CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance cyanamide[1]

European Food Safety Authority[2]

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SUMMARY

Cyanamide is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with Article 10(1) of the Regulation, Germany, being the designated rapporteur Member State (RMS), provided an initial evaluation of cyanamide in the format of a Draft Assessment Report (DAR), which was received by the EFSA on 3 January 2006. The Commission of the European Communities (hereafter referred to as 'the Commission') examined cyanamide in accordance with Article 11a of the Regulation and it was concluded that there were clear indications of harmful effects, leading to the adoption of a decision on non-inclusion in Annex I to Council Directive 91/414/EEC, in accordance with Articles 11f and 12 of the Regulation.

Following the Commission Decision of 18 September 2008 (2008/745/EC)[5] 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, the applicant AlzChem Trostberg GmbH made a resubmission application for the inclusion of cyanamide in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues identified in the conclusions leading to the Decision on non-inclusion, as set out in the Review Report (SANCO/1338/08 – rev.0).

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Germany, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 5 January 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 7 January 2010. The EFSA collated and forwarded all comments received to the Commission on 22 February 2010.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology, and deliver its conclusions on cyanamide.

1 On request from the European Commission, Question No EFSA-Q-2010-00783, issued on 21 October 2010.
2 Correspondence: praper@efsa.europa.eu
3 OJ L224, 21.08.2002, p.25
4 OJ L 246, 21.9.2007, p. 19
5 OJ L 251, 19.9.2008, p.45
6 OJ L 15, 18.01.2008, p.5
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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of cyanamide as a plant growth regulator and herbicide on grapes and kiwifruit as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

There are no data gaps or critical areas of concern in the section identity, physical and chemical properties and analytical methods.

Operator, bystander and residential exposure estimates are above the AOEL. This has been indicated as a critical area of concern in the mammalian toxicology section.

No data gaps or critical areas of concern are identified in the residues area.

The data available on fate and behaviour in the environment are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses. The potential for groundwater exposure by cyanamide is predicted to be high over a wide range of geoclimatic conditions represented by the relevant FOCUS groundwater scenarios. Also considering the toxicological properties of cyanamide, this has been identified as a critical area of concern.

A critical area of concern is indicated in relation to the risk assessment for birds. Mitigation measures comparable to 20 m no-spray buffer zones were required to identify a low risk to aquatic organisms for the majority of the FOCUS scenarios. The risk to mammals, bees, non-target arthropods, earthworms, non-target soil macro- and micro-organisms, non-target terrestrial plants, and biological methods of sewage treatment was assessed as low for the representative uses.

KEY WORDS

Cyanamide, peer review, risk assessment, pesticide, plant growth regulator, herbicide

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 1490/2002[7], as amended by Commission Regulation (EC) No 1095/2007[8] lays down the detailed rules for the implementation of the third stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008[9] lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicant(s) for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

Assessment conducted in accordance with Commission Regulation (EC) No 1490/2002

Cyanamide is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007.

In accordance with Article 10(1) of the Regulation, Germany, being the designated rapporteur Member State (RMS), provided an initial evaluation of cyanamide in the format of a DAR (Germany, 2005), which was received by the EFSA on 3 January 2006. In accordance with Article 11 of the Regulation, the EFSA dispatched the DAR to the Member States and the applicant Degussa AG on 16 May 2006 for consultation and comments.

In accordance with the provisions of Article 11a of the Regulation the Commission examined cyanamide, following which it was concluded that there were clear indications of harmful effects, leading to the adoption of a decision on non-inclusion in Annex I to Council Directive 91/414/EEC, in accordance with Articles 11f and 12 of the Regulation.

Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 18 September 2008 (2008/745/EC)[10] 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, the applicant AlzChem Trostberg GmbH made a resubmission application for the inclusion of cyanamide in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the conclusions leading to the Decision on non-inclusion, as set out in the Review Report (European Commission, 2008), as follows:

- the information available was insufficient to satisfy the requirements set out in Annex II and Annex III of Directive 91/414/EEC, in particular with regard to
    - the substantial lack of data to assess the risk to non-target arthropods and earthworms

[7] OJ L224, 21.08.2002, p.25
[8] OJ L246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 251, 19.9.2008, p.45

- concerns were identified with regard to

    - the operator exposure
    - the acute and long-term risk to small herbivorous mammals

In accordance with Article 18, Germany, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (Germany, 2010a). The Additional Report was received by the EFSA on 5 January 2010.

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 7 January 2010. Three addenda to the DAR were also distributed for comments in view of the fact that they had not previously been distributed for consultation. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 22 February 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 20 April 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on cyanamide within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 24 March 2010. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology. No further information was considered necessary to be requested from the applicant.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in August – September 2010.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a plant growth regulator and herbicide on grapes and kiwifruit, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2010) comprises the following documents:

- the comments received on the DAR and the Additional Report
- the Reporting Tables (revision 1-1; 26 March 2010),
- the Evaluation Table (12 October 2010),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of August 2010 containing all individually submitted addenda) (Germany, 2010b) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Cyanamide (IUPAC) has no allocated ISO common name.

The representative formulated product for the evaluation was 'Dormex', a soluble concentrate (SL), which contains 520 g/L cyanamide.

The representative uses evaluated are outdoor air-blast spraying for the stimulation of bud opening for grapes and kiwifruit. Full details of the representative uses can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

Cyanamide is manufactured as a technical concentrate (TK) and the active substance content should be in the range of 488 g/kg to 530 g/kg (min. 854 g/kg calculated on dry weight basis). There is currently no FAO specification for cyanamide. Cyanamide contains no known relevant impurities.

The main data regarding the identity of cyanamide and its physical and chemical properties are given in Appendix A. The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of cyanamide or the respective formulation, however it should be mentioned that the representative formulation was tested to be stable only for 6 months at 20°C and for 18 months at 15°C. It may therefore be necessary to store the product under similar conditions.

Adequate analytical methods are available for the determination of cyanamide in the technical material and in the representative formulation.

Residues of cyanamide in plants can be analysed by HPLC-UV. For products of animal origin no analytical method for cyanamide is necessary since there is no MRL proposed. Soil is analysed for cyanamide using a HPLC-UV method. Tap water is analysed for the active substance by Ion-HPLC-UV, river water is analysed by Ion-HPLC-UV or HPLC-MS/MS, and air is analysed by HPLC-UV. The analytical method for body fluids and tissues is HPLC-UV.

2. Mammalian toxicity

Cyanamide is acutely toxic via the oral and dermal routes (LD_{50} values are 142 and 848 mg/kg bw, respectively); it is a skin and eye irritant, and it is a sensitiser. The proposed classification is T; R25, R21, R38/36 and R43 (already classified in the Commission Directive 94/69/EC[11] - ATP 21). In subacute and subchronic tests the thyroid was the target organ (in both rats and dogs) together with the testes in dogs. The relevant No Observed Adverse Effect Level (NOAEL) in rats (90-day study) was set at 1.5 mg/kg bw/day. In dogs 0.6 mg/kg bw/day was found to be both a NOAEL and a Lowest Observed Adverse Effect Level (LOAEL) in two separate 90-day studies; in the 1-year study the relevant NOAEL was set at 1 mg/kg bw/day. Cyanamide showed some clastogenic potential *in vitro*, however it was negative *in vivo,* and it is unlikely to be genotoxic *in vivo*. Thyroid (decreased colloid) and reduced body weight/body weight gain in rats, and urinary bladder (chronic cystitis) in mice were affected after repeat-dose long-term exposure. The relevant long-term toxicity NOAELs were established at 1 mg/kg bw/day (rat) and 4.2 mg/kg bw/day (mouse). The PRAPeR 79 meeting of experts agreed to propose classification of cyanamide with R40 ('**Limited evidence of a carcinogenic effect**') based on findings in the three carcinogenicity studies available (showing granulosa-theca cell tumours in female mice and equivocal evidence for phaechromocytomas in female rats, and

[11] Commission Directive 94/69/EC of 19 December 1994 adapting to technical progress for the twenty-first time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. *Official Journal L 381 , 31/12/1994 P. 0001 – 1485.*

hemangiosarcomas in male mice). Cyanamide was considered to have effects on testis development of the F1 males during the late lactation period, leading to interstitial cell proliferation and tubular atrophy; fertility reduction was seen at a dose of 15 mg/kg bw/day, inducing general toxicity. The experts at PRAPeR 79 agreed with the proposal for classification as R62 ('**Possible risk of impaired fertility**'). The relevant parental and reproductive NOAEL is 3.75 mg/kg bw/day, whereas the offspring NOAEL was set at 1.3 mg/kg bw/day. Cyanamide induced teratogenic effects in rats at a dose of 45 mg/kg bw/day. Maternal net body weight gain was affected at a dose level of 15 mg/kg bw/day without any indication of more severe toxicity. It was agreed that the data may warrant classification as R63 ('**Possible risk of harm to the unborn child**') by EChA; the relevant maternal and developmental NOAELs in rats are < 5 mg/kg bw/day and 5 mg/kg bw/day, respectively, whereas in rabbits they are 6 mg/kg bw/day.

