects’ without verifying if the effect is based on fungicidal or fungistatic activity or whether it is caused by improved plant resistance, increased natural antagonism or by changes in the soil environment (pH). In reality, the ‘fungicidal effect’ of calcium cyanamide is always a combination of all those effects as they occur simultaneously and cannot be separated from each other. The British scientist Geoffrey Dixon, who worked his entire professional life on plant diseases and integrated crop protection, describes the effects of calcium cyanamide fertiliser as increasing the pH of the soil, increasing the available calcium in the soil and increasing microbial activity, which makes the soil suppressive to soil borne plant pathogens such as clubroot (Dixon, 2016).

Although there are several different modes of action, which together result in a lower expression of various fungal crop diseases, some of them are described in the following paragraphs.

a) Fungistatic effect. Research has shown that resting spores and resting bodies of soil borne fungi do not germinate or do not release spores for a certain time after being exposed to calcium cyanamide fertiliser in the soil. Naiki and Dixon (1987) found, that zoospore release from resting spores of clubroot is inhibited upon contact with calcium cyanamide. Jones and Gray (1973) showed in pot trials that the sclerotia of the fungus Sclerotinia sclerotiorum did not germinate in soil fertilised with calcium cyanamide but germinated after being transferred to untreated soil. This is considered a typical example for a fungistatic effect. The same authors showed that calcium cyanamide inhibited the germination to a higher extent than cyanamide, indicating that this effect cannot be attributed to the metabolite cyanamide alone. Last, but not least these authors could show a residual effect of calcium cyanamide applied on the soil surface even when the sclerotia were placed on the soil 50 days after application. As the cyanamide released from the calcium cyanamide (powdered material in this study) must have been broken down long before the sclerotia placement, the effect must have been caused by other modes of action such as pH increase or increased microbial activity.

b) Effect on soil pH. Soil borne fungi are favoured by slightly acidic soils whereas bacteria are favoured by slightly alkaline soils. Calcium cyanamide is a highly alkaline fertiliser; in an aqueous suspension it shows a pH of 12.5. Although the quantities applied as a nitrogen fertiliser are too small to increase the pH of the entire soil, close to the fertiliser granules the soil will undergo a strong pH increase. If the fertiliser is not or only shallowly incorporated at least temporarily, a noticeable increase of the soil pH in the top soil layer is to be expected. Ma, Sun et al. (2013) could show that the addition of calcium cyanamide to the soil strongly increased the number and activity of soil bacteria, reduced the amount of fungi and improved the ratio of bacteria to fungi. Based on his studies on fungi, Verona (1970) postulates that the pH effect of calcium cyanamide may be responsible for the fungistatic effect after the breakdown of the cyanamide molecule in the soil.

There is another indirect effect of the increasing soil pH: The calcium hydroxide released from calcium cyanamide stabilises and improves the soil’s structure. A good soil structure prevents crust formation at the soil surface and ensures a sufficient aeration of the soil. This is essential for a good root development and for root healthiness. Furthermore, a good soil structure increases the soils’ infiltration rate for water and thus prevents or at least reduces waterlogging after heavy rainfall. As the zoospores of *Plasmodiophora brassicae* need wet soils to actively swim to the root hairs for penetration, a better soil structure reduces the risk of clubroot infections.

c) Increased bacterial activity. As Ma and Sun (2013) could show, calcium cyanamide significantly increases the number and activity of soil bacteria without affecting the microbial biodiversity. As many bacteria are competitors or antagonists of soil borne fungal pathogens, a soil with a highly active bacterial community will be more suppressive to fungal pathogens. As bacteria break down infectious crop residues (i.e. straw infested with Fusarium) much faster after fertilisation with calcium cyanamide, the increased bacterial activity removes the substrate for pathogens and thus reduces the disease pressure.

d) Increased plant resistance. The plant nutrient calcium plays an important role in cell wall formation and cell wall stability. During breakdown in the soil, calcium cyanamide releases water soluble calcium and improves the calcium supply of the plant. By this way the plants develop stronger cell walls which in turn hampers the penetration of fungal pathogens.

e) It is also well-known that excessive uptake of nitrogen increases the plant's susceptibility to fungal attacks. Such excessive nitrogen-uptake is caused by high nitrate contents in the soil. Due to its retarded nitrification in the soil calcium cyanamide avoids nitrate accumulation in soils and plants and thus reduces the susceptibility of the plants to fungal diseases. If plants take up small amounts of cyanamide from calcium cyanamide, its metabolism in plants results in an increasing content of arginine and ornithine (Wünsch und Amberger, 1989). Arginine and ornithine play an important role in the ability of the plants to counter biotic and abiotic stress and thus increases plant resistance (Winter et al. 2015). Verona (1970) could show that bean leaves were more resistant to the fungal pathogen *Colletotrichum lindemuthianum* after they had taken up small quantities of cyanamide.

When calcium cyanamide is used as a fertiliser, all the aforementioned 'modes of action' are working in parallel and synergistically. The resulting effect is an improvement of soil health as defined by FAO (2011): 'Soil health is the capacity of soil to function as a living system. Healthy soils maintain a diverse community of soil organisms that help to control plant disease, insect and weed pests, form beneficial symbiotic associations with plant roots, recycle essential plant nutrients, improve soil structure with positive repercussions for soil water and nutrient holding capacity, and ultimately improve crop production'.

4. Secondary molluscicidal effect

Fertilisers with a high alkalinity are known to have a secondary effect on slugs and snails. Laznik and Trdan (2016) observed a high efficacy of hydrated lime (calcium hydroxide), a common lime fertiliser, against slugs. When getting in contact with moisture, calcium cyanamide is transformed into hydrogen cyanamide and calcium hydroxide. Thus, a secondary side effect of calcium cyanamide on slugs and snails due to the alkalinity of the calcium cyanamide can be expected. Indeed such secondary molluscicidal effects often have been described in literature. Van den Bruel (1967) achieved in most of his trials a good control of the pond dwarf snail (*Galba truncatula*) on moist grassland with an application of 300 kg/ha of calcium cyanamide in early spring. Baker and DeGraaf (2013) could show that the eggs of the White Italian Snail (*Theba pisana*) are highly sensitive to calcium cyanamide. An application of 200 kg/ha PERLKA® completely inhibited the egg hatch.

However, further research showed that mortality of juvenile and adults snails of Theba pisana was not increased when exposed to soil fertilised with calcium cyanamide before at a rate of 200 kg/ha PERLKA®. This may be due to the fact that the snails can move away from the zones of high alkalinity around the fertiliser granules or can hide in their shell whereas the eggs cannot. Variable effects of calcium cyanamide on slugs and snails may be caused by different environmental conditions. Zhao et al. (2011) observed 71 % mortality of golden apple snails (*Pomacea canaliculata*) with 0.2 grams calcium cyanamide per litre water in paddy rice. Based on a water layer of 50 mm this corresponds to 10 g/m2 or only 100 kg/ha of calcium cyanamide. This indicates that the secondary effect on slugs and snails depends on humidity/water as a transmitter for the effects of the metabolites hydrated lime and cyanamide, which are formed simultaneously and are both expected to affect snails, slugs and their eggs. There is no information available which of the two metabolites, hydrogen cyanamide or calcium hydroxide is mainly responsible for the secondary side effects on slugs.

5. Secondary effect on wireworm damage

Numerous calcium cyanamide fertiliser trials in potatoes conducted by official agricultural research institutes as well as advisory boards in Germany always showed a reduced percentage of tubers damaged by wireworms (Zellner et al. 2003, Martinez, 2018). On average the damage was reduced by 24 to 32 %. In potatoes, calcium cyanamide is applied shortly before tuber planting or shortly after planting, before ridging. According to research of Ritter and Katroschan (2011) the effect of calcium cyanamide on wireworms appears to be a deterrent effect. The authors found out that wireworms placed in pipes filled with earth always actively moved away from zones where the soil had been fertilised with calcium cyanamide. They did not notice an increased mortality of the wireworms. Calcium cyanamide seems to drive out wireworms from zones of the soil containing this fertiliser. This is also an explanation for the regularly observed reduction of wireworm damage in maize, when calcium cyanamide fertiliser is placed as a band 5 centimetres below and 5 centimetres beside the maize seeds. The observed reduction of wireworm damage to the young maize seedlings is about 30 to 50 %. As there is only a fertiliser band on one side of the seed row, wire worms still can attack from the other side.

6. Secondary effect on infections with endoparasites of grazing animals

Research showed that fertilisation with calcium cyanamide on infested grassland reduces the number of viable infectious larvae (Brozeit, Wieners; 1976, Podstatzky, 2012). Infectious larvae of gastrointestinal worms, when present on the soil surface, are sensitive to the application of calcium cyanamide fertiliser. Thus, infested pasture needs to be fertilised in spring, when the overwintering larvae of the parasites just start to come out of the soil but have not yet moved to the grass leaves . At this time calcium cyanamide is not tolerated by the larvae due to its high alkalinity and its transient cyanamide phase. As the fertiliser cannot be incorporated into the soil on grassland the metabolites are concentrated in the soil water of the soil surface, which is also the transient medium of the infectious larvae. Thus, alkalinity and exposure to hydrogen cyanamide may be the causal agents for this secondary effect.

The dwarf mud snail Galba truncatula acts as an intermediate host for the liver fluke Fasciola hepatica. As pointed out under para 3 (secondary molluscicidal effect) this snail is sensitive to calcium cyanamide (Konermann, Supper; 1973). By decimating the number of intermediate hosts calcium cyanamide fertiliser helps to avoid infestations with the liver fluke.

Appendix 3: Applications of calcium cyanamide (PERLKA®) on different crops (as described by the Registrant)

Table 47. Recommended application rates and methods of PERLKA®

Crop	Applications
1. Vegetables – non brassica crops:	a. Broadcast application on bare soil with disc spreader 1 – 2 weeks before sowing/planting followed by uniform incorporation (15 cm), typical application rate: 400 kg/ha, time of application: depending on planting/sowing date of the crop between March and September (DE, BE, UK); February – September (IT)
	b. Underground fertilisation (deep placement): Placement of a fertiliser band in the soil below plants/seeds at planting, application with the planting/sowing machine through a fertilising tine (1-2 cm width, 15 cm deep), typical application rate: 200 kg/ha, time of application: April – September (depending on planting or sowing date of the crop) (DE, BE, UK, IT)
2. Vegetables – brassica crops:	a. Broadcast application on bare soil with disc spreader 1 – 2 weeks before sowing/planting followed by uniform incorporation (15 cm) typical application rate: 500 kg/ha time of application: depending on planting/sowing date of the crop between April and June
	b. Top dressings broadcast over the standing crop, application with disc spreader, no incorporation or uniform incorporation (10 cm) between the rows typical application rate: 400 kg/ha, time of application: 2 – 4 weeks after planting; May – July conditions at application: dry foliage and damp soil plant cover at application: ca. 20-30 %
	c. Band / row fertilisation at planting or after planting, application with planting machine or by cultivator with row applicator for fertiliser, no incorporation or uniform incorporation (10 cm) application rate: 100 – 200 kg/ha Time of application: April – September (depending on planting date)

