Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Cyanamide

Product type: 3

ECHA/BPC/230/2019

Adopted

10 December 2019

Opinion of the Biocidal Products Committee

on the application for approval of the active substance cyanamide for product type 3

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 3 of the following active substance:

Common name:	**Cyanamide**
Chemical name:	**Cyanamide**
EC No.:	**206-992-3**
CAS No.:	**420-04-2**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by AlzChem AG on 4 July 2007, the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to the Commission on 30 July 2013. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-16 and BPC-33) and its Working Groups (WG I 2016, WG IV 2019). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at *http://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations* on 22 February 2016, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 21 April 2016. A second consultation was launched on 26 June 2019 with an invitation to submit relevant information by 25 August 2019.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the approval of the active substance cyanamide in product type 3 was adopted on 16 June 2016. Due to the entry into force of Regulation (EU) 2017/2100[1] the Commission returned the BPC opinion to the Agency on 26 April 2018 with the request to revise the opinion already adopted by the Biocidal Products Committee (BPC), related to the application of the criteria for endocrine disrupting properties as laid down in this regulation. The BPC opinion was then finally adopted on 10 December 2019.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

The first version of the BPC opinion was adopted by majority of the members present having the right to vote. The final version of the BPC opion was also adopted by majority. The opinion and the minority position including its ground are published on the ECHA webpage: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

[1] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the cyanamide in product type 3 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of cyanamide in product type 3. Cyanamide is regarded to be a multi-site inhibitor interfering with the respiratory metabolism. It is known to inhibit the activity of the enzymes catalase and dehydrogenase leading to accumulation of hydrogen peroxide in treated organisms.

The purity of the active substance is 96.8 % w/w (dry weight), but cyanamide is manufactured as aqueous solution with 50.5 % w/w. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are required and available for the relevant matrices soil, air, drinking and surface water, body fluids and body tissues.

Commission Decision of 18 September 2008 (2008/745/EC)[2] concerning the non-inclusion of cyanamide in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance was taken in 2008. Commission Regulation (EU) of 17 October 2014 (1126/2014/EU) in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof deleted the MRLs set out for cyanamide in Annex III[3]. Cyanamide was also evaluated for the use of calcium cyanamide as fertiliser by SCHER[4]. The SCHER concluded that harmful effects for humans and for the environment could not be excluded when calcium cyanamide is used at the current rates of application as a fertiliser.

The classification and labelling for cyanamide according to Regulation (EC) No 1272/2008 (CLP Regulation, 10th ATP) is:

[2] OJ L 251, 19.9.2008, p.45

[3] Commission Regulation (EU) No 1126/2014 of 17 October 2014 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for asulam, cyanamide, dicloran, flumioxazin, flupyrsulfuron-methyl, picolinafen and propisochlor in or on certain products

[4] SCHER (Scientific Committee on Health and Environmental Risks), Potential risks to human health and the environment from the use of calcium cyanamide as fertiliser, 22 March 2016

Classification according to theCLP Regulation	
Hazard Class and Category Codes	Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr 1, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 Carc. 2, H351 STOT RE 2, H373 Repr. 2, H361fd Aquatic Chronic 3, H412
Labelling	
Pictogram codes	GHS05 GHS06 GHS08
Signal Word	Danger
Hazard Statement Codes	H301: Toxic if swallowed H311: Toxic in contact with skin H314: Causes severe skin burns and eye damage H317: May cause an allergic skin reaction H351: Suspected of causing cancer H373: Causes damage to organs through prolonged or repeated exposure (thyroid gland) H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child H412: Harmful to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	-

b) Intended use, target species and effectiveness

The intended use of the representative biocidal product is the disinfection against *Brachyspira hyodysenteriae* of the liquid manure stored underneath the slatted floor in pig stables in order to protect fattening pigs against the pig disease dysenteria. The biocidal product is applied by professional users only in empty pig stables. After dilution it is rinsed from the treated surfaces into the liquid manure where it exerts its effects.

The data on cyanamide and the representative biocidal product have demonstrated sufficient efficacy against the target species for the specific use. Further studies should be provided for product authorisation. Cyanamide is regarded to be a multi-site inhibitor. It is not expected that resistance to cyanamide develops from its use in pig stables under PT 3.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Cyanamide is acutely toxic after oral and dermal exposure. Cyanamide is considered irritating to eyes, corrosive to skin and to be a sensitiser via the skin. Cyanamide was considered non-genotoxic but was classified by RAC for carcinogenicity Cat. 2 and reproduction as well as developmental toxicity Cat. 2. RAC also proposed classification as STOT RE2 based on thyroid effects. Furthermore, cyanamide is considered to have endocrine disrupting properties with respect to humans.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Application in animal housings	Primary inhalation and dermal exposure of a.s. in b.p. occurs during mixing & loading, application by watering can or half-automated movable cart and rinsing of floor and equipment in piggeries	Professional user	**Acceptable** with gloves, coverall, RPE, boots, safety goggles
Secondary exposure	Secondary inhalation and dermal exposure to a.s. in b.p. for any task inside the treated pig stables after application and cleaning.	Professional user	**Acceptable** without PPE
Secondary exposure of the general public – entry	Entry during/after application and cleaning in/of empty piggeries	General public	**Acceptable** provided that during application and cleaning access of uninvolved third parties has to be avoided.