The experts agreed that the Acceptable Daily Intake (ADI) and the Acceptable Operator Exposure Level (AOEL) should be based on the LOAEL of 0.6 mg/kg bw/day from the 90-day dog study, with a safety factor of 300, resulting in an ADI and an AOEL of 0.002 mg/kg bw/day. The Acute Reference Dose (ARfD) was set at 0.05 mg/kg bw, based on the NOAEL of 5 mg/kg bw/day for hypoactivity following the first two applications in the developmental toxicity study in rats, with a safety factor of 100. The operator exposure was calculated according to the German model. Tractor-mounted application was considered in grapevine and kiwifruit. The operator exposure estimates were above the AOEL (6433 %) even if personal protective equipment (PPE) is used (gloves and half-mask (filter A1P2) during mixing/loading, and gloves, coveralls, rubber boots, and hood and visor during spray application). No re-entry scenario is foreseen for workers, however, in case of inspection activities worker exposure estimates would represent 97.5 % of the AOEL (with the use of gloves, and considering a transfer factor of 100 cm^2/person/h, a dislodgeable foliar residue of 1 µg/cm^2, and a 2.5 h exposure). Bystander exposure estimates exceed the AOEL (1388 %), as well as residential exposure estimates (307 % for adults and 608 % for children). It is noted that for the time being there is no agreed and validated method to assess residential exposure.

3. Residues

The metabolism of cyanamide was investigated in grapes. The active substance was rapidly degraded and naturally incorporated into plant products; no significant metabolites were identified. As no significant metabolites will be present in the plant the default residue definition is cyanamide. As these crops are not fed to animals, there was no need for animal metabolism studies and no MRLs are proposed. Four overdosed residue trials were available for grapes and kiwifruit; residues were detected at a level of < 0.05 mg/kg, which is as expected from the metabolism data. Given this no residue situation the reduced data set is considered adequate. As these are permanent crops that are not rotated, rotational crop metabolism data are not required. Freezer storage stability demonstrated that residues are stable for up to 12 months, which covers the period of time the residue trial samples were stored for. Processing studies are not required as residues are low.

Consumer intakes were 10 % of the ADI and 6.5 % of the ARfD.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, cyanamide exhibited very low to low persistence. The formation of unextractable residues was a minimal sink, accounting for max. 9.5 % AR, but only 5.6 % AR at the end of the study; the mineralisation to carbon dioxide was an extremely significant sink, accounting for 94.6 % AR after 14 days, at the end of the study. No metabolites or transformation products were formed that would trigger further evaluations. Under anaerobic conditions the mineralisation to carbon dioxide was also a significant sink, accounting for 53.1 % AR after 60 days. The formation of unextractable residues accounted for 6.9 % AR after 60 days. In a soil photolysis study, where thin layer soil samples were irradiated, two major (> 10 % applied radioactivity (AR)) transformation products were formed. In another soil photolysis study, where thicker soil layers were used, these transformation products were also found, but at lower levels. The PRAPeR 78 meeting of experts concluded that, considering the representative uses, no further

assessments are necessary for these transformation products. Cyanamide exhibited very high mobility in soil. PECsoil (predicted environmental concentrations (PEC)) for cyanamide was calculated based on the worst-case normalized laboratory DT_{50} value.

Cyanamide is stable to hydrolysis, however the degradation in the irradiated samples of the aqueous photolysis study was faster than in the dark control, and urea as a major transformation product was formed. In laboratory incubations in aerobic natural water sediment systems in the dark, cyanamide exhibited relatively low persistence (single first-order DT_{50} 2.5 - 4.8 days), forming the major metabolite urea. The partition of cyanamide to the sediment was not significant (≤ 4.7 % AR). Mineralisation to carbon dioxide was significant, accounting for 84 - 86 % AR, while residues not extracted from the sediment represented 6 - 11 % AR at the end of the study. The necessary surface water and sediment exposure assessments (PEC) were appropriately carried out using the FOCUS tiered approach (FOCUS, 2001; FOCUS, 2007), up to step 4 for cyanamide (see Addendum 4 B.8 of the Additional Report; Germany, 2010b). In the step 4 calculations drift mitigation measures (equivalent to the effect of 10 m or 20 m no-spray buffer zones), and additionally the deposition of volatile losses during the application were considered. The exposure calculations for urea are based on the worst-case parent PECsw values (from step 4 level).

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2000) scenarios and models (PELMO 3.3.2 and PEARL 3.3.3[12)]. The updated calculations using the agreed input parameters are included in Addendum 4 B.8 of the Additional Report (Germany, 2010b), however it is noted that for the FOCUS PEARL calculations no detailed description (study report of the modelling exercise) is available. The potential for groundwater exposure from the representative uses by cyanamide above the parametric drinking water limit of 0.1 µg/L or above the trigger of 0.75 µg/L was concluded to be high over a wide range of geoclimatic situations that are represented by the relevant FOCUS groundwater scenarios. Also considering the toxicological properties of cyanamide (see section 2), a critical area of concern has been identified.

Cyanamide has a potential for volatilization and the estimated atmospheric half-life using Atkinson calculations is significantly longer than 2 days, therefore, based on this calculation, there is a potential for long-range transport of cyanamide through the atmosphere. The results indicated that cyanamide is not supposed to react with hydroxyl radicals or ozone. A theoretical model for the assessment of long-range transport potential using the ELPOS (v.1.0.1) model was available. The results of these model calculations indicated that the proportion of cyanamide that is expected 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, a field study was available. The results of this study indicated that deposition of cyanamide after volatilisation is a relevant process for the aquatic and terrestrial off-crop area.

5. Ecotoxicology

The risk to birds and mammals was assessed in accordance with the guidance document on birds and mammals (European Commission, 2002a). The acute, short-term and long-term risk to insectivorous birds via dietary exposure to cyanamide was assessed as high at tier 1 for the representative field uses in grapes and kiwifruit. Testing of the formulation was not required because the aqueous solution of hydrogen cyanamide tested in the submitted studies is nearly identical to the formulation. In order to refine the risk assessment, a higher tier field effect study (Additional Report, Vol.3 B.9.1.5.1; Doc. No.: 865-002; Germany, 2010a) was conducted in grapevine plantations to identify the effects of the application of the representative formulation 'Dormex' to birds using the plantations in winter. According to the study, no effects on the bird community were detected following the application of 'Dormex' in winter. However, the study was conducted to cover acute and short-term effects, and not reproductive effects. In addition, there is uncertainty whether the species considered (i.e. insectivorous bird) was the most representative for the time of application. Therefore, Member State experts

[12] Simulations correctly utilised the agreed Q10 of 2.58 (EFSA, 2007) and Walker equation coefficient of 0.7

(PRAPeR Expert Meeting 77; 1-4 June 2010) concluded that a data gap remains regarding the risk to birds, in particular with regard to the long-term risk. The applicant should prove that the application period will not overlap with the breeding season and ensure that all potential focal species are considered in the risk assessment.

The acute and long-term risk to mammals via dietary exposure was assessed as very high at tier 1 for the representative field uses. In order to refine the risk assessment, a higher tier field study (Additional Report, Vol.3 B.9.3.4.3; Doc. 865-001; Germany, 2010a) was conducted in grapevine and kiwifruit plantations to identify relevant small mammal species that could be exposed. The EFSA considered this study as sufficient to show that small mammals are not exposed under field conditions, since they do not use vineyards and kiwifruit orchards at the time of 'Dormex' application. Based on these data the EFSA considers the risk to mammals addressed for the representative uses in grapes and kiwifruit. A risk assessment for earthworm-eating and fish-eating birds and mammals (secondary poisoning) was not required, since cyanamide is unlikely to bioaccumulate (log P_{ow}= - 0.72). The risk to birds and mammals from consumption of contaminated drinking water was assessed as low.

Based on the available toxicity data cyanamide was assessed to be very toxic to aquatic organisms. The toxicity of the formulation does not significantly differ from that of the technical active substance. A risk assessment was not required for sediment-dwelling organisms. At $FOCUS_{sw}$ step 2, the risk to higher aquatic plants, as well as the acute and long-term risk to fish was assessed as low for all representative uses. The risk to algae was assessed as low at $FOCUS_{sw}$ step 3 for all relevant scenarios. A low acute and long-term risk for daphnia at $FOCUS_{sw}$ step 3 could only be established for the R1 pond scenario. At $FOCUS_{sw}$ step 4 the acute and long-term risk to daphnia was assessed as low for all scenarios (R1, R2, R3 and R4) except D6, based on risk mitigation measures comparable to a no-spray buffer zone of 20 m. No studies deriving a bioconcentration (BCF) value were submitted since the log P_{OW} for cyanamide was < 3, and the risk for bioconcentration was considered to be low. The risk from the metabolite urea was considered as low for aquatic organisms for all representative uses.

Cyanamide is classified as hazardous to bees, since the hazard quotients for oral toxicity are far beyond the trigger of 50. However, it is unlikely that honeybees are exposed when cyanamide is used for stimulation of bud opening in winter, therefore the risk to bees is considered low.

Whereas the tier 1 risk assessment indicated a low off-field risk to the non-target arthropods *Aphidius rhopalosiphi* and *Typhlodromus pyri*, further refinements were required to address the high in-field risk for these two standard test species (HQ > 20). Based on higher tier aged-residue studies, Member State experts concluded that the in-field risk to non-target arthropod species can be considered to be low based on the potential for recovery within a season.