3. Oil seed rape:	a. Broadcast application on bare soil with disc spreader immediately before sowing followed by uniform incorporation (10 cm) typical application rate: 200 kg/ha, time of application: August - September
	b. Underground fertilisation (deep placement): Placement of a fertiliser band in the soil below and besides the seeds during sowing, application by the sowing machine through a fertilising tine, (1-2 cm width, 10 cm deep) typical application rate: 100 kg/ha, time of application: August – September
	c. Top dressing broadcast application in late spring with disc spreader over the standing crop, application rate: 200 to 300 kg/ha, no incorporation, time of application: April conditions at application: dry foliage and damp soil plant cover at application: 100 %
4. Potatoes:	a. Broadcast application with disc spreader on bare soil followed by uniform incorporation (15 cm) , typical application rate: 400 kg/ha time of application (before planting or crop emergence, typically at the time of ridging): March – April
	b. Fertilisation only in the planting row (banding) followed by uniform incorporation (15 cm) application by the planting machine, application rate: 100 – 250 kg/ha time of application: April
	c. Underground fertilisation (deep placement): Fertiliser placement in the soil below plants/seeds at planting (15 cm), application with the planting machine through a fertilising tine, typical application rate: 250 kg/ha time of application: April
5. Maize, corn:	a. Presowing broadcast application with disc spreader on bare soil followed by uniform incorporation (10 cm), application rate: 400 kg/ha time of application: ca. 1 week before sowing, April

	b. Underground fertilisation (deep placement): Fertiliser placement in the soil below and besides the seeds at planting (10 cm), application with the sowing machine through a fertilising tine, typical application rate: 150 – 200 kg/ha time of application: April – May
6. Sugar beet:	a. Broadcast application about 10 days before sowing with disc spreader on bare soil followed by uniform incorporation (10 cm), typical application rate: 200 to 500 kg/ha time of application: March
	b. Underground fertilization (deep placement): Fertiliser placement in the soil below and besides the seeds at planting (10 cm), application with sowing machine through a fertilising tine, typical application rate: 100 – 200 kg/ha, time of application: March
7. Grassland:	a. Broadcast application with disc spreader over the grass at begin of vegetation in early spring, typical application rate: 300 kg/ha time of application: March – April plant cover: 100 %
	b. Second application in June – July depending on crop demand typical application rate: 250 kg/ha plant cover: 100 %
8. Pome/stone fruits:	a. Broadcast application with disc spreader shortly before sprouting in early spring, typical application rate: 250 kg/ha, usually no incorporation time of application: March – April
	b. Band application with row spreaders only in the planting row in early spring before sprouting, no incorporation typical application rate: 200 kg/ha time of application: March – April

9. Strawberries:	a. Preplant broadcast application 14 days before planting with disc spreader on bare soil followed by uniform incorporation (15 cm), typical application rate: 200 kg/ha application time: July – August
	b. Top dressing broadcast over overwintering crops in early spring with disc spreader, typical application rate: 200 kg/ha, usually no incorporation application time: March – April
10. Rice:	a. Presowing broadcast application latest one week before flooding (wet rice) or one week before sowing (dry rice); typical application rate: 300 kg/ha; application time March - April.
11. Vegetables under cover	a. Preplant/presowing broadcast application in glasshouse or under plastic cover followed by uniform incorporation (10 cm) typical application rate: 500 kg/ha; application time: June – August
12. Private gardens/consumer use	a. Preplant/presowing application on vegetable beds, spreading by hand or with a trolley spreader, uniform incorporation (10 cm) application rate 30 to 50 g/m^2 application time: spring, depending on crop typical application area: 20 – 40 m^2
	b. Top dressing on lawns, spreading by hand or with a trolley spreader, application rate 15 to 25 g/m^2 application time: April – September, up to 2 applications per year, min. application interval: 2 months typical application area: 100 - 300 m^2

(source: the Registrant)

Appendix 4: The release and transformation of cyanamide from PERLKA®F® in soil (Source The Registrant/Fraunhofer 2018a)

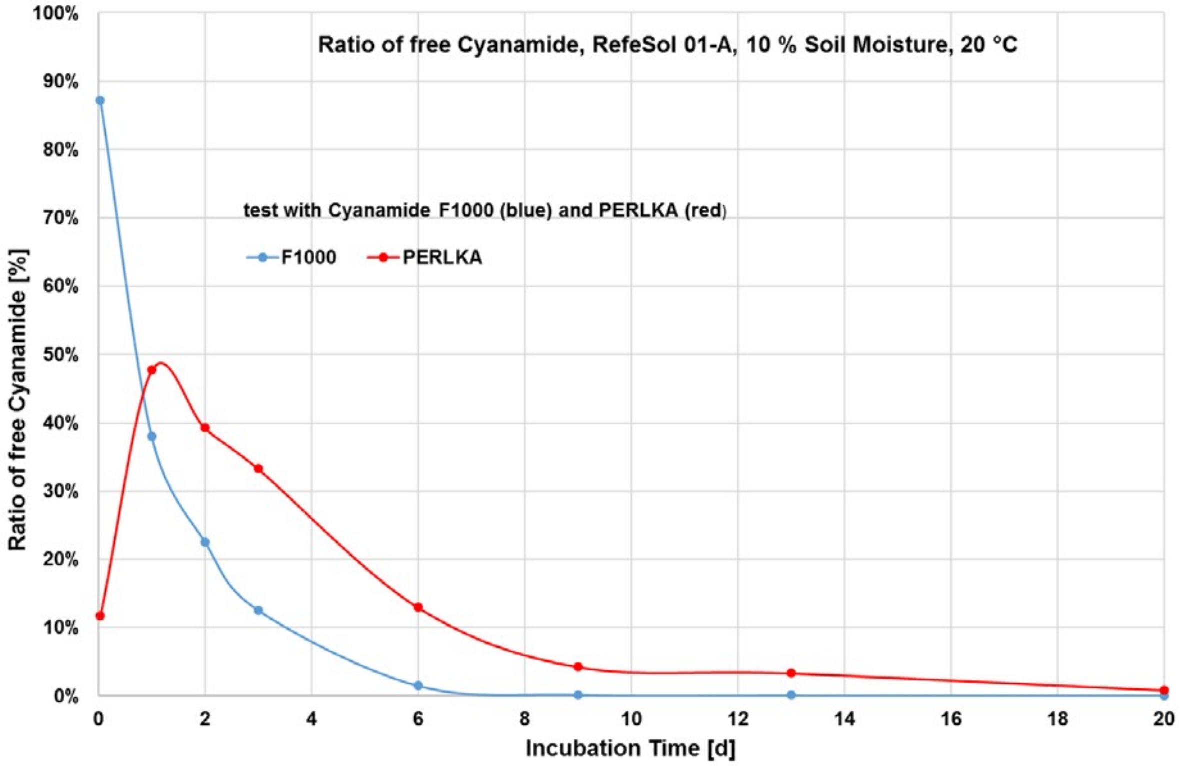


Figure 10. Ratio of free Cyanamide in RefeSol 01-A, 10 % soil moisture

The recovery for free cyanamide (measured as [$CY_{extractF1000}$/$CY_{addedF1000}$] after one hour of incubation was close to 90 %. Within six days less than 2 % of applied cyanamide could be found in the soil.

About 12 % of cyanamide were released from PERLKA® after one hour of incubation. The ratio [$CY_{extractPERLKA®}$/$CY_{addedPERLKA®}$] increased to a maximum of 47 % after one day.

Then the ratio [$CY_{extractPERLKA®}$/$CY_{addedPERLKA®}$] decreased slowly until day 20. The rate constants were calculated as:

RefeSol 01-A (10 % soil moisture):

k1 (degradation of cyanamide): 0.84205

k2 (degradation of calcium cyanamide (PERLKA®) to cyanamide): 1.1632 thus, resulting in

DT50 cyanamide: 0.82 days

DT50 PERLKA®: 0.60 days

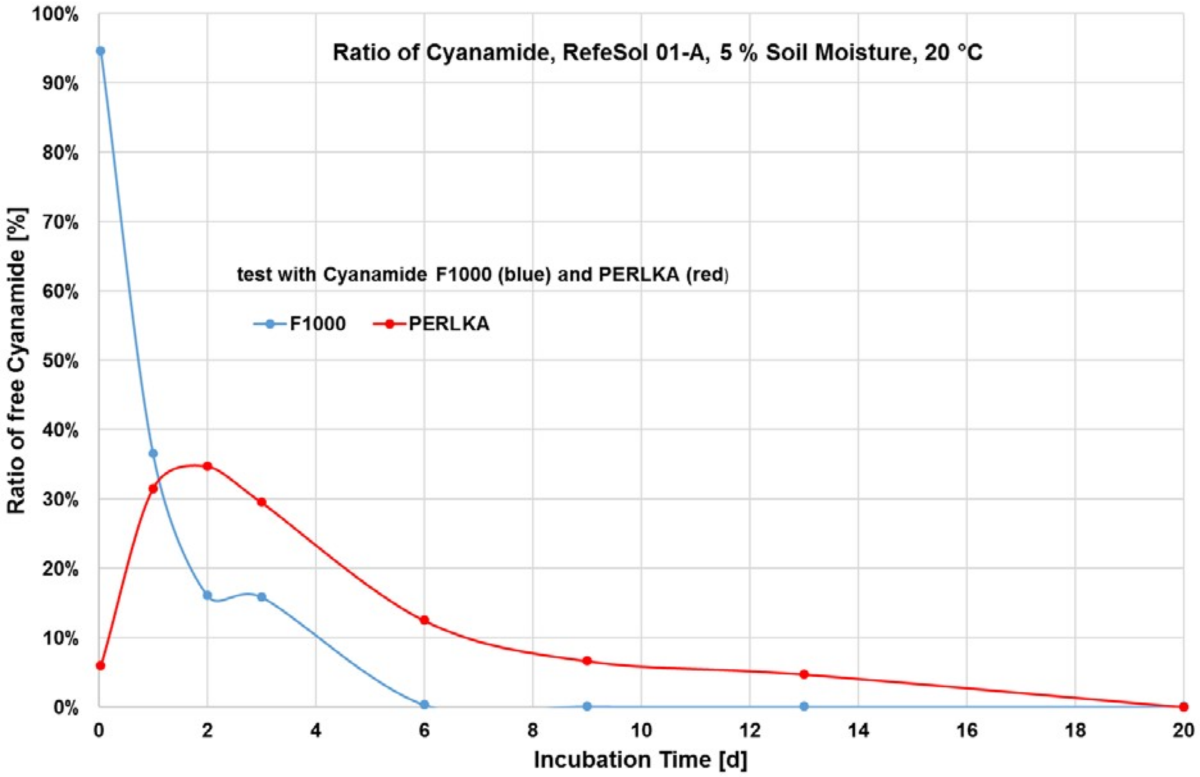


Figure 11. Ratio of free Cyanamide in RefeSol 01-A, 5 % soil moisture

RefeSol 01-A (5 % soil moisture):

k1 (degradation of cyanamide): 0.9020

k2 (degradation of calcium cyanamide (PERLKA®) to cyanamide): 0.5718 thus, resulting in

DT50 cyanamide: 0.77 days

DT50 PERLKA®: 1.21 days

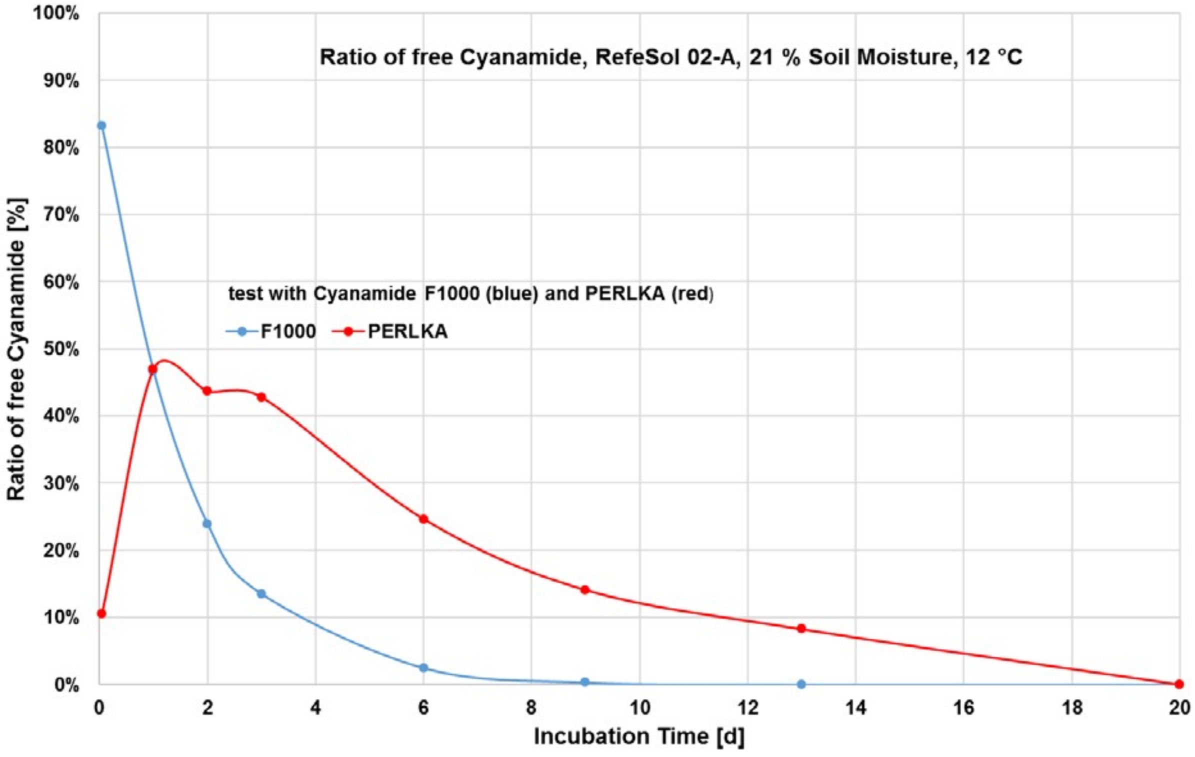


Figure 12. Ratio of Cyanamide in RefeSol 02-A, 21 % soil moisture

RefeSol 02-A (21 % soil moisture):

k1 (degradation of cyanamide): 0.7328

k2 (degradation of calcium cyanamide (PERLKA®) to cyanamide): 0.7944 thus, resulting in