Professionals:

A quantitative risk characterisation for systemic effects was performed for the active substance in the representative biocidal product. In addition, due to the skin corrosive (comprising serious eye damage) and skin sensitisation properties of cyanamide in the representative biocidal product, a qualitative risk assessment for local effects was necessary.

Since no applicable models are available to assess an application by watering can, an operator exposure study was conducted as a higher tier study to determine realistic occupational exposure conditions. In the study, a Pro-Chem® I"C" Typ3 coverall and Camatril® 732 gloves proved to be suitable protective clothing. In addition, some other coveralls were tested which did not result in the same level of protection.

According to the systemic and local risk assessment for cyanamide, exposure to cyanamide should be minimized with the following protection measures: effective chemically protective gloves, protective coverall, chemically protective boots, respiratory protective equipment (RPE) against gaseous cyanamide including full face mask or half face mask with safety goggles. If the prescribed risk mitigation measures are implemented, handling and use of the active substance cyanamide do not lead to concern for professionals.

Based on the results of a performed operator exposure study (Rath, 2011) the following specific personal protective equipment proved to be suitable to reduce dermal exposure to an acceptable level:

- chemically protective gloves (Camatril 732, Cat.III, EN 374 AJL, thickness ca. 0,40 mm, length ca. 400 mm),
- chemically protective suit, Cat. III, Type 3 (Pro-Chem I "C" has proven to be suitable to reduce the exposure to an acceptable level according to the study of Rath, 2011).

It is noted that the above specifications are an example of appropriate personal protective equipment to be worn when handling the product. However, if different PPE are proposed at product authorisation stage material test have to be provided demonstrating the same level of protection.

Non-Professionals:

The representative biocidal product is only used by professionals inside empty pig stables. The general public has normally no access to these buildings; thus exposure is also not expected and has not been assessed. Nevertheless, it cannot be totally excluded that persons enter the buildings for specific purposes (e.g. veterinarian, technicians). Therefore, it is still necessary to avoid access of uninvolved third parties during application due to the possible risk to non-protected persons.

However, after application and post-application phase, exposure to these persons is considered negligible since the biocidal product and residues are rinsed and diluted in the liquid manure after application and since they are under supervision of the user of the biocidal product (farmer, pest control operator). Therefore, relevant non-professional secondary exposure is not expected.

With regards to the fact that cyanamide is considered to have endocrine disrupting properties, there is no currently agreed methodology for undertaking a risk assessment based on such properties. Given the exposure of cyanamide to humans, a risk related to the ED properties cannot be excluded.

Environment

Cyanamide is hydrolytically stable and is not classified as “readily biodegradable”. However, rapid degradation was shown in aerobic water/sediment systems, the active substance can be considered to have a low persistence in aquatic systems. In soil, low and moderate persistence has been observed under aerobic and anaerobic conditions, respectively. It was concluded that cyanamide will be subject to significant levels of mineralisation in both the aquatic and terrestrial environments. Cyanamide can be considered as very mobile in soil. Cyanamide is harmful to aquatic organisms with long lasting effects. As the active substance is not considered to be volatile, the air compartment is not considered in the exposure assessment.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Aqueous solution used in animal housings (only indoor in pig fattening) directly in manure (professional use)	Application to • the liquid manure via the slatted floor of pig fattening housings using a watering can or a half-automated movable cart after the end of a fattening cycle Emission to • soil due to liquid manure applications carried out according to maximum nitrogen immission limits , afterwards to groundwater and aquatic compartment (surface water and sediment)	**Acceptable** risks for cyanamide and the minor metabolite thiourea for the use in housings of fattening pigs.

The intended use of the representative biocidal product as a disinfectant in animal housings (pig fattening) indicates no unacceptable risk for the aquatic compartment by cyanamide. In the aquatic and the sediment compartment, a risk characterisation was also carried out for the minor metabolite thiourea. No unacceptable risk for the aquatic compartment by thiourea was indicated. In summary, no unacceptable risks for the aquatic compartment including the sediment were identified for the use of the disinfectant containing cyanamide.