The risk to earthworms, non-target soil macro- and micro-organisms, non-target terrestrial plants, and biological methods of sewage treatment was assessed as low for all representative uses.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Cyanamide	Very low to low persistence Single first-order DT_{50} 0.7 – 4.6 days (20°C, pF2 soil moisture)	The risk to earthworms and non-target soil macro- and micro-organisms was assessed as low for the representative uses.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Cyanamide	Very high mobility K_{oc} 0 – 6.8 mL/g	Yes (FOCUS); Trigger of 0.1µg/L exceeded for 4 out of 5 scenarios and trigger of 0.75 µg/L exceeded for 2 out of 5 scenarios when early application time was simulated. For 'peak' application time triggers of 0.1µg/L and 0.75 µg/L were exceeded by 2 out of the 5 relevant scenarios. For late application time the trigger of 0.1µg/L was exceeded for 2 out of 5 scenarios and the trigger of 0.75 µg/L exceeded for 1 out of 5 scenarios.	Yes	Yes	Yes

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Cyanamide	Cyanamide was assessed to be very toxic to aquatic organisms based on the data available. The risk was assessed as low for the representative uses based on mitigation measures comparable to no-spray buffer zones of 20 m.
Urea	The risk for aquatic organisms was considered as low.

6.4. Air

Compound (name and/or code)	Toxicology
Cyanamide	Low acute toxicity. LC_{50}> 1 mg/L (4 hour, whole body; highest attainable concentration, mist)

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- The risk to birds from cyanamide, in particular the long-term risk, needs to be further addressed. Data should be provided to support that the application would not overlap with the breeding season; furthermore, all potential focal species should be considered in the risk assessment (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- The representative formulation was tested to be stable only for 6 months at 20°C and for 18 months at 15°C. It may therefore be necessary to store the product under similar conditions.

- Risk mitigation measures comparable to 20 m no-spray buffer zones were required to address the risk to aquatic organisms.

ISSUES THAT COULD NOT BE FINALISED

- The risk assessment for birds could not be finalised on the basis of the available data.

CRITICAL AREAS OF CONCERN

- Operator exposure estimates (even with the use of PPE) as well as bystander exposure estimates exceed the AOEL (6433% and 1388%, respectively). It is noted that residential exposure estimates are also above the AOEL (307 % for adults and 608 % for children).

- The potential for groundwater exposure by cyanamide above the parametric drinking water limit of 0.1 µg/L is predicted to be high over a wide range of geoclimatic conditions represented by the FOCUS groundwater scenarios. When early application time was simulated, the predicted concentrations exceeded the trigger of 0.1 µg/L for 4 out of 5 FOCUS groundwater scenarios, and the trigger of 0.75 µg/L was exceeded for 2 out of 5 FOCUS groundwater scenarios. A classification with Cat 3 R40 has been proposed for cyanamide.

- A high risk to birds from cyanamide was identified.

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APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Cyanamide (no ISO name allocated)
Function (*e.g.* fungicide)	Plant growth regulator and herbicide

Rapporteur Member State	Federal Republic of Germany
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Cyanamide
Chemical name (CA) ‡	Cyanamide
CIPAC No ‡	685
CAS No ‡	420-04-2
EC No (EINECS or ELINCS) ‡	206-992-3
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	488 g/kg to 530 g/kg or 520 g/L to 564 g/L (TK) 854 g/kg (dry weight basis, calculated)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	CH_2N_2
Molecular mass ‡	42.05 g/mol
Structural formula ‡	$N{\equiv}C{-}NH_2$

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	46.1°C (99.7 %)
Boiling point (state purity) ‡	Decomposition before boiling
Temperature of decomposition (state purity)	At about 141 °C the substance became solid and fluidified again at 208 °C (99.7 %)
Appearance (state purity) ‡	Colourless solid (> 96%)
Vapour pressure (state temperature, state purity) ‡	0.51 Pa at 20 °C (100.3 %) 1.0 Pa at 25 °C (100.3 %)
Henry's law constant ‡	$2.68x*10^{-5}$ Pa m^3 mol^{-1} (20°C)
Solubility in water (state temperature, state purity and pH) ‡	> 800 g/L at 20 °C (pH 3.8) (> 96 %) > 560 g/L at 20 °C (pH 7; from preliminary test) > 530 g/L at 20 °C (pH 9 – 11; from preliminary test)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20 °C in g/L (> 96 %) Isopropanol > 210 Acetone > 210 Methanol > 210 Ethylacetate > 210 *n*-Hexane 0.0024 Dichloromethane 0.41 Toluene 0.67
Surface tension ‡ (state concentration and temperature, state purity)	72.86 mN/m (1 g/L aqueous solution, 20 °C) (99.7 %)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = - 0.72 at 20°C (pH 6.8) (100 %) No influence of the pH-value.
Dissociation constant (state purity) ‡	Cyanamide does not dissociate in water.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	No absorption maximum above 290 nm.
Flammability ‡ (state purity)	Not flammable.
Explosive properties ‡ (state purity)	Not explosive under the test conditions (51.1 % TK) Pure cyanamide > 150 °C and concentrated alkaline solutions may be explosive.
Oxidising properties ‡ (state purity)	Cyanamide has no oxidising properties (statement).

Summary of representative uses evaluated (Dormex: 520 g/L cyanamide)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg a.s./hL min - max (l)	water L/ha min - max	kg a.s./ha min - max (l)		
Table grapes	SE**	Dormex	F	Stimulation of bud opening	SL	520 g/L	Spray: Air- blast	BBCH 00 – winter	1	n.r.	1.56 - 2.34	600 - 400	9.36	F***	Max. rate is 9.36 kg a.s./ha [I] [II] [III]
Wine grapes	SE**	Dormex	F	Stimulation of bud opening	SL	520 g/L	Spray: Air- blast	BBCH 00 – winter	1	n.r.	1.56 - 2.34	600 - 400	9.36	F***	Max. rate is 9.36 kg a.s./ha [I] [II] [III]
Kiwifruit	SE**	Dormex	F	Stimulation of bud opening	SL	520 g/L	Spray: Air blast	BBCH 00 – winter	1	n.r.	1.56 - 2.34	600 - 400	9.36	F***	Max. rate is 9.36 kg a.s./ha [I] [II] [III]

n.r. not relevant
** SE: Southern Europe
*** F = PHI covered by vegetation period
[I] Operator, bystander and residential exposure estimates are above the AOEL.
[II] The potential for groundwater exposure by cyanamide above the parametric drinking water limit of 0.1 µg/L is predicted to be high over a wide range of geoclimatic conditions represented by the FOCUS groundwater scenarios.
[III] A high risk is identified for birds.

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s). (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl). (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of application possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	Potentiometric-titration
Impurities in technical as (principle of method)	HPLC, Titration
Plant protection product (principle of method)	Potentiometric-titration

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Cyanamide
Food of animal origin		Not relevant, no MRL proposed, no residue definition for monitoring
Soil		Cyanamide
Water	surface	Cyanamide
	drinking/ground	Cyanamide
Air		Cyanamide
Body fluids and tissues		Cyanamide

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-UV, LOQ: 0.05 mg/kg (grapes), quantification after derivatisation with 1,2-naphthoquinone-4-sulfonate ILV is provided, confirmation by DAD spectra
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No method necessary, since no MRL proposed
Soil (analytical technique and LOQ)	HPLC-UV, LOQ: 0.05 mg/kg, quantification after derivatisation with 1,2-naphthoquinone-4-sulfonate, confirmation by DAD spectra
Water (analytical technique and LOQ)	Ion-HPLC-UV 0.1 µg/L (tap water) Ion-HPLC-UV 0.5 µg/L (river water) HPLC-MS/MS 0.1 µg/L (river water)
Air (analytical technique and LOQ)	HPLC-UV 2.0 µg/m³
Body fluids and tissues (analytical technique and LOQ)	HPLC-UV, LOQ: 0.05 mg/kg (blood, meat), quantification after derivatisation with 1,2-naphthoquinone-4-sulfonate, confirmation by DAD spectra

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	> 90 % (based on urine, expired CO_2 excretion over 7 d)
Distribution ‡	Widely distributed, highest residues in liver and kidney
Potential for accumulation ‡	No evidence for accumulation
Rate and extent of excretion ‡	Rapid (> 67 % first 24 hours post-dose); 79 % via urine, 4.2 % via faeces, 10 % via CO_2 over 7 d for single low dose
Metabolism in animals ‡	Intensively metabolised; major metabolite in urine and faeces: N-acetylcyanamide (≥ 58 % in urine)
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound
Toxicologically relevant compounds ‡ (environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	142 – 223 mg/kg bw	**R 25**
Rat LD_{50} dermal ‡	848 mg/kg bw	**R 21**
Rat LC_{50} inhalation ‡	> 1 mg/L (4 hr, whole body; highest attainable concentration, mist)	
Skin irritation ‡	Irritant	**R 38**
Eye irritation ‡	Irritant	**R 36**
Skin sensitisation ‡	Sensitising (Magnusson &Kligman)	**R 43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Thyroid (rat: colloid ↓, dog: T3 ↓, T4 ↓), testes (spermatogenesis ↓), anaemia	
Relevant oral NOAEL ‡	90-day rat: 1.5 mg/kg bw/day (30 ppm) 90-day dog: 0.6 mg/kg bw/day (Til, 1986: NOAEL; Til 1982: LOAEL) 1-year dog: 1 mg/kg bw/day	
Relevant dermal NOAEL ‡	Dermal: 12.5 mg/kg bw/day (21-day) Systemic: no acceptable data	
Relevant inhalation NOAEL ‡	< 0.15 mg/L (14 d, 6-hour exposure, head only, 5 day/week) (about 40 mg/kg bw/day)	