DT50 cyanamide: 0.95 days

DT50 PERLKA®: 0.87 days

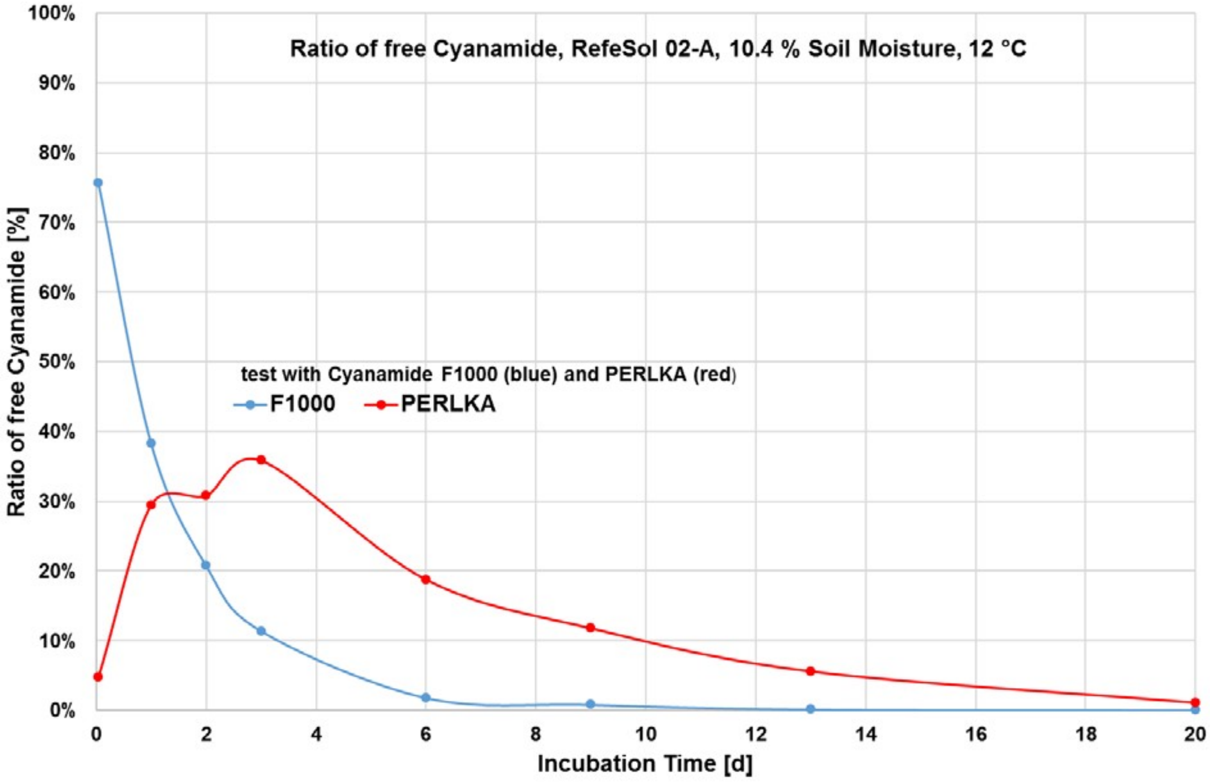


Figure 13. Ratio of Cyanamide in RefeSol 02-A, 10.4 % soil moisture

RefeSol02-A (10.4 % soil moisture):

k1 (degradation of cyanamide): 0.8789

k2 (degradation of calcium cyanamide (PERLKA®) to cyanamide): 0.4241 thus, resulting in

DT50 cyanamide: 0.79 days

DT50 PERLKA®: 1.63 days

Appendix 5: Results of the FOCUS surface water exposure modelling by the Dossier Submitter

Table 48. Results of FOCUS Step 3 surface water exposure modelling by the Dossier Submitter – worst case Application rate 700 kg/ha PERLKA® direct to bare soil surface; parent substance cyanamide.

Crop	Scenario	Maximum concentration in surface water (µg/l)		
		Cyanamide	Urea	Cyanoguanidine
Maize	D3_ditch	0.000079	0.001662	1594
Maize	D4_pond	0.008158	0.5088	3194.6
Maize	D4_stream	0.04359	1.272	1373.6
Maize	D5_pond	< 1e-6	< 1e-6	3770.3
Maize	D5_stream	< 1e-6	< 1e-6	1950.4
Maize	D6_ditch	2.769	0.9467	1835.3
Maize	R1_pond	3.214	3.213	2.384
Maize	R1_stream	612.7	603.3	444.2
Maize	R2_stream	105.2	569.9	395.8
Maize	R3_stream	0.1532	1.829	3.385

Maize	R4_stream	3478.3	3015.6	2442.9
Potatoes	D3_ditch	0.000027	0.000039	1535.5
Potatoes	D4_pond	0.000798	0.4936	2465.1
Potatoes	D4_stream	0.01134	2.08	994.9
Potatoes, 1st	D6_ditch	2.914	0.1963	1231.7
Potatoes, 2nd	D6_ditch	1.858	0.002674	1249.9
Potatoes	R1_pond	3.298	3.257	2.400
Potatoes	R1_stream	611.1	594.3	434.5
Potatoes	R2_stream	356.1	630.9	369.8
Potatoes	R3_stream	30397	5813.3	4451.5
Pome/stone fruit, early	D3_ditch	< 1e-6	< 1e-6	2079
Pome/stone fruit, early	D4_pond	0.000353	0.05425	3607.4
Pome/stone fruit, early	D4_stream	0.001886	0.1334	1677.4
Pome/stone fruit, early	D5_pond	< 1e-6	< 1e-6	3822.6
Pome/stone fruit, early	D5_stream	< 1e-6	< 1e-6	1962.2

Pome/stone fruit, early	R1_pond	0.00336	0.01353	0.008425
Pome/stone fruit, early	R1_stream	0.7906	3.134	1.935
Pome/stone fruit, early	R2_stream	9.147	17.29	9.927
Pome/stone fruit, early	R3_stream	8.318	92.24	78.09
Pome/stone fruit, early	R4_stream	0.000013	0.001569	0.001177
Vegetables, leafy, 1st	D3_ditch	0.000008	0.002528	1439.3
Vegetables, leafy, 2nd	D3_ditch	0.001549	0.0266	1494.1
Vegetables, leafy	D4_pond	0.000610	0.6385	2516.6
Vegetables, leafy	D4_stream	0.003272	1.797	1041.7
Vegetables, leafy	D6_ditch	2.357	0.005938	1452
Vegetables, leafy, 1st	R1_pond	0.3412	0.6106	0.5505
Vegetables, leafy, 2nd	R1_pond	< 1e-6	0.000207	0.000182
Vegetables, leafy, 1st	R1_stream	131.3	129.5	105.0
Vegetables, leafy, 2nd	R1_stream	< 1e-6	0.003294	0.002833
Vegetables, leafy, 1st	R2_stream	721.6	606.1	357.3

Vegetables, leafy, 2nd	R2_stream	< 1e-6	19.36	146
Vegetables, leafy, 1st	R3_stream	2888.4	768.3	527.9
Vegetables, leafy, 2nd	R3_stream	73.23	1003	987.8
Vegetables, leafy, 1st	R4_stream	4549.8	1692.8	1272.7
Vegetables, leafy, 2nd	R4_stream	244.4	2382.2	2390.4

Table 49. Results of FOCUS Step 3 surface water exposure modelling by the Dossier Submitter – reasonable worst case Application rate 300 kg/ha PERLKA® direct to bare soil surface; parent substance calcium cyanamide (PERLKA®)

Crop	Scenario	Maximum concentration in surface water (µg/l)		
		Cyanamide	Urea	Cyanoguanidine
Maize	D3_ditch	0.000041	no estimate possible	no estimate possible
Maize	D4_pond	0.005034	no estimate possible	no estimate possible
Maize	D4_stream	0.02697	no estimate possible	no estimate possible
Maize	D5_pond	< 1e-6	no estimate possible	no estimate possible
Maize	D5_stream	< 1e-6	no estimate possible	no estimate possible
Maize	D6_ditch	1.581	no estimate possible	no estimate possible

Maize	R1_pond	1.986	1.349	0.9901
Maize	R1_stream	378.6	253.4	184.4
Maize	R2_stream	58.21	245.9	168.6
Maize	R3_stream	0.09209	2.039	1.508
Maize	R4_stream	2052.1	1238	986.5
Potatoes	D3_ditch	0.000016	no estimate possible	no estimate possible
Potatoes	D4_pond	0.000494	no estimate possible	no estimate possible
Potatoes	D4_stream	0.006636	no estimate possible	no estimate possible
Potatoes, 1st	D6_ditch	1.739	no estimate possible	no estimate possible
Potatoes, 2nd	D6_ditch	0.9486	no estimate possible	no estimate possible
Potatoes	R1_pond	2.04	1.368	0.9967
Potatoes	R1_stream	378.0	249.6	180.4
Potatoes	R2_stream	205.2	268.9	155.6
Potatoes	R3_stream	15704.2	1948.6	1480.9
Pome/stone fruit, early	D3_ditch	< 1e-6	no estimate possible	no estimate possible

Pome/stone fruit, early	D4_pond	0.000227	no estimate possible	no estimate possible
Pome/stone fruit, early	D4_stream	0.001212	no estimate possible	no estimate possible
Pome/stone fruit, early	D5_pond	< 1e-6	no estimate possible	no estimate possible
Pome/stone fruit, early	D5_stream	< 1e-6	no estimate possible	no estimate possible
Pome/stone fruit, early	R1_pond	0.002625	0.006216	0.003867
Pome/stone fruit, early	R1_stream	0.6175	1.44	0.8883
Pome/stone fruit, early	R2_stream	5.25	7.373	4.184
Pome/stone fruit, early	R3_stream	6.268	46.1	38.9
Pome/stone fruit, early	R4_stream	0.000384	0.007051	0.006529
Vegetables, leafy, 1st	D3_ditch	0.000005	no estimate possible	no estimate possible
Vegetables, leafy, 2nd	D3_ditch	0.000963	no estimate possible	no estimate possible
Vegetables, leafy	D4_pond	0.000375	no estimate possible	no estimate possible
Vegetables, leafy	D4_stream	0.002014	no estimate possible	no estimate possible
Vegetables, leafy	D6_ditch	1.214	no estimate possible	no estimate possible
Vegetables, leafy, 1st	R1_pond	0.2045	0.2679	0.2350

