Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Calcium cyanamide

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

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

Agreed

11 June 2020

11 June 2020

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

11 June 2020

[SEAC opinion number]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

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

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

PROCESS FOR ADOPTION OF THE OPINIONS

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

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: *Kostas Andreou*

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

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

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

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

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: *Lars Fock*

Rapporteur, appointed by SEAC: *John Joyce*

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

The draft opinion of SEAC

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

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

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

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

The opinion of SEAC

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

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

[1] Delete the unnecessary part(s)

from interested parties during the public consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

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

Contents

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Calcium cyanamide EC number: 205-861-8 CAS number: 156-62-7	1. Shall not be placed on the market as a substance on its own or in a mixture for use as a fertiliser; 2. Shall not be used as a substance on its own or in a mixture as a fertiliser[2,]; 3. The restriction shall apply 36 months after dd/mm/yyyy[3]

THE OPINION OF RAC

See the opinion of RAC.

THE OPINION OF SEAC

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

[2] The dossier submitter originally proposed to derogate use in closed systems that do not result in emissions to the environment. However, as no request for such a derogation was raised in the consultation of the proposal, the Dossier submitter has withdrawn the proposed derogation

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

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

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

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

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

Information on hazard(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Information on emissions and exposures

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Characterisation of risk(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Uncertainties in the risk characterisation

See the opinion of RAC.

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

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

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

SEAC and RAC conclusions:

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

Key elements underpinning the SEAC [and RAC] conclusions:

The Dossier Submitter has identified that the use of calcium cyanamide as a fertiliser on arable land poses a risk for the environment wherever it is used in the EU.

Calcium cyanamide fertiliser is used in a number of EU Member States and since separate national policies will not ensure equal control of risk for the environment and in order to ensure level playing field, SEAC agrees that an EU-wide restriction would be justified.

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

Justification for the opinion of SEAC and RAC

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Justification for the opinion of SEAC

Summary of proposal:

Calcium cyanamide is a slow release nitrogen fertiliser used for a number of EU agricultural crops. The manufacturer claims that calcium cyanamide have several secondary effects that are useful for farmers, namely attributes such as a herbicide, fungicide, molluscicide, as plant protection attributes, such as managing wireworm in potatoes. However, the Dossier Submitter underlines, that calcium cyanamide is not approved for use in Plant Protection Products (PPPs), and the manufacturer has not applied for such an authorisation for PERLKA®. SEAC concurs with the Dossiers Submitters assessment.

The manufacturer, up to December 2017, sold a powdered form of calcium cyanamide fertilisers. However, due to risks for human health, the powdered form is now listed as a use advised against. The Dossier Submitter considered the originally proposed derogation for the use of granulated fertilisers in a closed system to be justified as by the definition there is no release to the environment from closed systems, however, the derogation was withdrawn as its enforcement was thought to be challenging.

SEAC conclusions:

SEAC agrees that the proposed restriction seems to be the most appropriate EU wide measure to address the identified [risks].

Key elements underpinning the SEAC conclusions:

The Dossier Submitter evaluated four different restriction options, of which three (RO2, RO3 and RO4 (the proposed option)) can be considered as restriction options related to addressing the identified risks for the environment.

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

RO2 lays down specific mandatory guidelines for the use of calcium cyanamide fertiliser, e.g. maximum application rates (kg/ha); mandatory adoption of buffer zones; limits for broadcasting on bare land; mandatory incorporation of fertiliser into soil. SEAC acknowledges that such measures could contribute to reducing risks, especially concerning those to surface water. However, RAC confirmed that, RO2 cannot address risks to soil organisms[4]. Furthermore, SEAC agrees with the Dossier Submitter that RO2 would not be practical as it would require complex sector-specific regulation, and the effectiveness of such measures can be variable and are site specific. In addition, it would be difficult to enforce within the REACH framework. SEAC concurs with this.

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

Other RMOs described by the DS were also deemed ineffective.

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

The Fertilising Products Regulation (FPR) Regulation (EC) 2019/1009 was also considered[5]. However, this regulates impact of fertilisers on the environment in case they are placed on the market as CE marked fertilisers. Hence, this Regulation does not address all fertilisers used in the EU.