Genotoxicity ‡ (Annex IIA, point 5.4)

Clastogenic potential *in vitro*, negative *in vivo*; unlikely to be genotoxic *in vivo*	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Thyroid (decreased colloid) and reduced body weight/ body weight gain in rats, urinary bladder (chronic cystitis) in mice	
Relevant NOAEL ‡	91-week rat: 1 mg/kg bw/day 100-/104-week mouse: 4.2 mg/kg bw/day (70 ppm)	
Carcinogenicity ‡	Increased ovarian granulosa-theca tumors at 39.0 mg/kg bw/day (600 ppm) in [Crl:CD-1 (ICR) BR] mice, but not observed in B6C3F1 mice or rats; equivocal evidence for phaechromocytomas in female rats and hemangiosarcomas in male mice	**R40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Reduced fertility, testicular degeneration, interstitial cell proliferation and atrophy, decreased pup weight and neonatal viability.	**R 62**
Relevant parental NOAEL ‡	3.75 mg/kg bw/day	
Relevant reproductive NOAEL ‡	3.75 mg/kg bw/day	
Relevant offspring NOAEL ‡	1.3 mg/kg bw/day (dietary study, based on decreased pup weight) < 1.25 mg/kg bw/day (gavage study, based on neonatal decreased viability; not appropriate for dietary or dermal risk assessment)	

Developmental toxicity

Developmental target / critical effect ‡	<u>Maternal:</u> Rat: decreased body weight gain; hypoactivity (at ≥ 15 mg/kg bw/day) Rabbit: decreased body weight ↓ <u>Developmental</u>: Rat: decreased foetal body weight; diaphragmatic hernia (at 45 mg/kg bw/day) Rabbit: decreased foetal body weight	**R 63**
Relevant maternal NOAEL ‡	Rat: < 5 mg/kg bw/day Rat: 5 mg/kg bw/day (acute)* Rabbit: 6 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat: 5 mg/kg bw/day Rabbit: 6 mg/kg bw/day	

* Based on hypoactivity following the first two applications at the mid and high dose (≥ 15 mg/kg bw/day)

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data, no evidence for neurotoxic potential in other studies	

Repeated neurotoxicity ‡	No data, no evidence for neurotoxic potential in other studies	
Delayed neurotoxicity ‡	No data, no evidence for neurotoxic potential in other studies	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	There was no indication that cyanamide induced hepatic inclusion bodies in rats after long-term administration; several publications reported abnormal liver histology ('ground glass hepatocytes') after treatment of chronic alcoholics. Published literature indicated that the reproductive toxicity effects observed in rats and rabbits could be a consequence of the inhibition of the tissue-specific aldehyde dehydrogenase. *In vitro* gene expression study in human, rat and dog hepatocytes indicated a greater similarity in patterns of gene regulation between humans and rats than between humans and dogs. *i.v.* injection of acetylcystein after acute oral dosing of cyanamide resulted in a higher mortality in male rats; the oral LD_{50} of cyanamide was found to increase with increasing amounts of cystein in rats; cyanamide preparation (Alzodef) in combination with ethanol given after treatment resulted in lower oral and inhalative LD_{50}.
Studies performed on metabolites or impurities ‡	Hydroxycyanamide was identified in *in vitro* studies as an intermediate instable metabolite, which decomposed to cyanide and nitroxyl; no indications that cyanide content in the blood of male human volunteers was affected by cyanamide intake. Impurity no. 1.10.1.1: Low acute oral, dermal and inhalation toxicity, non-irritant to skin and eye; no genotoxic potential *in vitro* using bacteria and mammalian cells; no carcinogenic potential in 2-year feeding study in Fischer 344 rats and Crl:CD®BR rats (NOAEL: 696 mg/kg bw/day); no impairment of fertility and development in two-generation study up to a dose of 1000 mg/kg bw/day.

Medical data ‡ (Annex IIA, point 5.9)

Cyanamide is used as a deterrent to alcohol consumption (>20 mg/person/day). Cyanamide exposure (ingestion or inhalation) alone when handled improperly, or more pronounced in combination with alcohol consumption, induces vasomotoric reactions, known as "Cyanamide Flush", including several clinical symptoms, e.g. facial flushing, tachycardia, dyspnoea, hypotension, headache, nausea, vomiting, tightness in the chest and sensation of coldness in the extremities. In general, these symptoms disappear with no residual effects on general health, without specific treatment. In the cases of exposure to larger quantities (gram range/day) severe irritating properties of hydrogen cyanamide to the mucous membranes were also observed. Additional effects such as trembling, convulsion, salivation, danger of aspiration, pains behind the sternum and in the epigastrum, unconsciousness and final exits can occur. No signs of diseases or health impairments caused by cyanamide were found during medical surveillance on manufacturing plant personnel. Medical examinations also included special investigations of functional disorders regarding the testes and the thyroid gland, and potential sensitising properties.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.002 mg/kg bw/day	90-day, dog	300*
AOEL ‡	0.002 mg/kg bw/day	90-day, dog	300*
ARfD ‡	0.05 mg/kg bw	Developmental toxicity, rat, supported by human experience	100

* an additional factor of 3 was added to the standard safety factor of 100 due to the use of a LOAEL to derive the reference value

Dermal absorption ‡ (Annex IIIA, point 7.3)

Cyanamide	1% dilution – 5 % 2.5% dilution – 14.3 % Concentrate – 100 %

Exposure scenarios (Annex IIIA, point 7.2)

Operator	German model: with PPE/RPE - exposure 6433 % of the systemic AOEL* * gloves and half-mask (filter A1P2) during mixing/loading, and gloves, coverall, sturdy footwear (rubber boots), and hood and visor during spray application
Workers	Re-entry scenario unlikely The model calculation indicates exposure below the AOEL for the worker if the "transfer factor" of 100 cm^2/person/h and a dislodgeable foliar residue of 1 $\mu g/cm^2$ is considered: 6240 % of the systemic AOEL (8 h, without PPE) 312 % of the systemic AOEL (8 h, with gloves) 97.5 % of the systemic AOEL (2.5 h, with gloves)
Bystanders	Estimated bystander exposure 1388 % of the AOEL Estimated residential exposure 307 % of the AOEL for adults and 608 % for children (grapevine: ≥ 10 m distance).

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Substance classified (cyanamide)	(Commission Directive 94/69/EC - ATP 21) T; R25 'Toxic if swallowed' Xn; R21 'Harmful in contact with skin' Xi; R36 'Irritating to eyes' R38 'Irritating to skin' R43 'May cause sensitisation by skin contact' Repro Cat 3 R62 'Possible risk of impaired fertility' R63 'Possible risk of harm to the unborn child' Carc Cat 3 R40 'Limited evidence of a carcinogenic effect'

Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Grapes (fruit)
Rotational crops	Not relevant.
Metabolism in rotational crops similar to metabolism in primary crops?	Not relevant.
Processed commodities	Not relevant.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant.
Plant residue definition for monitoring	Cyanamide
Plant residue definition for risk assessment	Cyanamide
Conversion factor (monitoring to risk assessment)	None

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	No data available, not required.
Time needed to reach a plateau concentration in milk and eggs	Not applicable.
Animal residue definition for monitoring	Not applicable.
Animal residue definition for risk assessment	Not applicable.
Conversion factor (monitoring to risk assessment)	Not applicable.
Metabolism in rat and ruminant similar (yes/no)	Not applicable.
Fat soluble residue: (yes/no)	No study available, but from log Pow it can be concluded that fat solubility is low.

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

No study available. Not required, because only uses in permanent crops are intended.

Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

12 months in predominantly water containing matrices

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Not relevant.		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)			
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			

	Ruminant:	Poultry:	Pig:
	Not relevant.		
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Grapes	Mediterranean	< 0.05 (4)	The trials do not match the GAP (excessive application rates). Since no residues occurred, the data are nevertheless considered adequate for MRL setting and risk assessment.	0.05		< 0.05
Kiwifruits	Mediterranean	< 0.05 (4)	The trials do not match the GAP (excessive application rates). Since no residues occurred, the data are nevertheless considered adequate for MRL setting and risk assessment.	0.05		< 0.05

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x < 0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.002 mg/kg bw/day
TMDI (% ADI) according EFSA PRIMO.2a	10 %
TMDI (% ADI) according to German diets	not required
IEDI (WHO European Diet) (% ADI)	not required
NEDI (specify diet) (% ADI)	not required
Factors included in IEDI and NEDI	-
ARfD	0.05 mg/kg bw
IESTI (% ARfD)	Table grapes: 6.5 % (DE child) Wine grapes: 0.8 % (UK infant) Kiwi fruits: 4.0 % (DE child)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	-
Factors included in IESTI and NESTI	-

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
No study available, not required (no residues detected in grapes and kiwifruits at harvest).				