Vegetables, leafy, 2nd	R1_pond	< 1e-6	0.00009	0.000078
Vegetables, leafy, 1st	R1_stream	78.69	53.73	42.91
Vegetables, leafy, 2nd	R1_stream	< 1e-6	0.001433	0.001217
Vegetables, leafy, 1st	R2_stream	434.8	251	147.0
Vegetables, leafy, 2nd	R2_stream	< 1e-6	8.371	62.47
Vegetables, leafy, 1st	R3_stream	1792.2	268.5	182.5
Vegetables, leafy, 2nd	R3_stream	37.81	434	423.2
Vegetables, leafy, 1st	R4_stream	2943.6	669.5	498.9
Vegetables, leafy, 2nd	R4_stream	117.3	1025.0	1022.6

Table 50. Results of FOCUS Step 3 surface water exposure modelling by the Dossier Submitter – reasonable worst case
Application rate 500 kg/ha PERLKA® by uniform incorporation to 10cm depth; parent substance calcium cyanamide (PERLKA®)

Crop	Scenario	Maximum concentration in surface water (µg/l)		
		Cyanamide	Urea	Cyanoguanidine
Maize	D3_ditch	0.000069	no estimate possible	no estimate possible
Maize	D4_pond	0.000899	no estimate possible	no estimate possible
Maize	D4_stream	0.004816	no estimate possible	no estimate possible
Maize	D5_pond	< 1e-6	no estimate possible	no estimate possible
Maize	D5_stream	< 1e-6	no estimate possible	no estimate possible
Maize	D6_ditch	0.05049	no estimate possible	no estimate possible
Maize	R1_pond	0.3753	0.2115	0.1553
Maize	R1_stream	71.55	39.71	28.93
Maize	R2_stream	7.365	28.16	19
Maize	R3_stream	0.00973	0.1958	0.143
Maize	R4_stream	246.7	147	117.1

Potatoes	D3_ditch	0.000027	no estimate possible	no estimate possible
Potatoes	D4_pond	0.000098	no estimate possible	no estimate possible
Potatoes	D4_stream	0.000931	no estimate possible	no estimate possible
Potatoes, 1st	D6_ditch	0.07662	no estimate possible	no estimate possible
Potatoes, 2nd	D6_ditch	0.04896	no estimate possible	no estimate possible
Potatoes	R1_pond	0.3822	0.2116	0.154
Potatoes	R1_stream	70.83	38.62	27.87
Potatoes	R2_stream	27.68	33.59	19.55
Potatoes	R3_stream	2115	241.5	182.7
Pome/stone fruit, early	D3_ditch	< 1e-6	no estimate possible	no estimate possible
Pome/stone fruit, early	D4_pond	0.000036	no estimate possible	no estimate possible
Pome/stone fruit, early	D4_stream	0.000194	no estimate possible	no estimate possible
Pome/stone fruit, early	D5_pond	< 1e-6	no estimate possible	no estimate possible
Pome/stone fruit, early	D5_stream	< 1e-6	no estimate possible	no estimate possible
Pome/stone fruit, early	R1_pond	0.000407	0.000714	0.000445

Pome/stone fruit, early	R1_stream	0.0958	0.1653	0.1023
Pome/stone fruit, early	R2_stream	0.6626	0.8767	0.4998
Pome/stone fruit, early	R3_stream	0.7593	4.813	4.023
Pome/stone fruit, early	R4_stream	0.000041	0.000607	0.000568
Vegetables, leafy, 1st	D3_ditch	0.000008	no estimate possible	no estimate possible
Vegetables, leafy, 2nd	D3_ditch	0.001596	no estimate possible	no estimate possible
Vegetables, leafy	D4_pond	0.00016	no estimate possible	no estimate possible
Vegetables, leafy	D4_stream	0.000865	no estimate possible	no estimate possible
Vegetables, leafy	D6_ditch	0.0763	no estimate possible	no estimate possible
Vegetables, leafy, 1st	R1_pond	0.04782	0.03423	0.0316
Vegetables, leafy, 2nd	R1_pond	< 1e-6	0.000007	0.000006
Vegetables, leafy, 1st	R1_stream	18.4	8.306	6.568
Vegetables, leafy, 2nd	R1_stream	< 1e-6	0.000106	0.000089
Vegetables, leafy, 1st	R2_stream	51.41	29.17	16.92
Vegetables, leafy, 2nd	R2_stream	< 1e-6	0.9174	6.708

Vegetables, leafy, 1st	R3_stream	253.6	29.69	20.13
Vegetables, leafy, 2nd	R3_stream	6.881	68.89	67.27
Vegetables, leafy, 1st	R4_stream	393.4	89.67	67.02
Vegetables, leafy, 2nd	R4_stream	34.32	161.3	153.6

Table 51. Results of FOCUS Step 3 surface water exposure modelling by the Dossier Submitter – reasonable worst case
Crop potatoes; parent substance calcium cyanamide (PERLKA®)

Step 3 results for potatoes

					PERLKA®		Cyanamide	
Application rate and method	season	Scenario	Water body	PAT	PECsw	PECsed	PECsw	PECsed
400 kg/ha PERLKA® (176 kg/ha calcium cyanamide) uniform incorporation 15 cm	1	D3	ditch	04.04.	0.000	0.000	0.000	0.000
		D4	pond	18.04.	0.000	0.000	0.001	0.001
			stream	18.04.	0.000	0.000	0.004	0.002
		D6	ditch	02.04.	0.000	0.000	0.096	0.010
		R1	pond	26.04.	0.000	0.001	0.240	0.044
			stream	26.04.	0.008	0.028	43.790	2.515
		R2	stream	22.04.	0.001	0.022	12.820	0.793
		R3	stream	04.04.	0.128	0.194	503.900	22.410
100 kg/ha PERLKA® (44 kg/ha calcium cyanamide) uniform incorporation 15 cm	1	D3	ditch	04.04.	0.000	0.000	0.000	0.000
		D4	pond	18.04.	0.000	0.000	0.000	0.000
			stream	18.04.	0.000	0.000	0.001	0.000
		D6	ditch	02.04.	0.000	0.000	0.024	0.003
		R1	pond	26.04.	0.000	0.000	0.060	0.011
			stream	26.04.	0.002	0.007	10.940	0.629
		R2	stream	22.04.	0.000	0.005	3.204	0.198
		R3	stream	04.04.	0.032	0.048	126.000	5.603

250 kg/ha PERLKA® (110 kg/ha calcium cyanamide) deep placement, 15 cm	1	D3	ditch	04.04.	0.000	0.000	0.000	0.000
		D4	pond	18.04.	0.000	0.000	0.001	0.001
			stream	18.04.	0.000	0.000	0.002	0.001
		D6	ditch	02.04.	0.000	0.000	0.060	0.006
		R1	pond	26.04.	0.000	0.000	0.000	0.000
			stream	26.04.	0.000	0.000	0.000	0.000
		R2	stream	22.04.	0.000	0.000	0.000	0.000
		R3	stream	04.04.	0.000	0.000	0.000	0.000

100 kg/ha PERLKA® (44 kg/ha calcium cyanamide) deep placement, 15 cm	1	D3	ditch	04.04.	0.000	0.000	0.000	0.000
		D4	pond	18.04.	0.000	0.000	0.000	0.000
			stream	18.04.	0.000	0.000	0.001	0.000
		D6	ditch	02.04.	0.000	0.000	0.024	0.003
		R1	pond	26.04.	0.000	0.000	0.000	0.000
			stream	26.04.	0.000	0.000	0.000	0.000
		R2	stream	22.04.	0.000	0.000	0.000	0.000
		R3	stream	04.04.	0.000	0.000	0.000	0.000

Table 52. Results of FOCUS Step 4 (including a buffer strip) surface water exposure modelling by the Dossier Submitter – reasonable worst case

Crop potatoes; parent substance calcium cyanamide (PERLKA®)

Step 4 results – potatoes - 10m buffer, including vegetated filter strip							
				PERLKA®		Cyanamide	
Application rate and method	season	Scenario	Water body	PECsw	PECsed	PECsw	PECsed
400 kg/ha PERLKA® (176 kg/ha calcium cyanamide) uniform incorporation 15 cm	1	D3	ditch	0.000	0.000	0.000	0.000
		D4	pond	0.000	0.000	0.001	0.001
			stream	0.000	0.000	0.004	0.002
		D6	ditch	0.000	0.000	0.096	0.010
		R1	pond	0.000	0.000	0.096	0.018
			stream	0.003	0.004	18.610	1.063
		R2	stream	0.000	0.003	5.726	0.352
		R3	stream	0.050	0.029	207.100	9.102
Step 4 results – potatoes - 20m buffer, including vegetated filter strip							
400 kg/ha PERLKA® (176 kg/ha calcium cyanamide) uniform incorporation 15 cm	1	D3	ditch	0.000	0.000	0.000	0.000
		D4	pond	0.000	0.000	0.001	0.001
			stream	0.000	0.000	0.004	0.002
		D6	ditch	0.000	0.000	0.096	0.010
		R1	pond	0.000	0.000	0.048	0.009
			stream	0.002	0.001	9.500	0.542
		R2	stream	0.000	0.001	2.977	0.183
		R3	stream	0.025	0.010	104.500	4.574

Table 53. Results of FOCUS Step 3 surface water exposure modelling by the Dossier Submitter – reasonable worst case
Crop winter oilseed rape; parent substance calcium cyanamide (PERLKA®)

Step 3 results - winter oilseed rape								
					PERLKA®		Cyanamide	
Application rate and method	season	Scenario	Water body	PAT	PECsw	PECsed	PECsw	PECsed
500 kg/ha PERLKA® (220 kg/ha calcium cyanamide) top dressing	1	D2	ditch	01.04.	0.000	0.000	8603.000	1244.900
			stream	01.04.	0.000	0.000	6085.600	674.800
		D3	ditch	04.04.	0.000	0.000	0.000	0.000
		D4	pond	18.04.	0.000	0.000	0.000	0.000
			stream	18.04.	0.000	0.000	0.000	0.000
		D5	pond	08.04.	0.000	0.000	0.000	0.000
			stream	08.04.	0.000	0.000	0.000	0.000
		R1	pond	26.04.	0.001	0.016	4.161	0.797
			stream	26.04.	0.173	0.475	1030.100	58.890
		R3	stream	04.04.	0.008	0.394	86.480	7.328
300 kg/ha PERLKA® (132 kg/ha calcium cyanamide) top dressing	1	D2	ditch	01.04.	0.000	0.000	5161.800	746.900
			stream	01.04.	0.000	0.000	3651.300	404.900
		D3	ditch	04.04.	0.000	0.000	0.000	0.000
		D4	pond	18.04.	0.000	0.000	0.000	0.000
			stream	18.04.	0.000	0.000	0.000	0.000
		D5	pond	08.04.	0.000	0.000	0.000	0.000
			stream	08.04.	0.000	0.000	0.000	0.000

		R1	pond	26.04.	0.001	0.010	2.496	0.478
			stream	26.04.	0.104	0.285	618.000	35.330
		R3	stream	04.04.	0.005	0.237	51.900	4.397
100 kg/ha PERLKA® (44 kg/ha calcium cyanamide) top dressing	1	D2	ditch	01.04.	0.000	0.000	1720.600	249.000
			stream	01.04.	0.000	0.000	1217.100	135.000
		D3	ditch	04.04.	0.000	0.000	0.000	0.000
		D4	pond	18.04.	0.000	0.000	0.000	0.000
			stream	18.04.	0.000	0.000	0.000	0.000
		D5	pond	08.04.	0.000	0.000	0.000	0.000
			stream	08.04.	0.000	0.000	0.000	0.000
		R1	pond	26.04.	0.000	0.003	0.832	0.159
			stream	26.04.	0.035	0.095	206.000	11.780
		R3	stream	04.04.	0.002	0.079	17.300	1.466
200 kg/ha PERLKA® (88 kg/ha calcium cyanamide) uniform incorporation 10 cm	1	D2	ditch	03.09.	0.000	0.000	19.840	2.023
			stream	03.09.	0.000	0.000	12.420	0.901
		D3	ditch	19.08.	0.000	0.000	0.137	0.087
		D4	pond	27.08.	0.000	0.000	0.008	0.005
			stream	27.08.	0.000	0.000	0.021	0.011
		D5	pond	27.08.	0.000	0.000	0.000	0.000
			stream	27.08.	0.000	0.000	0.000	0.000
		R1	pond	20.08.	0.000	0.000	0.000	0.000

			stream	20.08.	0.000	0.000	0.000	0.000
		R3	stream	28.08.	0.008	0.599	41.340	3.142
100 kg/ha PERLKA® (44 kg/ha calcium cyanamide) uniform incorporation 10 cm	1	D2	ditch	03.09.	0.000	0.000	9.922	1.012
			stream	03.09.	0.000	0.00	6.208	0.451
		D3	ditch	19.08.	0.000	0.000	0.069	0.044
		D4	pond	27.08.	0.000	0.000	0.004	0.002
			stream	27.08.	0.000	0.000	0.011	0.006
		D5	pond	27.08.	0.000	0.000	0.000	0.000
			stream	27.08.	0.000	0.000	0.000	0.000
		R1	pond	20.08.	0.000	0.000	0.000	0.000
			stream	20.08.	0.000	0.000	0.000	0.000
		R3	stream	28.08.	0.004	0.300	20.670	1.571