[4] On-going discussions of the Endocrine disruption properties of the substance are noted. The unclear endocrine status adds into uncertainty of the opinion.

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

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

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

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

SEAC takes into account that RAC agrees with the Dosser Submitter that only a restriction on placing on the market and use of calcium cyanamide (RO4) as a fertiliser (as a substance on its own or in a mixture) can fully address the identified risk. The proposed restriction appears to be effective, practical and monitorable.

SEAC agrees with the Dossier Submitter that a derogation for use in closed systems is not needed, since such a use has not been identified or requested in the consultation.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter estimates that a total emission reduction of calcium cyanamide to aquatic and terrestrial compartments could be obtained through the proposed restriction, as the restriction will address environmental risks to surface water and to soil.

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

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of proposal:

According to the RAC opinion the proposed restriction is effective in removing the calcium cyanamide-induced risk from total current use area. The Dossier Submitter noted that only a small proportion of farmers in the EU use calcium cyanamide even for the same conditions and crops. This implies that suitable alternatives are available and in use in the EU. The

Dossier Submitter's analysis highlights that the proposed restriction would result in significant impacts for affected farmers due to decreased quantity and quality of yields. The Dossier submitter estimated the yearly loss to farmers to be € 35-50 million underlining differences from year to year. The potential costs in case alternative N-fertilisers are to be applied was estimated by the Dossier Submitter. The Dossier Submitter's analysis highlights that the proposed restriction would significantly impact the manufacturer and farmers through reduced profits. The Dossier Submitter did not quantify potential direct costs to other parties besides farmers. The Dossier Submitter refers to costs to the manufacturers supply chain and costs to society (e.g. possible job losses).

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

SEAC conclusions:

1. SEAC concurs with the Dossier Submitter that some farmers will incur productivity losses in the short to medium term. A summary of this analysis is presented in Table 1. SEAC estimates farm level costs to be €10-16 million/year, which is lower than the Dossier Submitter's estimates of €35-50 million/year. However, the Dossier Submitter did not quantitatively or monetarily account for possible costs that farmers may incur as they transition to use of authorised PPPs, or alternative farm production inputs or farm production methods to substitute for the secondary effects of calcium cyanamide.

2. SEAC concurs with the Dossier Submitter that the manufacturer will incur direct costs due to profit losses. Only one manufacturer is directly affected. However, the Dossier Submitter's cost analysis did not quantitatively or monetarily account for possible actions taken by the manufacturer to reduce their losses, such as possible redeployment of financial or human capital. SEAC considers that including the profit losses of the manufacturer over a long period does not consider the possibility of actions that could reduce the economic impacts (e.g. human and financial capital being redeployed by the manufacturer) and may overstate any long-term impacts.

3. Although acknowledging the manufacturer's losses, SEAC concurs with the Dossier Submitter that economic activity in the EU (societal level) is unlikely to change, as manufacturers of other N-fertilisers or PPPs in the EU are likely to gain most of the market share.

4. SEAC concurs with the Dossier Submitter that society will incur some job losses at the manufacturers' site which might not be replaced by job increases in other N-fertiliser manufacturers in the short term. SEAC considers that job losses over a long period do not consider the possibility of workers obtaining new jobs or being redeployed by the manufacturer. SEAC concurs with the Dossier Submitter that the supply of the different crops on the **EU-market** is not likely to change significantly, as other farmers may

modify their production.