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Plant matrices (cyanamide)	Grapes: 0.05* mg/kg Kiwifruits: 0.05* mg/kg
Animal matrices (cyanamide)	Not applicable

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

Fate and behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	94.6 % after 14 days (study end), ^{14}C-hydrogen cyanamide (n = *1*)
Non-extractable residues after 100 days ‡	5.64 % after 14 days (study end), ^{14}C-hydrogen cyanamide (n = *1*)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	none

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Mineralization after 100 days	53.1 % after 60 days, ^{14}C-hydrogen cyanamide (n = *1*)
Non-extractable residues after 100 days	6.93 % after 60 days, ^{14}C-hydrogen cyanamide (n = *1*)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	none

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	none

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	% OC	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	chi2 error (%)	Method of calculation
Sandy loam (Ashland, USA)	0.93	6.8	25 / 75 % of 1/3 bar	0.58/1.94	0.70	5.8	SFO
Loamy sand (SP 257)	2.19	5.6	20 / 40	0.90/2.99	0.96*	16.1	SFO
Loamy sand (SP 357)	1.10	7.2	20 / 40	1.61/5.35	1.24	3.1	SFO
Sand (SP 1106)	0.48	6.5	20 / 40	5.33/17.7	4.56	11.1	SFO
Geometric mean/median					1.40		

* Pseudo-SFO DT_{50} for modelling purposes derived from FOMC DT_{90} (DT_{90}/3.32)

Field studies	No reliable data for the representative uses are available
Soil accumulation and plateau concentration ‡	no data - not required

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sand (8.97 mg/L)	1.35	5.3	0.092	6.81			
Sand (0.89 mg/L)	1.35	5.3	0.059	4.35			
Loamy silt	0.95	7.1	0.060	6.34			
Silty sand	1.35	5.8	0	0			
Arithmetic mean				4.0 *			
pH dependence, Yes or No			no				

* considering the mean of the two Koc values originating from the acidic sand soil

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Eluation (mm): 200 mm Time period (d): 2 d
	Leachate: 0.13 – 2.8 % active substance in leachate
Aged residues leaching ‡	Not required

Lysimeter/ field leaching studies ‡

Location: SLFA Neustadt/Weinstrasse, Germany

Study type: 2 lysimeters

Soil properties: sandy loam, pH = 7.3, OC= 0.9 %

Number of applications: 1 application per year

Dates of application : May 15, 1991; April 23, 1992

Crop rotation: 1st year: winter wheat, rape, winter barley, 2nd year: rape, 3rd year: sugar beets.

Duration:

Application rate: 1st year: 94.3 kg cyanamide/ha; 2nd year: 91 kg a.s./ha; (non-radiolabelled cyanamide)

Average annual rainfall (mm): 1st year 820; 2nd year 863.8; 3rd year 926.2

Average annual leachate volume: 223 L

Concentrations of cyanamide in percolate:

	Lysimeter	leachate (µg/L)	leachate (L)
1st year	L9	< 0.03	199.1
	L10	< 0.02	174.8
2nd year	L9	< 0.03	236.0
	L10	< 0.02	202.6
3rd year	L9	< 0.02	268.0
	L10	< 0.02	258.6

Concentrations of cyanamide in soil:

	Lysimeter	(mg/kg)	soil layer
1st year	L9	< 0.05	(0-30 cm)
	L10	< 0.05	(0-30 cm)
2nd year	L9	< 0.05	(0-30 cm)
	L10	< 0.05	(0-30 cm)
3rd year	L9	< 0.05	(0-30 cm)
	L9	< 0.05	(30-110 cm)
	L10	< 0.05	(0-30 cm)
	L10	< 0.05	(30-110 cm)

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation

DT_{50}: 4.56 days (20 °C/Q_{10} = 2.58, pF2)

Kinetics: SFO

Field or Lab: worst case from laboratory studies.

Application data

Crop: vines

Depth of soil layer: 5 cm

Soil bulk density: 1.5 g/cm^3

% plant interception: 40

Number of applications: 1

Interval (d): -

Application rate: 9.36 kg a.s./ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		7.49			
Short term	24h	6.43	6.95		
	2d	5.53	6.46		
	4d	4.08	5.61		
Long term	7 d	2.58	4.61		
	28d	0.106	1.73		
	50d	0.004	0.985		
	100d	< 0.001	0.493		
Plateau concentration		Not required			

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: 1200 d at 22 °C
	pH 7: 2300 d at 22 °C
	pH 9: 810 d at 22 °C
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : 28.9 d (pH 5), 38.5 d (pH 7), irradiated with artificial light from Xenon lamp (290-400 nm) DT_{50} 116 d (pH 5), 139 d (pH 7) in non-irradiated control Metabolite: Urea: 12.2 % of initial measured dose after 30 days
Quantum yield of direct phototransformation in water at Σ > 290 nm	No data
Readily biodegradable ‡ (yes/no)	not ready biodegradable

Degradation in water / sediment

Parent	Distribution (max in water 101 % on day 0. Max. sed. 4.7 % after 2-6 days)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (days)	St. (r^2)	DT_{50}-DT_{90} water (days)	St. (r^2)	DT_{50}- DT_{90} sed. (days)	St. (r^2)	Method of calculation
System I River	8.19-8.44	7.2-8.0	20	2.5/8.2	0.996	2.3/7.7	0.997	-/-	-	SFO
System II Pond	8.31-8.66	7.5-8.9	20	4.8/15.8	0.990	4.3/14.4	0.990	-/-	-	SFO
Geometric mean				3.5/11.4		-		-		
Urea	Distribution (max in water 11.8 % after 1 d. Max. sed. 1.6 % after 1-2 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (days)	St. (r^2)	DT_{50}-DT_{90} water (days)	r^2	DT_{50}- DT_{90} sed. (days)	St. (r^2)	Method of calculation
System I River	8.19-8.44	7.2-8.0	20	2.9/9.6	0.965	2.7/9.1	0.966	-/-	-	SFO
System II Pond	8.31-8.66	7.5-8.9	20	8.0/26.7	0.935	7.5/11.6	0.939	-/-	-	SFO
Geometric mean				4.8/16		-		-		

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
System I River	8.19-8.44	7.2-8.0	86.1 % after 28 d	11.0 % after 28 d	11.0 % after 28 d
System II Pond	8.31-8.66	7.5-8.9	83.5 % after 28 d	7.8 % after 21 d	6.0 % after 28 d

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: ver. 1.1, FOCUS 2001 Spray drift (% of application rate): 2.699 Molecular weight (g/mol): 42.1 Water solubility (mg/L): 560000 K_{OC} (mg/L): 3.97 DT_{50} soil (d): 1.40 days (Lab. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 3.5 DT_{50} water (d): 3.5 DT_{50} sediment (d): 1000
Parameters used in FOCUSsw step 3 (if performed)	Spray drift (% of application rate): Vine Ditch: 1.718 Vine Pond: 0.1933 Vine Stream: 1.702

	Vapour pressure: 0 Pa; the real vapour pressure of cyanamide is 0.51 Pa at 20°C. K_{OC}: 3.97 1/n: 1 DT_{50} soil (d): 1.40 days (Lab. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 3.5 DT_{50} water (d): 3.5 DT_{50} sediment (d): 1000 Q_{10fac}: 2.58
Parameters used in FOCUSsw step 4 (if performed)	Spray drift (% of application rate): Vine Ditch, 10 m: 0.3606 Vine Pond, 10 m: 0.1216 Vine Stream, 10 m: 0.4328 * Vine Ditch, 20 m: 0.1228 Vine Pond, 20 m: 0.0598 Vine Stream, 20 m: 0.1474 * deposition value, 10 m: 0.292 mg/m^2 hour deposition value, 20 m: 0.172 mg/m^2 hour Reduction values run-off (R scenarios): no Reduction values erosion (R scenarios): no
Application rate	Crop: vines, early application Number of applications: 1 Interval (d): - Application rate(s): 9360 g a.s./ha Application window:10/12 to 15/02 Application dates: 10/12 to 14/01
	*For streams the aeric mean deposition (spray drift), as calculated by the FOCUS Drift Calculator, has been multiplied by a factor 1.2 to account for pesticide mass incoming from the upstream catchment.

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU Vines 1 × 9360 g a.s./ ha	0 h	209.42		8.31	
	24 h	171.76	190.59	6.82	7.56
	2 d	141.07	173.50	5.60	6.89
	4 d	95.15	145.24	3.78	5.77
	7 d	52.71	113.89	2.09	4.52
	14 d	13.28	71.29	0.53	2.83
	21 d	3.35	49.94	0.13	1.98
	28 d	0.84	37.91	0.034	1.51
	42 d	0.054	25.37	0.002	1.01

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	50 d	0.011	21.31	<0.001	0.85
	100 d	<0.001	10.66	<0.001	0.42

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	ditch	0 h	53.357		8.044	
		24 h	48.613	50.820	7.899	8.031
		2 d	44.590	48.693	7.544	7.992
		4 d	35.379	44.478	6.564	7.846
		7 d	17.328	36.666	5.176	7.488
		14 d	1.192	21.545	3.782	6.404
		21d	2.261	15.275	3.098	5.579
		28 d	2.349	12.053	2.601	4.978
		42 d	1.592	8.638	2.010	4.147
		50 d	1.703	7.525	1.835	3.809
		100 d	0.039	4.363	0.892	2.662
R1	pond	0 h	1.805		0.390	
		24 h	1.702	1.751	0.390	0.390
		2 d	1.608	1.703	0.388	0.390
		4 d	1.437	1.611	0.384	0.390
		7 d	1.215	1.488	0.372	0.388
		14 d	0.847	1.250	0.335	0.383
		21 d	0.602	1.073	0.292	0.373
		28 d	0.428	0.932	0.251	0.362
		42 d	0.216	0.725	0.182	0.333
		50 d	0.146	0.638	0.152	0.315
		100 d	0.010	0.345	0.061	0.220
R1	stream	0 h	37.008		0.719	
		24 h	<0.001	2.939	0.132	0.265
		2 d	<0.001	1.470	0.093	0.189
		4 d	<0.001	0.735	0.066	0.133
		7 d	<0.001	0.420	0.049	0.100
		14 d	<0.001	0.212	0.032	0.070
		21 d	<0.001	0.141	0.023	0.056