Table 54. Results of FOCUS Step 4 surface water exposure modelling by the Dossier Submitter – reasonable worst case
Crop winter oilseed rape; parent substance calcium cyanamide (PERLKA®)

Step 4 results - winter oilseed rape - 10m buffer, including vegetated filter strip								
					PERLKA®		cyanamide	
Application rate and method	season	Scenario	Water body	PAT	PECsw	PECsed	PECsw	PECsed
300 kg/ha PERLKA® (132 kg/ha calcium cyanamide) top dressing	1	D2	ditch	01.04.	0.000	0.000	5161.800	746.900
			stream	01.04.	0.000	0.000	3651.300	404.900
		D3	ditch	04.04.	0.000	0.000	0.000	0.000
		D4	pond	18.04.	0.000	0.000	0.000	0.000
			stream	18.04.	0.000	0.000	0.000	0.000
		D5	pond	08.04.	0.000	0.000	0.000	0.000
			stream	08.04.	0.000	0.000	0.000	0.000
		R1	pond	26.04.	0.000	0.001	0.998	0.191
			stream	26.04.	0.043	0.044	260.000	14.780
		R3	stream	04.04.	0.001	0.036	23.680	1.998
200 kg/ha PERLKA® (88 kg/ha calcium cyanamide) uniform incorporation 10 cm	1	D2	ditch	03.09.	0.000	0.000	19.840	2.023
			stream	03.09.	0.000	0.000	12.420	0.901
		D3	ditch	19.08.	0.000	0.000	0.137	0.087
		D4	pond	27.08.	0.000	0.000	0.008	0.005
			stream	27.08.	0.000	0.000	0.021	0.011
		D5	pond	27.08.	0.000	0.000	0.000	0.000
			stream	27.08.	0.000	0.000	0.000	0.000
		R1	pond	20.08.	0.000	0.000	0.000	0.000

			stream	20.08.	0.000	0.000	0.000	0.000
		R3	stream	28.08.	0.001	0.090	18.870	1.382
Step 4 results - winter oilseed rape - 20m buffer, including vegetated filter strip								
300 kg/ha PERLKA® (132 kg/ha calcium cyanamide) top dressing	1	D2	ditch	01.04.	0.000	0.000	5161.800	746.900
			stream	01.04.	0.000	0.000	3651.300	404.900
		D3	ditch	04.04.	0.000	0.000	0.000	0.000
		D4	pond	18.04.	0.000	0.000	0.000	0.000
			stream	18.04.	0.000	0.000	0.000	0.000
		D5	pond	08.04.	0.000	0.000	0.000	0.000
			stream	08.04.	0.000	0.000	0.000	0.000
		R1	pond	26.04.	0.000	0.000	0.499	0.095
			stream	26.04.	0.022	0.015	132.300	7.508
		R3	stream	04.04.	0.001	0.012	12.430	1.047
200 kg/ha PERLKA® (88 kg/ha calcium cyanamide) uniform incorporation 10 cm	1	D2	ditch	03.09.	0.000	0.000	19.840	2.023
			stream	03.09.	0.000	0.000	12.420	0.901
		D3	ditch	19.08.	0.000	0.000	0.137	0.087
		D4	pond	27.08.	0.000	0.000	0.008	0.005
			stream	27.08.	0.000	0.000	0.021	0.011
		D5	pond	27.08.	0.000	0.000	0.000	0.000
			stream	27.08.	0.000	0.000	0.000	0.000
		R1	pond	20.08.	0.000	0.000	0.000	0.000
			stream	20.08.	0.000	0.000	0.000	0.000

		R3	stream	28.08.	0.000	0.030	9.898	0.720

Table 55. Results of FOCUS Step 3 surface water exposure modelling by the Dossier Submitter – reasonable worst case

Crop leafy vegetables; parent substance calcium cyanamide (PERLKA®)

Step 3 results – leafy vegetables								
					PERLKA®		Cyanamide	
Application rate and method	season	Scenario	Water body	PAT	PECsw	PECsed	PECsw	PECsed
400 kg/ha PERLKA® (176 kg/ha calcium cyanamide) top dressing	1	D3	ditch	14.06.	0.000	0.000	0.000	0.000
		D4	pond	01.06.	0.000	0.000	0.004	0.003
			stream	01.06.	0.000	0.000	0.019	0.009
		D6	ditch	01.06.	0.000	0.000	0.000	0.000
		R1	pond	01.06.	0.000	0.000	0.785	0.123
			stream	01.06.	0.000	0.012	16.630	1.270
		R2	stream	04.06.	0.000	0.007	8.984	0.817
		R3	stream	02.06.	0.001	0.107	34.410	3.004
		R4	stream	01.06.	0.003	0.107	154.100	11.880
500 kg/ha PERLKA® (220 kg/ha calcium cyanamide) uniform incorporation 15cm	1	D3	ditch	04.05.	0.000	0.000	0.000	0.000
		D4	pond	16.05.	0.000	0.000	0.001	0.000
			stream	16.05.	0.000	0.000	0.002	0.001
		D6	ditch	03.05.	0.000	0.000	0.001	0.000
		R1	pond	02.05.	0.000	0.001	0.184	0.040
			stream	02.05.	0.011	0.035	28.160	1.502

		R2	stream	07.05.	0.008	0.280	160.200	11.280
		R3	stream	18.05.	0.022	0.357	185.000	11.180
		R4	stream	04.05.	0.181	4.725	310.500	24.490
150 kg/ha PERLKA® (66 kg/ha calcium cyanamide) uniform incorporation 15cm	1	D3	ditch	04.05.	0.000	0.000	0.000	0.000
		D4	pond	16.05.	0.000	0.000	0.000	0.000
			stream	16.05.	0.000	0.000	0.000	0.000
		D6	ditch	03.05.	0.000	0.000	0.000	0.000
		R1	pond	02.05.	0.000	0.000	0.055	0.012
			stream	02.05.	0.003	0.010	8.452	0.451
		R2	stream	07.05.	0.002	0.084	48.030	3.382
		R3	stream	18.05.	0.006	0.107	55.480	3.352
		R4	stream	04.05.	0.054	1.418	93.130	7.347
200 kg/ha PERLKA® (88 kg/ha calcium cyanamide) deep placement 15cm	1	D3	ditch	04.05.	0.000	0.000	0.000	0.000
		D4	pond	16.05.	0.000	0.000	0.000	0.000
			stream	16.05.	0.000	0.000	0.001	0.000
		D6	ditch	03.05.	0.000	0.000	0.000	0.000
		R1	pond	02.05.	0.000	0.000	0.000	0.000
			stream	02.05.	0.000	0.000	0.000	0.000
		R2	stream	07.05.	0.000	0.000	0.000	0.000
		R3	stream	18.05.	0.000	0.000	0.000	0.000
		R4	stream	04.05.	0.000	0.000	0.000	0.000
100 kg/ha PERLKA®	1	D3	ditch	04.05.	0.000	0.000	0.000	0.000

(44 kg/ha calcium cyanamide) deep placement 15cm		D4	pond	16.05.	0.000	0.000	0.000	0.000
			stream	16.05.	0.000	0.000	0.000	0.000
		D6	ditch	03.05.	0.000	0.000	0.000	0.000
		R1	pond	02.05.	0.000	0.000	0.000	0.000
			stream	02.05.	0.000	0.000	0.000	0.000
		R2	stream	07.05.	0.000	0.000	0.000	0.000
		R3	stream	18.05.	0.000	0.000	0.000	0.000
		R4	stream	04.05.	0.000	0.000	0.000	0.000

Table 56. Results of FOCUS Step 4 surface water exposure modelling by the Dossier Submitter – reasonable worst case
Crop leafy vegetables; parent substance calcium cyanamide (PERLKA®)

Step 4 results - leafy vegetables - 10m buffer, including vegetated filter strip							
				PERLKA®		Cyanamide	
Application rate and method	season	Scenario	Water body	PECsw	PECsed	PECsw	PECsed
500 kg/ha PERLKA® (220 kg/ha calcium cyanamide) uniform incorporation 15cm	1	D3	ditch	0.000	0.000	0.000	0.000
		D4	pond	0.000	0.000	0.001	0.000
			stream	0.000	0.000	0.002	0.001
		D6	ditch	0.000	0.000	0.001	0.000
		R1	pond	0.000	0.000	0.074	0.016
			stream	0.005	0.005	11.320	0.603
		R2	stream	0.003	0.042	71.390	5.007
		R3	stream	0.009	0.054	84.050	5.092
		R4	stream	0.081	0.712	140.600	10.870

Step 4 results - leafy vegetables - 20m buffer, including vegetated filter strip							
500 kg/ha PERLKA® (220 kg/ha calcium cyanamide) uniform incorporation 15cm	1	D3	ditch	0.000	0.000	0.000	0.000
		D4	pond	0.000	0.000	0.001	0.000
			stream	0.000	0.000	0.002	0.001
		D6	ditch	0.000	0.000	0.001	0.000
		R1	pond	0.000	0.000	0.037	0.008
			stream	0.002	0.002	5.670	0.302
		R2	stream	0.002	0.014	37.070	2.599
		R3	stream	0.005	0.018	43.990	2.671
		R4	stream	0.042	0.238	73.570	5.663

Appendix 6: Results of the FOCUS surface water exposure modelling by the Registrant (Fraunhofer: STEP 3: 2018b and STEP 4: 2019b)

Table .: Application pattern of PERLKA® in various crops considered for the simulations

Crop	App. method	Incorp. Depth (cm)	App. Rate (kg/ha)	Start of the application window
Maize	Incorporated	at 10 cm	400	14 days before emergence (= planting)
Potatoes	Incorporated	at 15 cm	400	14 days before emergence (= planting)
Sugar Beets	Incorporated	at 10 cm	350	14 days before emergence (= planting)
Sugar Beets	deep placement	at 10 cm	200	14 days before emergence (= planting)
cabbage*	Incorporated	at 15 cm	500	14 days before emergence (= time of planting)
cabbage*	Incorporated	at 15 cm	400	14 days before emergence (= time of planting)
cabbage*	Incorporated	at 10 cm	320^	4 weeks after planting
Grass	Granular app	at 0 cm	300	March-April
Vegetables (fruiting)	Incorporated.	at 15 cm	200	14 days before emergence (= time of planting)
Vegetables (fruiting)	Granular app.	at 0 cm	200	14 days before emergence (= time of planting)

* The FOCUS crop ‘leafy vegetables’ was used ^400 kg/ha with 20% crop interception

Table 57. Global maximum concentrations or PERLKA® and Cyanamide at FOCUS Step 3

Crop		PERLKA®	Cyanamide	
		PECsw (µg/L)	PECsw (µg/L)	PECsed (µg/kg)
Maize, 400kg, uniform incorp. 10 cm	D3_Ditch	0	0	0
	D4_Pond	0	0	0
	D4_Stream	0	0	0
	D5_Pond	0	0	0
	D5_Stream	0	0	0
	D6_Ditch	0	0	0
	R1_Pond	0	0	0
	R1_Stream	0	9	0
	R2_Stream	0	0	0
	R3_Stream	0	0	0
	R4_Stream	0	17	1
Potatoes, 400kg uniform incorp. 15 cm	D3_Ditch	0	0	0