Table 1: Cost Categories, Estimates, Uncertainties and Assumptions		
Cost Categories	**Cost Estimates**	**Uncertainties / assumptions**
Profit losses for farmers.	Estimated monetarily for farmers the change in profits due substituting CaCN2 fertiliser with another N-fertiliser – (change in fertiliser costs and change in product returns).	Possible other costs related to substitution (i.e. additional use of authorised PPPs, or alternative methods (farm production measures) not quantified, therefore leading to a possible underestimation of the costs to farmers.
Manufacturer losses	Monetary costs estimate on profit losses (claimed confidential by the manufacturer, however known to SEAC). There will be financial consequences directly on the manufacturer.	Data has not been provided on the manufacturer's ability to redeploy financial and human resources to other productive activities, leading to a possible overestimation of manufacturers losses.
EU-economic manufacturing activity	No quantified or monetised cost estimates provided.	Qualitatively described that on the societal level (EU economic activity). There are gains to other (competing) EU manufacturers which may gain market share.
EU-agricultural production	No quantified or monetised cost estimates provided.	Qualitatively described that crop volumes at the EU will remain largely unchanged as (share of CaCN2 of the total N-fertilisers is little.
Supply chain	No quantified or monetised cost estimates provided.	Qualitatively described that risks to supply chain are expected to be low.
Unemployment	Job losses claimed confidential by the manufacturer, however, known to SEAC.	Unemployment at the manufacturer's site are likely to occur. The unemployment estimates did not account for the possibility of human resources been redeployed to other uses. The unemployment estimates did not account for the net (EU) societal impact in terms of jobs.

Key elements underpinning the SEAC conclusions:

1. **Productivity Losses**

SEAC notes that the Dossier Submitter has highlighted that calcium cyanamide delivers specific added value compared to other N-fertilisers. Besides slow-release nature of the nitrogen, an additional advantage of using calcium cyanamide relates to the secondary effects – attributed to the transformation products of calcium cyanamide, namely, cyanamide and DCD. These secondary effects could be regarded as Plant Protection Product (PPP)-type effects, e.g. pesticidal, herbicidal, fungicidal, molluscicidal and pest and spore-

germination suppression)[6]. As an illustration, the Dossier Submitter refers to a scientific study by Dixon et al., (2017) which shows how calcium cyanamide reduces plant diseases caused by soil-born microbes. Similarly, information from the consultation and the registrant emphasised the secondary benefits as one justification for using calcium cyanamide.
SEAC notes several points related to the cost analysis:

1) The Dossier Submitter performed a partial analysis of the main costs related to farm profit losses.
2) The Dossier Submitter's quantitative analysis of farmer profit losses focused mainly on the value added of calcium cyanamide as N-fertiliser and the costs associated with farmers switching to an alternative N-fertilisers. The Dossier Submitter used quantity and cost information of fertilisers and quantity, quality and price information of output to estimate profit losses to the farmer. Here the Dossier Submitter performed detailed cost analysis across a range of scenarios, which SEAC subsequently evaluated. A summary of this analysis is presented in Table 1. SEAC estimates farm level profits to be €10-16M/year - lower than the Dossier Submitters estimates of €35-50M/year.
3) The Dossier Submitter did not quantitatively or monetarily account for consequences of the proposed restriction on farm profits from farmers potentially increasing their use of authorised PPPs or alternative farm production measures to derive the value added related to the secondary effects from calcium cyanamide (e.g. pesticidal, herbicidal, fungicidal, molluscicidal and pest and spore-germination suppression).
4) As a consequence of 2) and 3) above, SEAC regards the cost analysis performed by the Dossier Submitter as a partial analysis. SEAC notes that to arrive at a more balanced impact assessment regarding costs, this could be achieved by the analysis of scenarios where farmers switch to authorised PPPs or alternative farm production measures to replace the aforementioned secondary benefits. In practice, this would have required the Dossier Submitter to analyse cost scenarios where farmers would achieve the same or similar secondary effects, either through the use of PPPs or other farm production measures, for example, crop rotation or mechanical treatments.

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

Table 2: Dossier Submitter's Cost Analysis – focused on profit losses associated with farmers switching to an alternative N-fertilisers.

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

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

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

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[7]/61	€113/61
Cost decrease per ha using ammonium nitrate (20% price reduction), high value crops/low value crops	€376/82	€151/82

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

[7] 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.

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

Regarding the secondary effects from the use of calcium cyanamide, SEAC notes that the calcium cyanamide produced by the manufacturer is not approved as an active substance for use in Plant Protection Products (PPPs). SEAC concurs with the Dossier Submitter that to replace the secondary effects of calcium cyanamide, farmers may decide to use authorsied PPPs or alternative farm production measures.