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		28 d	<0.001	0.106	0.017	0.047
		42 d	<0.001	0.071	0.011	0.036
		50 d	<0.001	0.059	0.009	0.031
		100 d	<0.001	0.030	0.004	0.019
R2	stream	0 h	50.538		0.911	
		24 h	0.001	3.716	0.170	0.334
		2 d	<0.001	1.858	0.118	0.238
		4 d	<0.001	0.929	0.083	0.168
		7 d	<0.001	0.531	0.061	0.126
		14 d	<0.001	0.265	0.039	0.088
		21 d	<0.001	0.177	0.028	0.070
		28 d	<0.001	0.133	0.021	0.058
		42 d	<0.001	0.089	0.013	0.044
		50 d	<0.001	0.074	0.011	0.039
		100 d	<0.001	0.037	0.005	0.023
R3	stream	0 h	54.250		1.975	
		24 h	0.014	13.831	0.638	1.210
		2 d	0.003	6.918	0.450	0.891
		4 d	0.001	3.460	0.318	0.639
		7 d	<0.001	1.977	0.236	0.484
		14 d	<0.001	0.989	0.151	0.337
		21 d	<0.001	0.659	0.108	0.268
		28 d	<0.001	0.494	0.081	0.224
		42 d	<0.001	0.330	0.052	0.171
		50 d	<0.001	0.277	0.042	0.151
		100 d	<0.001	0.138	0.020	0.090
R4	stream	0 h	38.342		1.082	
		24 h	0.001	5.570	0.255	0.502
		2 d	<0.001	2.785	0.180	0.361
		4 d	<0.001	1.393	0.127	0.257
		7 d	<0.001	0.796	0.094	0.194
		14 d	<0.001	0.398	0.060	0.134
		21 d	<0.001	0.265	0.043	0.107
		28 d	<0.001	0.199	0.032	0.089
		42 d	<0.001	0.133	0.021	0.068

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		50 d	<0.001	0.111	0.017	0.060
		100 d	<0.001	0.056	0.008	0.036

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Single Application Use on vine – 10 m buffer, including the deposition of volatilized cyanamide						
D6	ditch	0 h	21.633		3.393	
		24 h	19.820	20.805	3.334	3.387
		2 d	18.137	20.008	3.185	3.371
		4 d	13.943	18.361	2.773	3.309
		7 d	6.447	15.331	2.187	3.158
		14 d	3.427	9.087	1.932	2.710
		21d	2.241	6.964	1.780	2.459
		28 d	2.243	5.820	1.604	2.289
		42 d	1.616	4.482	1.374	2.040
		50 d	1.691	4.034	1.316	1.934
		100 d	0.031	2.616	0.646	1.537
R1	pond	0 h	2.796		0.618	
		24 h	2.640	2.723	0.617	0.618
		2 d	2.495	2.651	0.615	0.618
		4 d	2.230	2.515	0.607	0.617
		7 d	1.886	2.329	0.589	0.615
		14 d	1.319	1.967	0.530	0.606
		21 d	0.937	1.693	0.462	0.591
		28 d	0.666	1.473	0.397	0.573
		42 d	0.337	1.147	0.288	0.527
		50 d	0.227	1.009	0.240	0.499
		100 d	0.015	0.546	0.096	0.349
R1	stream	0 h	10.826		0.236	
		24 h	<0.001	1.472	0.070	0.128
		2 d	<0.001	0.736	0.049	0.094
		4 d	<0.001	0.368	0.034	0.067
		7 d	<0.001	0.210	0.025	0.051
		14 d	<0.001	0.107	0.016	0.036

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Single Application Use on vine – 10 m buffer, including the deposition of volatilized cyanamide						
		21 d	<0.001	0.071	0.012	0.029
		28 d	<0.001	0.053	0.009	0.024
		42 d	<0.001	0.036	0.006	0.018
		50 d	<0.001	0.030	0.005	0.016
		100 d	<0.001	0.015	0.002	0.010
R2	stream	0 h	14.635		0.293	
		24 h	<0.001	1.857	0.088	0.162
		2 d	<0.001	0.929	0.061	0.118
		4 d	<0.001	0.464	0.043	0.084
		7 d	<0.001	0.265	0.031	0.064
		14 d	<0.001	0.133	0.020	0.045
		21 d	<0.001	0.089	0.014	0.035
		28 d	<0.001	0.066	0.011	0.030
		42 d	<0.001	0.044	0.007	0.023
		50 d	<0.001	0.037	0.006	0.020
		100 d	<0.001	0.019	0.003	0.012
R3	stream	0 h	17.415		0.724	
		24 h	0.015	7.007	0.331	0.582
		2 d	0.002	3.512	0.231	0.442
		4 d	0.001	1.756	0.163	0.321
		7 d	<0.001	1.004	0.120	0.245
		14 d	<0.001	0.502	0.077	0.171
		21 d	<0.001	0.335	0.055	0.136
		28 d	<0.001	0.251	0.041	0.114
		42 d	<0.001	0.167	0.026	0.087
		50 d	<0.001	0.141	0.021	0.077
		100 d	<0.001	0.070	0.010	0.046
R4	stream	0 h	12.016		0.368	
		24 h	0.001	2.814	0.137	0.243
		2 d	<0.001	1.407	0.094	0.180
		4 d	<0.001	0.704	0.065	0.129
		7 d	<0.001	0.402	0.048	0.098
		14 d	<0.001	0.201	0.031	0.068
		21 d	<0.001	0.134	0.022	0.054

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Single Application Use on vine – 10 m buffer, including the deposition of volatilized cyanamide						
		28 d	<0.001	0.101	0.017	0.046
		42 d	<0.001	0.067	0.011	0.035
		50 d	<0.001	0.056	0.009	0.031
		100 d	<0.001	0.028	0.004	0.018

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Single Application Use on vine – 20 m buffer, including the deposition of volatilized cyanamide						
D6	ditch	0 h	10.104		1.579	
		24 h	9.255	9.710	1.552	1.577
		2 d	8.472	9.329	1.482	1.569
		4 d	6.533	8.549	1.290	1.540
		7 d	3.037	7.119	1.018	1.470
		14 d	3.417	4.230	1.210	1.276
		21d	2.240	3.726	1.266	1.253
		28 d	2.243	3.391	1.215	1.252
		42 d	1.616	2.862	1.125	1.226
		50 d	1.690	2.673	1.113	1.210
		100 d	0.030	1.935	0.551	1.099
R1	pond	0 h	1.540		0.340	
		24 h	1.454	1.500	0.340	0.340
		2 d	1.374	1.460	0.339	0.340
		4 d	1.228	1.385	0.335	0.340
		7 d	1.039	1.282	0.325	0.339
		14 d	0.727	1.083	0.292	0.334
		21 d	0.516	0.932	0.255	0.326
		28 d	0.367	0.811	0.219	0.315
		42 d	0.186	0.632	0.159	0.290
		50 d	0.125	0.556	0.133	0.275
		100 d	0.008	0.301	0.053	0.192

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Single Application Use on vine – 20 m buffer, including the deposition of volatilized cyanamide						
R1	stream	0 h	4.039		0.094	
		24 h	<0.001	0.681	0.033	0.059
		2 d	<0.001	0.341	0.023	0.043
		4 d	<0.001	0.170	0.016	0.031
		7 d	<0.001	0.097	0.012	0.024
		14 d	<0.001	0.050	0.008	0.017
		21 d	<0.001	0.034	0.006	0.013
		28 d	<0.001	0.025	0.004	0.011
		42 d	<0.001	0.017	0.003	0.009
		50 d	<0.001	0.014	0.002	0.008
		100 d	<0.001	0.007	0.001	0.005
R2	stream	0 h	5.428		0.117	
		24 h	<0.001	0.859	0.042	0.074
		2 d	<0.001	0.430	0.029	0.055
		4 d	<0.001	0.215	0.020	0.039
		7 d	<0.001	0.123	0.015	0.030
		14 d	<0.001	0.061	0.010	0.021
		21 d	<0.001	0.041	0.007	0.017
		28 d	<0.001	0.031	0.005	0.014
		42 d	<0.001	0.021	0.003	0.011
		50 d	<0.001	0.017	0.003	0.009
		100 d	<0.001	0.009	0.001	0.006
R3	stream	0 h	7.055		0.339	
		24 h	0.008	3.254	0.141	0.268
		2 d	0.001	1.631	0.103	0.204
		4 d	<0.001	0.816	0.074	0.149
		7 d	<0.001	0.466	0.055	0.114
		14 d	<0.001	0.233	0.036	0.080
		21 d	<0.001	0.156	0.025	0.063
		28 d	<0.001	0.117	0.019	0.053
		42 d	<0.001	0.078	0.012	0.041
		50 d	<0.001	0.065	0.010	0.036
		100 d	<0.001	0.033	0.005	0.021

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Single Application Use on vine – 20 m buffer, including the deposition of volatilized cyanamide						
R4	stream	0 h	4.668		0.148	
		24 h	0.001	1.306	0.065	0.111
		2 d	<0.001	0.653	0.044	0.083
		4 d	<0.001	0.327	0.031	0.060
		7 d	<0.001	0.187	0.023	0.046
		14 d	<0.001	0.093	0.014	0.032
		21 d	<0.001	0.062	0.010	0.025
		28 d	<0.001	0.047	0.008	0.021
		42 d	<0.001	0.031	0.005	0.016
		50 d	<0.001	0.026	0.004	0.014
		100 d	<0.001	0.013	0.002	0.008

Urea

Parameters used in FOCUSsw step 4 (if performed)

Calculation based on the worst-case cyanamide PECsw, using a cyanamide-to-urea-conversion rate in water/sediment systems of 13.4 %, and taking into account the ratio between the molar masses of the active substance cyanamide (42.1 g/mol) and the metabolite urea (60.1 g/mol).