	D4_Pond	0	0	0
	D4_Stream	0	0	0
	D6_Ditch	0	0	0
	D6_Ditch	0	0	0
	R1_Pond	0	0	0
	R1_Stream	0.002	5.721	0.328
	R2_Stream	0.002	0.8747	0.06844
	R3_Stream	0.304	554.8	26.03
Sugar beet, 350kg, uniform incorp. 10 cm	D3_Ditch	0	0	0
	D4_Pond	0	0.000	0.000
	D4_Stream	0	0.000	0.000
	R1_Pond	0	0.007	0.001
	R1_Stream	0.001	2.357	0.126
	R3_Stream	0.557	672.800	31.510
Sugar beet, 200kg, deep placement 10 cm	D3_Ditch	0	0	0

	D4_Pond	0	0.000	0.000
	D4_Stream	0	0.000	0.000
	R1_Pond	0	0.000	0.000
	R1_Stream	0.000	0.000	0.000
	R3_Stream	0.000	0.000	0.000
Leafy vegetables, 400kg, uniform incorp. 15 cm	D3_Ditch	0	0	0
	D3_Ditch	0	0	0
	D4_Pond	0	0	0
	D4_Stream	0	0.000002	0
	D6_Ditch	0	0.000009	0
	R1_Pond	0.000	0.003	0.000
	R1_Pond	0.000	0.000	0
	R1_Stream	0.001	1.092	0.058
	R1_Stream	0.000	0.000	0.000
	R2_Stream	0	3.436	0

	R2_Stream	0.000	0	0
	R3_Stream	0.091	44.130	2.450
	R3_Stream	0	0.065	0.006
	R4_Stream	0.061	45.140	3.492
	R4_Stream	0.000	0.686	0.053
Cabbage, 500kg, uniform incorp. 15 cm	D3_Ditch	0	0	0
	D3_Ditch	0	0.000	0.000
	D4_Pond	0	0.000	0.000
	D4_Stream	0	0.000	0.000
	D6_Ditch	0	0.000	0.000
	R1_Pond	0	0.004	0.001
	R1_Pond	0	0	0
	R1_Stream	0	1.365	0.073
	R1_Stream	0.000	0	0
	R2_Stream	0.001	4.296	0.2522

	R2_Stream	0	0	0
	R3_Stream	0.114	55.16	3.063
	R3_Stream	0.000016	0.08145	0.007124
	R4_Stream	0.077	56.42	4.366
	R4_Stream	0.000	0.8571	0.06677
Cabbage, 320kg (400 kg/ha with 20% crop interception), uniform incorp. 10 cm	D3_Ditch	0	0	0
	D3_Ditch	0	0.000065	0.000042
	D4_Pond	0	0.000102	0.000062
	D4_Stream	0	0.000325	0.000162
	D6_Ditch	0	0.01036	0.000751
	R1_Pond	0.002102	3.022	0.4173
	R1_Pond	0.000004	0.009265	0.00172
	R1_Stream	0.06669	151.8	9.029
	R1_Stream	0.002066	5.124	0.2266
	R2_Stream	0.02484	99.31	5.189

	R2_Stream	0	0	0
	R3_Stream	0	0.001346	0.000114
	R3_Stream	0.000004	0.09803	0.007621
	R4_Stream	0.08801	71.42	5.547
	R4_Stream	0.00062	3.324	0.256
Grassland, 300kg, uniform incorp. 0 cm	D1_Ditch	-	-	-
	D1_Stream	-	-	-
	D2_Ditch	0	1900.400	375.500
	D2_Stream	0	1792.900	184.300
	D3_Ditch	0	0	0
	D4_Pond	0	0	0
	D4_Stream	0	0	0
	D5_Pond	0	0	0
	D5_Stream	0	0	0
	R2_Stream	0	0	0

	R3_Stream	0	0.365	0.031
Strawberries, 200kg, uniform incorp. 15 cm	D6_Ditch	0	0.001	0.000
	R2_Stream	0	0.460	0.036
	R3_Stream	0	3	0
	R4_Stream	0	5.854	0.500
Strawberries, 200kg, uniform incorp. 0 cm	D6_Ditch	0	0.001	0.000
	R2_Stream	0	2.961	0.235
	R3_Stream	0	19	1
	R4_Stream	0	37.530	3.253

Table 58. FOCUS STEP 4 modelling: maximum concentrations of PERLKA® with vegetated buffer strips of varying widths

Crop		PERLKA®	Cyanamide (PECsw (µg/L))			
		PECsw (µg/L)	Vegetated buffer strip widths			
Vegetables, 400kg, uniform incorp. 0 cm	R4_Stream	0	1m	5m	10m	20m
			281.9	183.4	127.7	66.8

Appendix 7: Results of the FOCUS PEARL groundwater modelling by the Dossier Submitter

Table 59. Results of FOCUS PEARL groundwater exposure modelling by the Dossier Submitter – worst case Application rate 700 kg/ha PERLKA® direct to bare soil surface; parent substance cyanamide.

Location	Crop	Concentration closest to the 80th percentile (µg/L)	
		Cyanamide	Cyanoguanidine
Chateaudun	Apples	0.260815	9910.4
Chateaudun	Maize	0.000005	7726.1
Chateaudun	Potatoes	0.000004	10322.9
Hamburg	Apples	67.529555	15355.0
Hamburg	Maize	0.000037	9680.8
Hamburg	Potatoes	0.000035	9072.2
Jokioinen	Apples	196.26763	17592.2
Jokioinen	Potatoes	0.001122	10040.8
Kremsmuenster	Apples	5.808471	6755.9
Kremsmuenster	Maize	0.001692	5456.3
Kremsmuenster	Potatoes	0.00185	5640.9

Okehampton	Apples	24.450515	5487.9
Okehampton	Maize	0.005163	4710.8
Okehampton	Potatoes	0.008996	4751.1
Piacenza	Apples	12.59813	9157.9
Piacenza	Maize	0.000325	8388.5
Piacenza	Potatoes	0.001882	7543.5
Porto	Apples	21.394151	3513.9
Porto	Maize	0.000053	3221.1
Porto	Potatoes	0.071545	3675.6
Porto	Vegbeans	1.211644	3822.7
Sevilla	Apples	0.187476	12684.1
Sevilla	Maize	0	15791.7
Sevilla	Potatoes	0.016901	12368.3
Thiva	Apples	0.150782	19306.8
Thiva	Maize	0	16763.3

Thiva	Potatoes	0.000065	16694.3
Thiva	Vegbeans	0	10274.9

Table 60. Results of FOCUS PEARL groundwater exposure modelling by the Dossier Submitter – reasonable worst case
Application rate 300 kg/ha PERLKA® direct to bare soil surface; parent substance calcium cyanamide (PERLKA®)

Location	Crop	Concentration closest to the 80th percentile (µg/L)		
		Calcium cyanamide	Cyanamide	Cyanoguanidine
Chateaudun	Apples	0	0.0982	4249.7
Chateaudun	Maize	0	0.000003	3305.8
Chateaudun	Potatoes	0	0.000002	4415.7
Hamburg	Apples	0	23.459407	6515.2
Hamburg	Maize	0	0.000019	4138.0
Hamburg	Potatoes	0	0.000018	3877.5
Jokioinen	Apples	0	16.012706	7299.4
Jokioinen	Potatoes	0	0.000683	4296.4
Kremsmuenster	Apples	0	1.068757	2923.2

Kremsmuenster	Maize	0	0.001105	2337.9
Kremsmuenster	Potatoes	0	0.000258	2412.7
Okehampton	Apples	0	9.725799	2356.4
Okehampton	Maize	0	0.002852	2007.1
Okehampton	Potatoes	0	0.004258	2030.3
Piacenza	Apples	0	6.503681	3915.1
Piacenza	Maize	0	0.000168	3561.4
Piacenza	Potatoes	0	0.000244	3234.1
Porto	Apples	0	7.91493	1502.3
Porto	Maize	0	0.000027	1377.6
Porto	Potatoes	0	0.01447	1585.4
Porto	Vegbeans	0	0.357177	1642.2
Sevilla	Apples	0	0.081746	5426.4
Sevilla	Maize	0	0	6755.0
Sevilla	Potatoes	0	0.009271	5293.7

Thiva	Apples	0	0.08504	8260.8
Thiva	Maize	0	0	7171.7
Thiva	Potatoes	0	0.000017	7141.3
Thiva	Vegbeans	0	0	4394.2

Table 61. Results of FOCUS PEARL groundwater exposure modelling by the Dossier Submitter – reasonable worst case Application rate 500 kg/ha PERLKA® by uniform incorporation to 10cm depth; parent substance calcium cyanamide (PERLKA®)

Location	Crop	Concentration closest to the 80th percentile (µg/L)		
		Calcium cyanamide	Cyanamide	Cyanoguanidine
Chateaudun	Apples	0	0.374248	7076.7
Chateaudun	Maize	0	0.000011	5502.5
Chateaudun	Potatoes	0	0.000007	7355.2
Hamburg	Apples	0	63.583486	10856.7
Hamburg	Maize	0	0.000133	6915.6
Hamburg	Potatoes	0	0.000154	6467.0
Jokioinen	Apples	0	70.124519	11932.0

Jokioinen	Potatoes	0	0.005219	6997.0
Kremsmuenster	Apples	0	3.24382	4859.9
Kremsmuenster	Maize	0	0.007683	3887.1
Kremsmuenster	Potatoes	0	0.002903	4014.8
Okehampton	Apples	0	22.789639	3901.0
Okehampton	Maize	0	0.007932	3352.8
Okehampton	Potatoes	0	0.018591	3389.1
Piacenza	Apples	0	15.531634	6534.1
Piacenza	Maize	0	0.000802	5969.0
Piacenza	Potatoes	0	0.001745	5419.5
Porto	Apples	0	19.311801	2505.9
Porto	Maize	0	0.000218	2315.1
Porto	Potatoes	0	0.106598	2632.9
Porto	Vegbeans	0	1.446913	2715.0
Sevilla	Apples	0	0.187209	9061.6

Sevilla	Maize	0	0	11227.7
Sevilla	Potatoes	0	0.024226	8798.1
Thiva	Apples	0	0.261114	13802.2
Thiva	Maize	0	0	11946.2
Thiva	Potatoes	0	0.000134	11892.4
Thiva	Vegbeans	0	0	7351.7

Appendix 8: Results of the FOCUS PEARL groundwater modelling by the Registrant (Fraunhofer 2018c)

Table 62. Characteristics of the nine weather and soil scenarios created by FOCUS PEARL

Location	Soil type (USDA)	Organic Matter [%]	Annual average air temperature [°C]	Annual sum of precipitation [mm]
Châteaudun	silty clay loam	2.4	11.3	648+ I*
Hamburg	sandy loam	2.6	9.0	786
Jokioinen	loamy sand	7.0	4.1	638
Kremsmünster	loam/silt loam	3.6	8.6	900
Okehampton	loam	3.8	10.2	1038
Piacenza	loam	2.2	13.2	857 + I*
Porto	loam	2.5	14.8	1150
Sevilla	silt loam	1.6	17.9	493 + I*
Thiva	loam	1.3	16.2	500 + I*

*irrigation

Table 63. Results of FOCUS PEARL groundwater exposure modelling by the Registrant – reasonable worst case 80th percentile of annual leaching concentration for PERLKA® and cyanamide

Crop: cabbage, application rate 500 kg/ha PERLKA®, application by uniform incorporation to 15cm.