SEAC notes that farm productivity and thus profits are affected by a wide range of variables, such as crop choice, soil type, production capacities, use of fertilisers and PPPs. SEAC cannot exclude that the restriction may impose some costs on some farmers due to loss of yields for certain crops. SEAC cannot exclude that farmers may incur decreased profitability in the short to medium term while transitioning production to (a combination, as relevant) use of alternative N-Fertilisers and authorised PPPs or alternative farm production measures for example through the use of crop rotation. For example, in the public consultation the German Farmers Association (#2748) indicated possible severe problems for the production of some crops (asparagus and apples and cabbage), as higher need for hydrated lime (calcium hydroxide), soil steaming or use of PPP would be needed, and that for some producers the only solution would be to change crops. SEAC notes that these impacts may materialise, but that the impacts likely relate to a small subset of farmers in the EU and a small subset of crops.

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

2. Cost to the manufacturer of calcium cyanamide

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

3. Cost to EU economic activity

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

4. Cost to society – job losses

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

5. Cost to the supply chain

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

Benefits

Summary of proposal:

The Dossier Submitter highlights impacts to two main benefit categories as a result of the proposed restriction. The first category relates to benefits to the environment as a result of a reduction in environmental risks mainly to soil micro-organisms, macro-organisms (e.g. spiders or beetles), aquatic organisms and non-target species (i.e. species that are not intentionally targeted for control by a pesticide or herbicide, but which may suffer damage because of exposure to it). The benefits also relate to groundwater as a source of drinking water supply and human health mainly as a result of effects on human health via the environment (drinking water). The second category relates to the benefits of regulation and functioning internal market.

SEAC conclusions:

SEAC concurs with the Dossier Submitter that the net change in environmental risks as a result of the proposed restriction are uncertain. SEAC considers that the net change in environmental benefits as a result of the proposed restriction, as well as in resource benefits (the status of groundwater bodies and drinking water quality) are uncertain. SEAC notes that the benefits of environmental risk reduction have not been monetised by the Dossier Submitter.

SEAC supports the Dossier Submitter assumption that the restriction could contribute to regulatory control of fertilisers and PPPs, market surveillance and the functioning of the single market (e.g. competition effects).

The benefit categories are summarised in Table 3, below.

Table 3: Benefit Categories, Estimates and Uncertainties		
Benefit Categories	**Benefit Estimates**	**Uncertainties / assumptions**
Environmental risk reduction	Quantified modelled data provided from RAC stating that the risk exists. No description of impacts. No monetised benefits data provided.	Impact: risk would be removed from 230,000 hectares. Net environmental risk reduction is uncertain. Qualitative data provided, assuming that farmers would switch to alternatives (e.g. N-fertilisers; PPPs or alternative methods). The switch would lead to a new set of environmental risks.
Regulatory control	No quantified or monetised data provided.	Assumed to contribute to regulatory control of fertilisers and PPPs.
Positive functioning of the internal market.	No quantified or monetised data provided.[8]	Qualitative data provided on PPPs regulation, which aims to improve the functioning of the internal market through harmonisation of rules associated with placing of PPPs on the market. The Fertiliser Product Regulation (2019/1009) complements this in terms of the management of dual function fertilisers. Assumed to improve competition in the EU and market surveillance.
Endocrine disrupting properties	No quantified or monetised data estimates provided.	Only mentioned, not assessed in the dossier as the endocrine disrupting properties regulatory process was still on-going at the time of the submission of the dossier. Increases uncertainties. Qualitatively described that on the societal level, the classification of calcium cyanamide as having endocrine disrupter properties, would imply further avoided costs (i.e. an additional benefit for society).