Geometric mean of the DT_{50} = 4.82 d of urea in the total system

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Single Application Use on vine – 10 m buffer						
D6	ditch	0 h	4.138			
		24 h	3.584	3.854		
		2 d	3.104	3.596		
		4 d	2.328	3.147		
		7 d	1.512	2.608		
		14 d	0.553	1.781		
		21d	0.202	1.303		
		28 d	0.074	1.009		
		42 d	0.010	0.683		
		50 d	0.003	0.575		
		100 d	<0.001	0.288		
FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Single Application Use on vine – 20 m buffer						
D6	ditch	0 h	1.933			
		24 h	1.674	1.800		
		2 d	1.450	1.680		
		4 d	1.087	1.470		
		7 d	0.706	1.219		
		14 d	0.258	0.832		
		21d	0.094	0.609		
		28 d	0.034	0.471		
		42 d	0.005	0.319		
		50 d	0.001	0.269		
		100 d	<0.001	0.134		

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: PELMO 3.3.2, PEARL 3.3.3 Scenarios: Châteaudun, Piacenza, Porto, Sevilla, Thiva Crop: vine early, peak, late Crop interception: 40 % Geometric mean parent DT_{50lab} 1.4d (normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58). K_{OC}: parent, arithmetic mean 4.4, $^1/_n$= 1 Vapour pressure: 0 Pa (PELMO), 0.51 Pa (PEARL) * Metabolites: none		
	* the real vapour pressure of cyanamide is 0.51 Pa at 20°C. This was considered only in the FOCUS PEARL calculations.		
Application rate	Application rate: 9360 g a.s./ha. No. of applications: 1 Time of application (month or season):		
	Early application: Chat.: 21. Dez. Piac.: 24. Dez. Porto: 10. Jan. Sevilla: 10. Jan. Thiva: 15. Jan.	Peak application: Chat.: 15. Jan. Piac.: 15. Jan. Porto: 20. Jan. Sevilla: 20. Jan. Thiva: 31. Jan.	Late application: Chat.: 1. Feb. Piac.: 10. Feb. Porto: 30. Jan. Sevilla: 30. Jan. Thiva: 15. Feb.

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario		Parent (µg/L)		
			Vine early application	Vine peak application	Vine late application
PELMO 3.3.2	Chateaudun		0.025	0.018	0.011
	Piacenza		6.283	3.573	4.774
	Porto		1.220	0.970	0.614
	Sevilla		0.193	0.045	0.033
	Thiva		0.121	0.035	0.013

PEARL 3.3.3	Scenario		Parent (µg/L)		
			Vine early application	Vine peak application	Vine late application
	Chateaudun		0.0349	0.0189	0.0090
	Piacenza		1.7388	0.7888	1.0981
	Porto		0.1410	0.1335	0.0802
	Sevilla		0.0056	0.0190	0.0074
	Thiva		0.0110	0.0012	0.0001

$PEC_{(gw)}$ From lysimeter

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	< 0.03	< 0.03	not detected

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	No data
Photochemical oxidative degradation in air ‡	DT_{50} 8.3 x 10^{12} years derived by the Atkinson model that indicates that cyanamide is not supposed to react with hydroxyl radicals or ozone
Volatilisation ‡	Cyanamide has a potential for volatilisation due to its vapour pressure of 0.51 Pa at 20 °C. A field study to investigate volatilisation, its subsequent downwind short-range transport and deposition was performed. Crop: onions (10 cm high, field 100 x 100 m), 40 L Alzodef/ha (20.8 kg a.s./ha). Cyanamide concentrations were analysed in air, grass cultures and water reservoirs up to 24 hours after application. Maximum air concentration was 8.1 µg a.s./m³ at field edge, 8.44 µg a.s./m³ at 10 m distance during 0 - 0.5 hour after treatment. Conclusions: deposition of cyanamide after volatilisation is a relevant process for the aquatic and terrestrial off-crop area.
Metabolites	None

PEC (air)

Method of calculation	A field study to investigate volatilisation, its subsequent downwind short-range transport and deposition was performed. Crop: onions (10 cm high, field 100 x 100 m), 40 L Alzodef/ha (20.8 kg a.s./ha). Cyanamide concentrations were analysed in air, grass cultures and water reservoirs up to 24 hours after application. Theoretical approach for the assessment of long-range transport potential (LRTP); Model ELPOS v.1.0.1

PEC$_{(a)}$

Maximum concentration	Field study: maximum air concentration was 8.1 µg a.s./m³ at field edge, 8.44 µg a.s./m³ at 10 m distance during 0 - 0.5 hours after treatment. Modelling of LRTP: fraction occurring in air: 0.3 % of amount applied; characteristic travel distance 2 km, residence time in air 0.01 d

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil:	Cyanamide
	Surface water:	Cyanamide, urea
	Ground water:	Cyanamide
	Air:	Cyanamide

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	No data
Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

	RMS/peer review proposal
Active substance	R 53

Ecotoxicology

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw(/day))	End point (mg/kg feed)
Birds ‡				
Colinus virginianus	a.s.	Acute	350	n.a.
	Preparation	Acute	No data	n.a.
Anas platyrhynchos	Metabolite dicyandiamide	Acute	>2000	Not reported
Colinus virginianus	a.s.	Short-term	>1042	>5000
Anas platyrhynchos	a.s.	Short-term	>435	>5000
Colinus virginianus	Metabolite dicyandiamide	Short-term	Not reported	>5000
Anas platyrhynchos	Metabolite dicyandiamide	Short-term	Not reported	>5000
Colinus virginianus	Metabolite urea	Short-term	Not reported	>5620
Anas platyrhynchos	Metabolite urea	Short-term	Not reported	>5620
Colinus virginianus	a.s.	Long-term	13.3	152
Mammals ‡				
rat	a.s.	Acute	223	n.a.
rat	Preparation	Acute		
rat	Metabolite 1	Acute		
rat	a.s.	Long-term	3.75	Not reported
Additional higher tier studies ‡				
A higher tier field effect study (Wilkens, 2009; Doc. No.: 865-002, point 10.1.7; Additional Report Vol3 B.9.1.5.1; Germany, 2010a) was conducted in grapevine plantations to identify the effects of the application of 'Dormex' to birds using the plantations in winter. In the course of the study a wide range of bird species were monitored intensively by means of radio-telemetry, visual observations and carcass searches. No effects of the application of 'Dormex' on the bird community were detected.				
A higher tier field study (Staedler, 2007; Doc. 865-001; Annex IIIA, point 10.3; Additional Report Vol3 B.9.3.4.3; Germany, 2010a) was conducted in grapevine and kiwifruit plantations to identify relevant small mammal species. It was shown that small mammals do not use vineyards and kiwifruit orchards at the time of 'Dormex' application and are thus not at risk.				

n.a. not applicable

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Grapes at 9360 g a.s./ha (covers also kiwi)

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 – uptake via diet (Birds)				
insectivorous bird	Acute	506	**0.69**	10
insectivorous bird	Short-term	282	**1.54**	10
insectivorous bird	Long-term	282	**0.05**	5
Higher tier refinement – uptake via diet (Birds): Higher tier studies available. Further data required to support that the application would not overlap with the breeding season; furthermore, all potential focal species should be considered in the risk assessment.				
Tier 1– uptake via drinking water (Birds)				
insectivorous bird	Acute	0.063	5555	10
insectivorous bird	Short-term	0.063	> 6904	10
insectivorous bird	Long-term	0.063	211	5
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird (not required due to log K_{ow} < 3 of cyanamide)	Long-term	-/-	-/-	5
Fish-eating bird (not required due to log K_{ow} < 3 of cyanamide)	Long-term	-/-	-/-	5
Tier 1– uptake via diet (Mammals)				
small herbivorous mammal	Acute	1106	**0.20**	10
small herbivorous mammal	Long-term	317	**0.01**	5
Higher tier refinement – uptake via diet (Mammals)				
Not required due to results of higher tier studies	Acute	-/-	-/-	10
Not required due to results of higher tier studies	Long-term	-/-	-/-	5
Tier 1– uptake via drinking water (Mammals)				
small herbivorous mammal	Acute	0.03	7433	10
small herbivorous mammal	Long-term	0.03	125	5
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammals (not required due to log K_{ow} < 3 of cyanamide.)	Long-term	-/-	-/-	5
Fish-eating mammals (not required due to log K_{ow} < 3 of cyanamide.)	Long-term	-/-	-/-	5