Computer model	FOCUS PEARL	
Scenario	Cabbage, 500 kg/ha, 15 cm uniform incorporation.	
Location	80th percentile of concentration in leachate	80th percentile of concentration in leachate
	(µg Ca CN2/L)	(µg cyanamide/L)
CHATEAUDUN	0	0
HAMBURG	0	0.000002
JOKIOINEN	0	0.000066
KREMSMUENSTER	0	0.000065
PORTO	0	0.102289
SEVILLA	0	0
THIVA	0	0

Table 64. Reasonable 80th percentile of annual leaching concentration for PERLKA® and cyanamide

Crop: potatoes, application rate 400 kg/ha PERLKA®, application by uniform incorporation to 15cm.

Computer model	FOCUS PEARL	
Scenario	Potatoes, 400 kg/ha,15 cm uniform incorp.	
Location	80th percentile of concentration in leachate	80th percentile of concentration in leachate
	(µg Ca CN2/L	(µg cyanamide/L)
CHATEAUDUN	0	0
HAMBURG	0	0.000002
JOKIOINEN	0	0.000111
KREMSMUENSTER	0	0.000099
OKEHAMPTON	0	0.001687
PIACENZA	0	0.000064
PORTO	0	0.002696
SEVILLA	0	0.00124

THIVA	0	0.000008

Appendix 9: Results of the soil exposure modelling by the Dossier Submitter

Table 65. Summary of the most relevant results of soil exposure modelling carried out by the Dossier Submitter (28-day time weighted average values)

Scenario, application rate and method	Time weighted average concentrations (mg kg^{-1} dry wt.)			
	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine
Surface application – high 500 kg/ha PERLKA®	2.18E+01	2.03E+01	9.20E+01	6.26E+00
Surface application – mid 300 kg/ha PERLKA®	1.31E+01	1.22E+01	5.52E+01	3.76E+00
Surface application – low 150 kg/ha PERLKA®	6.55E+00	6.10E+00	2.76E+01	1.88E+00
Uniform incorporation to 7.5 cm depth – high 500 kg/ha PERLKA®	1.46E+01	1.41E+01	6.84E+01	4.72E+00
Uniform incorporation 7.5 cm depth – mid 300 kg/ha PERLKA®	8.73E+00	8.45E+00	4.11E+01	2.83E+00
Uniform incorporation 7.5 cm depth – low 150 kg/ha PERLKA®	4.37E+00	4.22E+00	2.05E+01	1.42E+00

Uniform incorporation 15 cm depth – high 500 kg/ha PERLKA®	7.28E+00	7.32E+00	3.81E+01	2.69E+00
Uniform incorporation 15 cm depth – mid 300 kg/ha PERLKA®	4.37E+00	4.39E+00	2.28E+01	1.61E+00
Uniform incorporation 15 cm depth – low 150 kg/ha PERLKA®	2.18E+00	2.20E+00	1.14E+01	8.07E-01

All modelling assuming molar conversion of cyanamide to urea and DCD based on (Dixon 2017); including degradation, leaching and volatilisation

Table 66. Results of the soil exposure modelling carried out by the Dossier Submitter – application to soil surface (1 of 3)
Application rate 500 kg/ha PERLKA® (220 kg/ha $CaCN_2$), mixing depth 5cm
Scenario: surface application – high

Time (days)	28-d Time weighted average concentrations (mg kg^{-1} dry wt.)			
	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine
1	2.32E+02	2.94E+01	4.03E+00	2.51E-01
2	1.88E+02	4.64E+01	1.22E+01	7.63E-01
4	1.30E+02	5.93E+01	3.25E+01	2.04E+00
7	8.38E+01	5.72E+01	5.98E+01	3.79E+00
14	4.35E+01	3.86E+01	9.11E+01	5.92E+00
21	2.91E+01	2.69E+01	9.61E+01	6.40E+00
28	2.18E+01	2.03E+01	9.20E+01	6.26E+00

42	1.46E+01	1.36E+01	7.80E+01	5.53E+00
50	1.22E+01	1.14E+01	7.03E+01	5.08E+00

Table 67. Results of the soil exposure modelling carried out by the Dossier Submitter – application to soil surface (2 of 3)
Scenario: surface application – mid
Application rate 300 kg/ha PERLKA® (132 kg/ha $CaCN_2$), mixing depth 5cm

Time (days)	28-d Time weighted average concentrations (mg kg^{-1} dry wt.)			
	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine
1	1.39E+02	1.77E+01	2.42E+00	1.51E-01
2	1.13E+02	2.78E+01	7.32E+00	4.58E-01
4	7.77E+01	3.56E+01	1.95E+01	1.23E+00
7	5.03E+01	3.43E+01	3.59E+01	2.28E+00
14	2.61E+01	2.32E+01	5.47E+01	3.55E+00
21	1.74E+01	1.62E+01	5.77E+01	3.84E+00
28	1.31E+01	1.22E+01	5.52E+01	3.76E+00
42	8.75E+00	8.15E+00	4.68E+01	3.32E+00
50	7.35E+00	6.85E+00	4.22E+01	3.05E+00

Table 68. Results of the soil exposure modelling carried out by the Dossier Submitter – application to soil surface (3 of 3)
Scenario: surface application – low
Application rate 150 kg/ha PERLKA® (66 kg/ha $CaCN_2$), mixing depth 5cm

Time (days)	28-d Time weighted average concentrations (mg kg^{-1} dry wt.)			
	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine
1	6.97E+01	8.83E+00	1.21E+00	7.53E-02
2	5.63E+01	1.39E+01	3.66E+00	2.29E-01
4	3.89E+01	1.78E+01	9.76E+00	6.13E-01
7	2.51E+01	1.72E+01	1.79E+01	1.14E+00
14	1.30E+01	1.16E+01	2.73E+01	1.77E+00
21	8.72E+00	8.08E+00	2.88E+01	1.92E+00
28	6.55E+00	6.10E+00	2.76E+01	1.88E+00
42	4.37E+00	4.08E+00	2.34E+01	1.66E+00
50	3.67E+00	3.43E+00	2.11E+01	1.52E+00

Table 69. Results of the soil exposure modelling carried out by the Dossier Submitter – application by uniform incorporation to 7.5cm (1 of 3)
Scenario: 7.5 cm depth – high
Application rate 500 kg/ha PERLKA® (220 kg/ha $CaCN_2$), mixing depth 7.5cm

Time (days)	28-d Time weighted average concentrations (mg kg^{-1} dry wt.)			
	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine
1	1.55E+02	1.97E+01	2.70E+00	1.68E-01
2	1.25E+02	3.11E+01	8.21E+00	5.14E-01
4	8.64E+01	4.01E+01	2.21E+01	1.39E+00
7	5.58E+01	3.89E+01	4.12E+01	2.62E+00
14	2.90E+01	2.66E+01	6.46E+01	4.22E+00
21	1.94E+01	1.86E+01	6.99E+01	4.70E+00
28	1.46E+01	1.41E+01	6.84E+01	4.72E+00
42	9.72E+00	9.41E+00	6.02E+01	4.36E+00
50	8.17E+00	7.91E+00	5.51E+01	4.09E+00

Table 70. Results of the soil exposure modelling carried out by the Dossier Submitter – application by uniform incorporation to 7.5cm (2 of 3)
Scenario: 7.5 cm – mid
Application rate 300 kg/ha PERLKA® (132 kg/ha $CaCN_2$), mixing depth 7.5cm

Time (days)	28-d Time weighted average concentrations (mg kg^{-1} dry wt.)			
	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine
1	9.30E+01	1.18E+01	1.62E+00	1.01E-01
2	7.51E+01	1.87E+01	4.93E+00	3.08E-01
4	5.18E+01	2.40E+01	1.33E+01	8.34E-01
7	3.35E+01	2.34E+01	2.47E+01	1.57E+00
14	1.74E+01	1.60E+01	3.88E+01	2.53E+00
21	1.16E+01	1.12E+01	4.20E+01	2.82E+00
28	8.73E+00	8.45E+00	4.11E+01	2.83E+00
42	5.83E+00	5.65E+00	3.61E+01	2.62E+00
50	4.90E+00	4.74E+00	3.31E+01	2.46E+00

Table 71. Results of the soil exposure modelling carried out by the Dossier Submitter – application by uniform incorporation to 7.5cm (3 of 3)
Scenario: 7.5 cm – low
Application rate 150 kg/ha PERLKA® (66 kg/ha $CaCN_2$), mixing depth 7.5cm

Time (days)	28-d Time weighted average concentrations (mg kg^{-1} dry wt.)			
	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine
1	4.65E+01	5.90E+00	8.09E-01	5.05E-02
2	3.75E+01	9.33E+00	2.46E+00	1.54E-01
4	2.59E+01	1.20E+01	6.63E+00	4.17E-01
7	1.68E+01	1.17E+01	1.24E+01	7.85E-01
14	8.70E+00	7.98E+00	1.94E+01	1.27E+00
21	5.82E+00	5.58E+00	2.10E+01	1.41E+00
28	4.37E+00	4.22E+00	2.05E+01	1.42E+00
42	2.92E+00	2.82E+00	1.81E+01	1.31E+00
50	2.45E+00	2.37E+00	1.65E+01	1.23E+00

Table 72. Results of the soil exposure modelling carried out by the Dossier Submitter – application by uniform incorporation to 15cm (1 of 3)
Scenario: 15 cm depth – high
Application rate 500 kg/ha PERLKA® (220 kg/ha $CaCN_2$), mixing depth 15cm

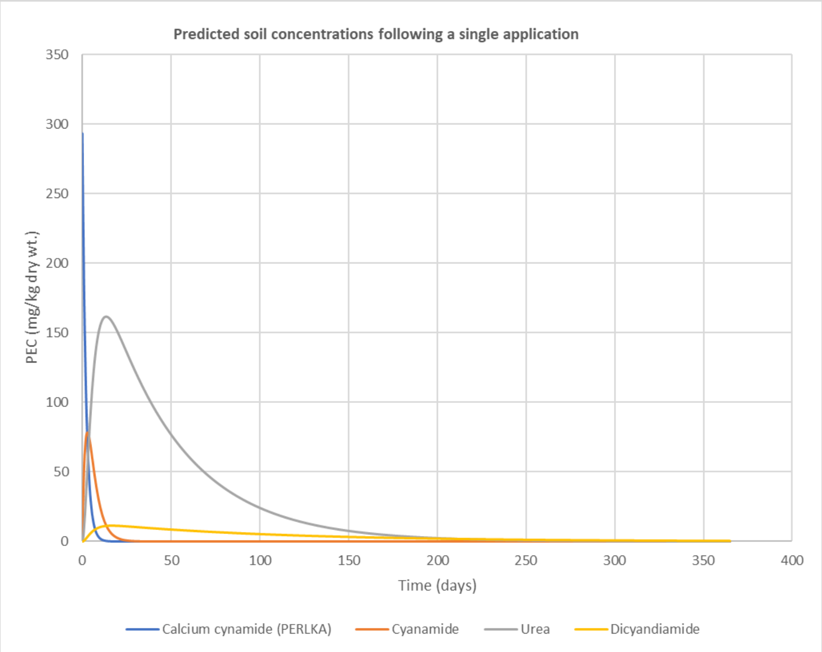
Time (days)	28-d Time weighted average concentrations (mg kg^{-1} dry wt.)			
	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine
1	7.75E+01	9.87E+00	1.35E+00	8.97E-02
2	6.26E+01	1.57E+01	4.14E+00	2.64E-01
4	4.32E+01	2.03E+01	1.12E+01	7.14E-01
7	2.79E+01	1.99E+01	2.12E+01	1.36E+00
14	1.45E+01	1.38E+01	3.43E+01	2.26E+00
21	9.69E+00	9.67E+00	3.80E+01	2.60E+00
28	7.28E+00	7.32E+00	3.81E+01	2.69E+00
42	4.86E+00	4.89E+00	3.47E+01	2.61E+00
50	4.08E+00	4.11E+00	3.23E+01	2.52E+00

Table 73. Results of the soil exposure modelling carried out by the Dossier Submitter – application by uniform incorporation to 15cm (2 of 3)
Scenario: 15 cm depth – mid
Application rate 300 kg/ha PERLKA® (132 kg/ha $CaCN_2$), mixing depth 15cm