Key elements underpinning the SEAC conclusions:

1. Environmental Risks

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

1.1. Switching

SEAC concurs with the Dossier Submitter that as a result of farmers switching from calcium cyanamide to some combination of N-fertilisers and PPPs, the overall net environmental risk reduction of the proposed restriction is uncertain. SEAC's assessment is based on the hypothesis that as a result of the proposed restriction, farmers who today use calcium cyanamide would instead use other farming inputs, based on some combination of authorised PPPs and N-fertilisers or other farm production measures that are specific to their farming needs. SEAC notes that the Dossier Submitter states that there is no information on the actual PPP and application rates that would be needed to provide similar

[8] Some supporting evidence for this is found in a recent assessment that shows that the administrative costs created by national sector-specific requirements in the areas of regulated business services and construction services can go up to € 10 000 and more. Per company level total compliance costs for European businesses are estimated to amount to 0.48 % of turnover.[8] SEAC notes however, that no specific estimates have been provided by the Dossier Submitter for the agricultural/fertiliser sectors.

‘secondary effects’ under different agronomic and environmental conditions.

1.2. Environmental risks

SEAC acknowledges RACs evaluation that environmental risks associated with the use of calcium cyanamide relate to macro organisms in soil and the aquatic environment and soil microorganisms. SEAC notes that due to an absence of site level evidence, any unintended or unplanned environmental pressures, risks and impacts on specific environmental media, including soil, groundwater and surface water, it is not possible to describe environmental impacts, estimate the magnitude of the impacts, or value the impacts (in quantitative or monetary terms).

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

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

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

Overall proportionality

Summary of proposal:

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. 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 profit losses per hectare induced by the restriction appear to be relatively high (circa €70/ha[9]). The recent finding, that one of transformation products of calcium cyanamide may be an endocrine disruptor would, if agreed, increase the expected benefits. This makes the proportionality assessment more robust and improves the proportionality of the proposed restriction.

[9] This uses SEAC profit loss estimates related to substitution with N-Fertiliser only (16m) and the Dossier Submitters estimate of hectares affected (230,000).

RAC and SEAC conclusions:

SEAC concurs with the Dossier Submitter that the use of calcium cyanamide as a fertiliser is not adequately controlled.

SEAC concurs with the Dossier Submitter that the overall net environmental risk reduction of the proposed restriction is uncertain.

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

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

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

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

SEAC finds overall proportionality uncertain.

SEAC notes that the transition period of 36 months is needed.

Table 4 summarises the opinion in terms of proportionality.

Table 4: Proportionality

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

Key elements underpinning the RAC and SEAC conclusions:

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

assumption that net change in environmental risks will be affected by the substitution of calcium cyanamide with some combination of N-fertilizers and authorised Plant Protection Products (PPPs) or other production inputs that are specifically assessed and authorised for use under relevant regulatory instruments.

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

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

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

Uncertainties in the proportionality section

SEAC notes that it is uncertain how effectively and efficiently the manufacturer could redeploy human and financial resources. SEAC notes that the proportion or farmers who would be unable to successfully adjust their production is uncertain.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

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

RAC and SEAC conclusions:

The restriction is implementable. Calcium cyanamide is only used by a small proportion of farmers in the EU, for growing the specific crops. Substitutes of N-fertilisers and authorised PPPs is available to farmers in the EU. Similarly, additional measures may also be available to the farmers to substitute for the benefits of using calcium cyanamide. It is enforceable as it relates to one manufacturer.

Key elements underpinning the RAC and SEAC conclusions:

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

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

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

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

Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

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

RAC and SEAC conclusion(s):

Analytical methods are available which can verify whether a fertiliser contains $CaCN_2$.

Key elements underpinning the RAC and SEAC conclusion(s):

SEAC notes that the proposed restriction in principle follows the traditional way of ensuring that chemicals are used safely. Same procedures can be used.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

SEAC

Summary of proposal:

The Dossier Submitter notes several uncertainties:

- The net change in environmental risks of removing calcium cyanamide.
- The net cost to the farmers of replacing calcium cyanamide to alternative solutions calcium cyanamide.
- The net cost to the manufacturer of the proposed restriction.

SEAC conclusions:

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

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

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

Key elements underpinning the SEAC conclusions:

SEAC notes that the net environmental risk reduction of removing calcium cyanamide from the market is uncertain as the users (i.e. farmers) are likely to switch to some combination of a N-Fertilisers and authorised PPP-products.

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

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

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

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