No unacceptable risk for the terrestrial compartment including groundwater (tier 2) is identified for the use of the disinfectant containing cyanamide. In the terrestrial compartment, a risk characterisation was also carried out for the minor metabolite thiourea, where no unacceptable risk for the terrestrial compartment including groundwater (tier 2) by thiourea was indicated. Due to the intended use of the biocidal product for product type 3 which is limited to indoor application and on basis of the available substance information the environmental risk of cyanamide for the atmosphere can be assumed as negligible.

Thus, for the environment, an acceptable risk for all compartments could be demonstrated for the use as direct manure application by professionals in piggeries. However, cyanamide is considered to have endocrine disrupting properties with respect to non-target organisms.

With regards to the fact that cyanamide is considered to have endocrine disrupting properties, there is no currently agreed methodology available on how to consider the data used for the identification of whether a substance is an endocrine disruptor in risk assessment. Given the exposure of cyanamide to the environment, a risk related to the ED properties cannot be excluded.

Overall conclusion

An acceptable risk for both, human health and the environment could be demonstrated for the only applied use (disinfection in empty pig stables by professionals, application by using watering cans or half-automated movable carts). However, the risk for the professional user is only acceptable with adequate PPE. With regards to the fact that cyanamide is considered to have endocrine disrupting properties, there is no currently agreed methodology for undertaking a risk assessment based on such properties and no agreed methodology available on how to consider the data used for the identification of whether this substance is an endocrine disruptor in risk assessment for the environment. Given the exposure of

cyanamide to humans and the environment, a risk related to the ED properties cannot be excluded.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	Cat. 2	Cyanamide does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	Cat. 2	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Cyanamide is not P and not vP The relevant major metabolites urea, dicyandiamide and guanidine are not P and not vP The minor metabolite thiourea is P and vP	Cyanamide does not fulfil criterion (e) of Article 5(1) and criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Cyanamide is not B and not vB The minor metabolite thiourea is not B and not vB	
	Toxic (T)	Cyanamide is T The minor metabolite thiourea is not T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	Yes	Cyanamide fulfils criterion (d) of Article 5(1) and criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	Yes	
	Article 57(f) and 59(1) of REACH	No	

	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required. Cyanmide does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	Cyanamide does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Cyanamide has a purity of 96.8 % w/w (dry weight) and does therefore not fulfil criterion (f) of Article 10(1)		

The major metabolites dicyandiamide and guanidine were only found in relevant amounts in the liquid manure study and were quickly degraded in soil. Therefore, they do not meet the P or vP criteria. For soil, effect values for dicyandiamide were available for earthworms; the value of 3000 mg/kg indicates that the T criterion is not fulfilled. In addition urea, dicyandiamide and guanidine are not expected to fulfil the B and vB criteria based on their low log Kow value.

Consequently, the following is concluded:

Cyanamide meets the exclusion criteria laid down in Article 5(1)(d) of Regulation (EU) No 528/2012.

Cyanamide meets the conditions laid down in Article 10(1)(a) and (e) of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR" [5], with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[6] and with "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[7] agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

According to the CA guidance[5] for draft CARs submitted before 1 September 2013, the exclusion and substitution criteria as defined in the BPR have to be assessed, but the principles of the BPD will apply for the decision-making. This means that though cyanamide

[5] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)
[6] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)
[7] See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/48320db7-fc33-4a91-beec-3d93044190cc/details).

fullfills Article 5(1)(d) of Regulation (EU) No 528/2012, Article 5(2) of Regulation (EU) No 528/2012 is not of relevance for the approval decision

2.2.2. POP criteria

Cyanamide does not fulfil the criteria for being a persistent, organic pollutant.

The minor metabolite thiourea does not fulfil the criteria for being a persistent, organic pollutant.

2.2.3. Identification of potential alternatives substances or technologies, including the results of the public consultation for potential candidates for substitution

Two public consultations were carried out to determine if any chemical or non-chemical alternatives are available for the intended use. According to the applicant, cyanamide is used for the disinfection of liquid manure in animal houses (pig stables) against the bacterium *Brachyspira hyodysenteriae* (use in PT 3) and to control fly larvae in liquid manure in animal houses (pig stables) (use in PT 18).

During the first consultation, six contributions were received. All contributions stated that cyanamide is particularly suited for the intended use due to its unique characteristics. Most contributors emphasized that no suitable chemical or non-chemical alternatives are available.

According to the submitted statements, swine dysentery caused by *B. hyodysenteriae* is a major cause of loss to pig industry throughout the world. *B. hyodysenteriae* is transmitted by flies and rodents or when pigs come into contact with contagious manure.

The following reasons for the need of a disinfection of the liquid manure were given. To prevent the spread of swine dysentery a strict program of antibiotic treatment and biosafety/ hygiene measures has to be followed. The treatment of the infected animals with antibiotics alone is not sufficient because *B. hyodysenteriae* can survive and proliferate in the liquid manure for months and re-infect newly housed animals when they come into contact with even small amounts of the contagious manure. Furthermore, *B. hyodysenteriae* has already developed resistances against a variety of antibiotics. Because the animals excrete 70-90% of the administered antibiotics unchanged or as active metabolites the risk of the development of further antibiotic resistances increases if *B. hyodysenteriae* is present in the manure.