Time (days)	28-d Time weighted average concentrations (mg kg^{-1} dry wt.)			
	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine
1	4.65E+01	5.92E+00	8.13E-01	5.38E-02
2	3.75E+01	9.39E+00	2.48E+00	1.59E-01
4	2.59E+01	1.22E+01	6.74E+00	4.28E-01
7	1.68E+01	1.19E+01	1.27E+01	8.16E-01
14	8.70E+00	8.26E+00	2.06E+01	1.36E+00
21	5.82E+00	5.80E+00	2.28E+01	1.56E+00
28	4.37E+00	4.39E+00	2.28E+01	1.61E+00
42	2.92E+00	2.94E+00	2.08E+01	1.57E+00
50	2.45E+00	2.47E+00	1.94E+01	1.51E+00

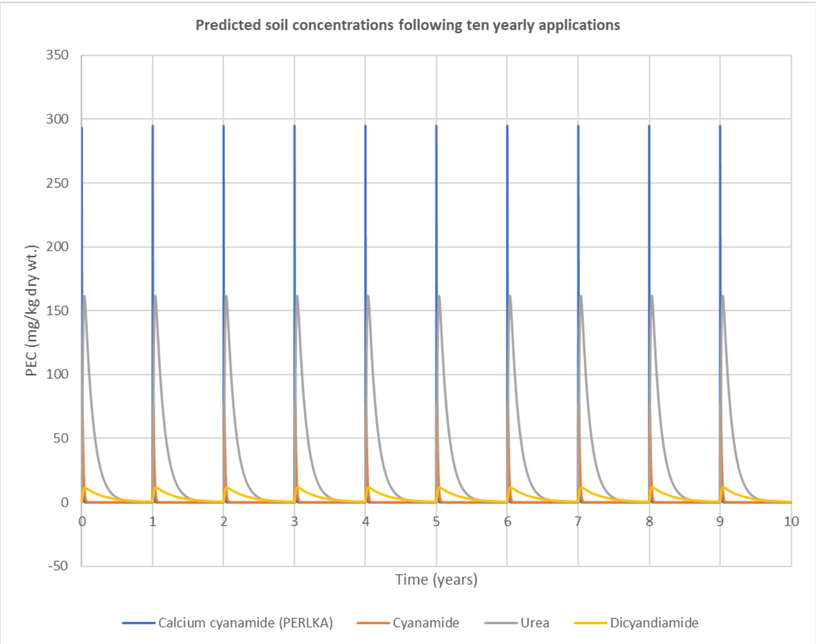
Table 74. Results of the soil exposure modelling carried out by the Dossier Submitter – application by uniform incorporation to 15cm (3 of 3)
Scenario: 15 cm depth – low
Application rate 150 kg/ha PERLKA® (66 kg/ha $CaCN_2$), mixing depth 15cm

Time (days)	28-d Time weighted average concentrations (mg kg^{-1} dry wt.)			
	Calcium cyanamide (PERLKA®)	Cyanamide	Urea	Cyanoguanidine
1	2.32E+01	2.96E+00	4.06E-01	2.69E-02
2	1.88E+01	4.70E+00	1.24E+00	7.93E-02
4	1.30E+01	6.09E+00	3.37E+00	2.14E-01
7	8.38E+00	5.97E+00	6.37E+00	4.08E-01
14	4.35E+00	4.13E+00	1.03E+01	6.79E-01
21	2.91E+00	2.90E+00	1.14E+01	7.79E-01
28	2.18E+00	2.20E+00	1.14E+01	8.07E-01
42	1.46E+00	1.47E+00	1.04E+01	7.84E-01
50	1.22E+00	1.23E+00	9.70E+00	7.55E-01



(Source: Dossier Submitter)

Figure 14. Soil exposure modelling - variation in concentration of calcium cyanamide and transformation substances with time following a single application
Application rate 500 kg/ha PERLKA® (220 kg/ha $CaCN_2$) – application at surface (mixing depth 5cm)



(Source: Dossier Submitter)

Figure 15. Soil exposure modelling - variation in concentration of calcium cyanamide and transformation substances following 10 once-yearly applications
Application rate 500 kg/ha PERLKA®® (220 kg/ha $CaCN_2$) – application at surface (mixing depth 5cm)

Appendix 10: Results of the soil modelling by the Registrant (Alzchem, 2018)

Table 75. Soil exposure modelling carried out by the Registrant for Calcium cyanamide and cyanamide All simulations using ESCAPE modelling v2.0

Computer Model	ESCAPE V2.0			
Scenario numbers[1]	PECmax	PECtwa 28d	PECmax	PECtwa 28d
	(mg calcium cyanamide/kg dry soil)		(mg cyanamide/kg dry soil)	
2b without interception (worst case)	400 kg PERLKA® /ha, no incorporation			
	240.0	17.5	60.6	11.8
1a, 4a	400 kg PERLKA® /ha, 15cm incorporation			
	80.0	5.8	20.2	3.9
1b, 2c, 5b, 6b, 8b, 9b	200 kg PERLKA® /ha, no incorporation, or deep placement			
	120.0	8.8	30.3	5.9
2a	500 kg PERLKA® /ha, 15cm incorporation			
	100.0	7.3	25.2	4.9
2b	400 kg PERLKA® /ha, no incorporation, 20% interception			
	192.0	14.0	48.5	9.4
3a	200 kg PERLKA® /ha, 10cm incorporation			
	60.0	4.4	15.0	2.9
3b	100 kg PERLKA® /ha, deep placement			
	20.0	1.5	2.0	0.4

3c	300 kg PERLKA® /ha, no incorporation, 80% interception			
	36.0	2.6	9.1	1.8
4b	250 kg PERLKA® /ha, 15cm incorporation			
	50.0	3.7	12.6	2.5
4c, 8a	250 kg PERLKA® /ha, no incorporation			
	150.0	11.0	37.9	7.4
5a	400 kg PERLKA® /ha, 10cm incorporation			
	120.0	8.8	30.3	5.9
6a	500 kg PERLKA® /ha, 10cm incorporation			
	150.0	11.0	37.9	7.4
7a	300 kg PERLKA® /ha, no incorporation, 40% interception			
	72.0	5.3	18.2	3.5
7b	250 kg PERLKA® /ha, no incorporation, 40% interception			
	60.0	4.4	15.1	2.9
9a	200 kg PERLKA® /ha, 15cm incorporation			
	40.0	2.9	10.1	2.0

Appendix 11: Information related to impact analysis – referred in the Annex C

Promotional information by the registrant used in the Impact analysis – the insert (reproduced from the registrant's website 20 Nov 2018)

The straight tip for oil seed rape growers: Crop development of oil seed rape in the autumn determinates already two thirds of the potential yield in the following summer. In particular yield results of 2018 underline again, that what has been missed in the autumn hardly can be caught up in the spring. Thus, take care that your crops establish evenly and healthy in the autumn and develop a strong and healthy root system!

Only with an effective root system the current oil seed rape varieties can utilize their high yield potentials in a sufficient way. Thus, all possibilities have to be used to prevent early infections with clubroot. A starter fertilization with calcium cyanamide PERLKA®® has proved to be extremely helpful in preventing clubroot as it suppresses the germination of clubroot resting spores in the soil. Furthermore slugs and the eggs of slugs react highly sensitive when exposed to this type of fertiliser. Thus, such a starter fertilization with calcium cyanamide PERLKA®® perfectly accomplishes a molluscicide application after sowing and by this way offers best growing conditions for germinating rape plants even on fields with a well-known risk for slug damage.

Our recommendation: Apply 40 kg/ha of nitrogen in form of calcium cyanamide fertiliser PERLKA®® directly before sowing. No incorporation and no waiting period is required. First yield results of 2018 confirm again: Such a starter fertilization with PERLKA®® results in an extra yield of 200 to 500 kg/ha of seeds!

Information by the manufacturer of controlled-release fertilisers Agromaster© and Agrocote Max© (published 23 September 2016, reproduced from the manufacturer website)

Amsterdam, The Netherlands, September 22, 2016 - ICL Specialty Fertilisers, a business unit of the ICL Group *(NYSE and TASE: ICL)*, has begun producing controlled release fertilisers using its new E-Max Release Technology at its production facility in Heerlen, The Netherlands. The new products will be marketed under the brand names Agromaster© and Agrocote Max©. The new E-Max Release Technology, specifically designed for use in agriculture, was developed at the R&D facility in The Netherlands over several years and has been tested worldwide. The production line in The Netherlands has a capacity of 25 thousand tonnes per year.

E-Max Release Technology is a new controlled release fertiliser technology that releases nutrients such as nitrogen, potassium and phosphate in an even more precise manner. It also matches the crops' needs exactly, while limiting leaching of nutrients. Experimental trials have shown that the use of controlled release fertilisers significantly increases the efficiency of nutrient use, and as a result improves crop yield and quality in specific climate and soil conditions around the globe.

Leon Terlingen, Director of Research & Development, ICL Specialty Fertilisers: 'We have developed a unique process and technology for adding a very thin coating to a fertiliser granule. The new thin coating allows us to keep the nutrient level very high, while also assuring a very good release curve for the crops. A new production process enables us to produce the controlled release fertiliser in a faster way than with previous technologies. We have tested and developed this new technology in our laboratories on a special pilot installation over a number of years in order to exactly formulate and tailor the desired products to fit specific crop needs'.

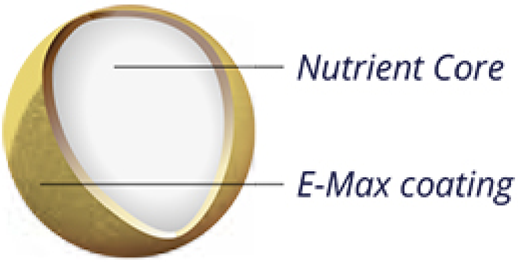


Illustration of E-Max coating of a granule

The usage of controlled release fertilisers is expected to grow rapidly worldwide. Controlled release fertilisers were initially used in ornamental crops, turf and specialty crops in agriculture. Now controlled release fertilisers are used in a wide range of crops such as field vegetables, soft and hard fruit, maize, potatoes, rice and sugarcane.

Fred Bosch, Senior Vice President of ICL Specialty Fertilisers Europe & Asia Pacific: "The new products Agromaster© and Agrocote Max© with E-Max Release Technology offer tremendous benefits for growers. There is a strong trend towards precision nutrition as growers experience the added value of these products. In specific growing conditions, such as sandy and loamy soils and regions where there is substantial rainfall during the growing season, nutrient use efficiency is obviously higher. The results I have seen during my visits to field trials and to growers who use our product have been very good, with higher yielding and better quality crops and fewer fertiliser applications.

Our ICL Specialty Fertilisers agronomists are able to design and offer the right Agromaster NPK with the desired release pattern and longevity of the products. We know, for example, that potatoes need nitrogen in a specific period of the growth cycle and we are able to design a product that has a nitrogen release that suits the potato crop and creates balanced NPK fertilization."

ICL Specialty Fertilisers presented the new E-Max Release Technology to its distribution partners on September 22, 2016. Some 150 visitors have been informed of the latest news including the field trial results worldwide at that time.

A warm welcome!

Fred Bosch, Senior Vice President of ICL Specialty Fertilisers Europe & Asia Pacific

A tour of the Heerlen facility

Let's raise our glasses

Photos of the E-Max event and celebration of the launch

Karl Mielke, Executive Vice President of ICL Specialty Fertilisers: "The production line in Heerlen is another step in our expansion and growth plan for the controlled release fertilisers. We have started production of this technology in Summerville, USA in 2014. We have advanced plans for new production facilities in Asia and Latin America as the market is expected to grow also substantially in these regions. Controlled release fertilisers are a very important product category for ICL Specialty Fertilisers alongside our great range of product brands in soluble and liquid fertilisers. With E-Max Release Technology, we can increase the nutrient use efficiency in key crops. There are a number of areas due to soil conditions and rainfall where the nutrient use efficiency can be enhanced."

For more information on E-Max, Agromaster and Agrocote Max, check your local ICL Specialty Fertilisers site, contact your local advisor or read the E-Max leaflet.

For more information on the ICL Group, see www.icl-group.com.

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