According to the contributions, cyanamide is essential for the disinfection of the liquid manure to prevent the spread of swine dysentery caused by *B. hyodysenteriae.* It is emphasized that cyanamide, in contrast to other active substances, is effective even under the difficult circumstances of the intended use (e.g. it is effective at a high organic load in the liquid manure and at low temperatures, which is important if the treatment is carried out in winter). Furthermore, treatment of the liquid manure with cyanamide is effective against *B. hyodysenteriae* as well as against fly larvae, which can function as a vector. Consequently, it is suitable to interrupt the re-infection cycle without the use of a (second) larvaecide. No resistances of fly larvae or *B. hyodysenteriae* against cyanamide have been reported although the active substance has been used for decades. The development of resistance is not to be expected because cyanamide acts as a multi-site inhibitor.

Except for two submissions the validity of the submitted statements could not be checked because no references were given or can easily be found by literature research. It remains unclear whether cyanamide is the only active substance suitable for the intended use.

In the second public consultation in 2019, 10 contributions (8 non-confidential and 2 confidential) were received, mainly from Germany but also from Austria and Spain. In general, the statements in the newly submitted documents are very similar to the documents submitted in the first public consultation.

It is stated that cyanamide is the only active substance that combined the effects against *B. hyodysenteriae* and its vector, the fly larvae in liquid manure. According to the contributions, the use of other larvicides (e.g. diflubenzuron or cyromazine) is not necessary. Other larvicided approved for the same use are limited and are generally characterized by a specific mode of action entailing the risk of resistence build-up. It is claimed that if cyanamide is not used, more antibiotics will be necessary, resulting also in a greater risk for antibiotic resistence. Furthermore, one contributions claims that cyanamide is a biodegradable and natural occurring substance synthesized by plants, allowing the use of the pig slurry as manure.

In none of the contributions received, neither in the first nor in the second round of the consultation, an alternative is mentioned.

In Denmark and Norway, cyanamide is not used in pig stables. Instead, the pig stables are cleaned and afterwards the clean surfaces are treated with a surface disinfectant. The manure itself is never treated.

Potential alternative active substances:

For PT 3 the following active substances have already been approved: active chlorine released from calcium hypochlorite, active chlorine released from sodium hypochlorite, Amines, N-C10-16-alkyltrimethylenedi-, reaction products with chloroacetic acid (Ampholyt 20), Bacillus amyloliquefaciens, Benzoic acid, Biphenyl-2-ol, Calcium dihydroxide, Calcium magnesium oxide, Calcium magnesium tetrahydroxide, Calcium oxide, Chlorocresol, Glutaraldehyde, Hydrogen peroxide, Iodine/Polyvinylpyrrolidone iodine, L-(+)-lactic acid, Peracetic acid, Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate , PHMB(1600;1.8).

None of these active substances was evaluated with the same intended use as cyanamide. Therefore, it cannot be concluded whether any of these active substances might be an alternative for the disinfection of liquid manure in pig stables against the bacterium *Brachyspira hyodysenteriae*.

2.3. BPC opinion on the application for approval of the active substance cyanamide in product type 3

In view of the conclusions of the evaluation, it is proposed that cyanamide shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: minimum purity in 96.8 % w/w (dry weight), manufactured as an aqueous solution with 50.5 % w/w

2. The authorisations of biocidal products are subject to the following condition(s):

    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation

(EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.

b. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.

c. According to point (d) of Article 19(4) of Regulation (EU) No 528/2012, products shall not be authorised for making available on the market for use by the general public.

d. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

   i. professional users.

e. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

3. The placing on the market of treated articles is subject to the following condition(s):

   a. The person responsible for the placing on the market of a treated article treated with or incorporating the active substance cyanamide shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 as it is classified as Carc. 2, Repr. 2, Acute Tox. 3 via dermal and oral route, Skin Sens. 1 and STOT RE2. Furthermore, the active substance is considered to have endocrine disrupting properties according to Section A and B of Regulation (EU) 2017/2100.

2.4. Elements to be taken into account when authorising products

1. The active substance cyanamide is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for national authorisation.

2. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

   a. If an unacceptable risk is identified for professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means taking into account the properties of cyanamide.

3. An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs.

4. Similar to active substances approved according to Article 5(2) of Regulation (EU) No 528/2012, the use of biocidal products containing cyanamide should be subject to appropriate risk mitigation measures to ensure that exposure of humans, animals and the environment is minimised taking into account that it is considered to have endocrine disrupting properties.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of cyanamide.

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