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Lepomis macrochirus	Hydrogen cyanamide LH 21 810 A	96 hr (flow-through)	Mortality, EC_{50}	88.0 (43.1 a.s.) [2)]
Oncorhynchus mykiss	Hydrogen cyanamide LH 21 810 A	21 d (flow-through)	NOEC mortality and sublethal effects	7.5 (3.7 a.s.) [3]
Lepomis macrochirus	Metabolite dicyandiamide	96 h (static)	LC_{50}	> 1000 [2]
Lepomis macrochirus	Metabolite urea (data taken from literature)	96 h (static)	LC_{50}	> 1000 [2]
Tilapia mossambica	Metabolite urea (data taken from literature)	90 d (static)	Mortality (LC_0)	≥ 376 mg/L
Aquatic invertebrate				
Daphnia magna	Hydrogen cyanamide LH 21 810 A	21 d (flow-through)	NOEC reproduction	0.21 (0.1 a.s.) [3]
Daphnia magna	Preparation Alzodef	48 h (static)	EC_{50}	6.5 (3.2 a.s.)
Daphnia magna	Metabolite dicyandiamide	48 h (static)	EC_{50}	3177 mg/L [2]
Daphnia magna	Metabolite urea (data taken from literature)	24 h (static)	EC_{50}	> 10 000
Sediment-dwelling organisms				
Chironomus riparius	Cyanamide L 500 (51.1 % w/w)	28 d (static)	NOEC emergence, development	36.0 (18.4 a.s.) 13.0 (6.6 a.s.)
Algae				
Pseudokirchneriella subcapitata	Cyanamide L 500 (51.1 % w/w)	96 h (static)	E_bC_{50} cell density NOEC cell density E_rC_{50} biomass NOEC biomass	13.2 (6.7 a.s.) 5.0 (2.6 a.s.) 32.5 (16.6 a.s.) 5.0 (2.6 a.s.)
Anabaena flos-aquae	Cyanamide L 500 (51.1 % w/w)	72 h (static)	E_bC_{50} biomass NOEC biomass E_rC_{50} growth rate NOEC growth rate	1.33 (0.69 a.s.) 0.1 (0.05 a.s.) 1.29 (0.65 a.s.) 0.21 (0.11 a.s.)
Anabaena flos-aquae	Alzodef	72 h (static)		not valid

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Pseudokirchneriella subcapitata	Metabolite dicyandiamide	96 h (static)	E_rC_{50} growth rate NOEC growth rate	2040 mg/L[2] 560 mg/L
Scenedesmus quadricauda	Metabolite urea (data taken from literature)	8 d (static)	toxic threshold conc.	> 10 000
Higher plant				
Lemna gibba	Cyanamide L 500 (51.1 % w/w)	7 d (static)	E_bC_{50} biomass E_rC_{50} growth rate NOEC	4.56 (2.4 a.s.) 10.98 (5.7 a.s.) 1.0 (0.5 a.s.)
Microcosm or mesocosm tests				
not performed, not required				

1) nominal, analytically confirmed;
2) nominal, not measured;
3) measured

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Maximum PEC_{sw} values and TER values for cyanamide – application to grapes at 9360 g a.s./ha (covers also kiwi)

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			Lepomus macrochirus	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***A. flos-aquae***	***Lemna gibba***	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	ErC_{50}	NOEC	NOEC
			43100 µg/L	3700 µg/L	3200 µg/L	100 µg/L	650 µg/L	5700 µg/L	not required	--
FOCUS Step 1	not conducted									
FOCUS Step 2										
South Europe	209.42	37.91	205.8	97.6	**15.3**	**0.5**	**3.1**	27.2		
FOCUS Step 3										
D6 / ditch	53.357	12.053	807.8	307.0	**60.0**	**1.9**	12.2	106.8		
R1 / pond	1.805	0.932	23878.1	3970.0	1772.9	55.4	360.1	3157.9		
R1 / stream	37.008	0.106	1164.6	34905.7	**86.5**	**2.7**	17.6	154.0		
R2 / stream	50.538	0.133	852.8	27819.5	**63.3**	**2.0**	12.9	112.8		
R3 / stream	54.250	0.494	794.5	7489.9	**59.0**	**1.8**	12.0	105.1		
R4 / stream	38.342	0.199	1124.1	18593.0	**83.5**	**2.6**	17.0	148.7		
Annex VI Trigger			100	10	100	10	10	10	10	5

* 28 d-PECtwa to be used in connection with the 21 d-NOEC from the flow-through toxicity studies with *Oncorhynchus mykiss.*

FOCUS$_{sw}$ step 4

TERa and TERlt calculations for *Daphnia magna*: (EC_{50} 3200 µg a.s./L, NOEC reproduction = 100 µg a.s./L) including different mitigation options for FOCUS Step 4 scenario – application to grapes at 9360 g a.s./ha (covers also kiwi)

Mitigation options	10 m non-spray buffer zone ***		Xx % input reduction required – all scenarios.		Max drift reduction (95 %)		Max run-off reduction (90%)		Max drainage reduction (90%)	
	PECsw	TERa/TERlt	PECsw	TER	PECsw	TER	PECsw	TER	PECsw	TER
FOCUS Step 4										
D6 / ditch	21.633	148/**4.62**								
R1 / pond	2.796	1144/35.77								
R1 / stream	10.826	296/**9.24**								
R2 / stream	14.635	219/**6.83**								
R3 / stream	17.415	184/**5.74**								
R4 / stream	12.016	266/**8.32**								
Annex VI Trigger		100/10								

*** including the deposition of volatilised cyanamide

Mitigation options	20 m non-spray buffer zone ***		Xx % input reduction required – all scenarios.		Max drift reduction (95 %)		Max run-off reduction (90%)		Max drainage reduction (90%)	
	PECsw	TERlt	PECsw	TER	PECsw	TER	PECsw	TER	PECsw	TER
FOCUS Step 4										
D6 / ditch	10.104	**9.90**								
R1 / pond	1.540	64.94								
R1 / stream	4.039	24.76								
R2 / stream	5.428	18.42								
R3 / stream	7.055	14.17								
R4 / stream	4.668	21.42								
Annex VI Trigger		10								

*** including the deposition of volatilised cyanamide

Bioconcentration

	Active substance	Metabolite1
$logP_{O/W}$	- 0.72	
Bioconcentration factor (BCF)[1] ‡	no data, not required	
Annex VI Trigger for the bioconcentration factor	100	
Clearance time (days) (CT_{50})	no data, not required	
(CT_{90})	no data, not required	
Level and nature of residues (%) in organisms after the 14 day depuration phase	no data, not required	

[1] only required if log $P_{O/W}$ >3.

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	-	-
Preparation (Alzodef)	> 10 < 52	
Metabolite 1	-	-
Field or semi-field tests	No data have been presented.	

Hazard quotients for honeybees (Annex IIIA, point 10.4)

Grapes 1 x 9360 g a.s./ha (covers also kiwi)

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	-	50
a.s.	oral	-	50
Preparation (Alzodef, 51.6 g a.s./L)	Contact	-	50
Preparation	oral	< 936 >180	50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50})
Typhlodromus pyri ‡	Cyanamide L500	Mortality	0.446 kg a.s./ha
Aphidius rhopalosiphi ‡	Cyanamide L500	Mortality	0.432 kg a.s./ha

Grapes 1 x 9360 g a.s./ha (covers also kiwi)

Test substance	Species	Effect (LR_{50})	HQ in-field	HQ off-field[1]	Trigger
Cyanamide L500	*Typhlodromus pyri*	0.446 kg a.s./ha	21.0	3 m: 1.44* 3 m: 0.72**	2
Cyanamide L500	*Aphidius rhopalosiphi*	0.432 kg a.s./ha	21.6	3 m: 1.50* 3 m: 0.75**	2

[1] based on Ganzelmeier drift data and deposition after volatilisation; distance assumed to calculate the drift rate

* vdf of 5

** vdf of 10

Further laboratory and extended laboratory studies ‡
Grapes 1 x 9360 g a.s./ha (covers also kiwi)

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha)	End point	% effect	Trigger value[1]
Aphidius rhopalosiphi	adults	Cyanamide L500 on potted barley seedlings; 2 d	200 340 580 980 1670	Mortality; no effects on reproduction	LR_{50} = 620 g a.s./ha	n.a.
Typhlodromus pyri	protony mphs	Cyanamide L500 on bean leaves; 14 d	200 1020 1730 2950 5000	Mortality; no effects on reproduction	LR_{50} = 2070 g a.s./ha	n.a.
Chrysoperla carnea	larvae	Cyanamide L500, glass plate, 2d	300 900 2500 7300 21200	Mortality, sublethal effects not determined	LR_{50} = 3400 g a.s./ha	n.a.
Aleochara bilineata	adults	Cyanamide L500, quartz sand	300 900 2500 7300 21200	Reproduction	ER_{50} = 930 g a.s./ha	n.a.
Aleochara bilineata	adults	Cyanamide L500; on natural soil (LUFA 2.1); 28d	20000, aged residues	Reproduction	aged for 5 days : 15.6 % aged for 10 days : - 1.7 % aged for 14 days: 7.6 %	50 %
Poecelius cupreus	adults	Cyanamide L500, quartz sand; 14 d	20000	Mortality	0 %	50 %
Pardosa spp.	adults	Cyanamide L500; Quartz sand; 14 d	300 900 2500 7300 21200	Mortality; Lethal effects were more pronounced than sublethal effects	LR_{50} =2100 g a.s./ha	n.a.

[1] Trigger at field rate according to SANCO/10329/2002 (European Commission, 2002b)

Field or semi-field tests
not performed, not required

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia fetida	Preparation Cyanamide L500 + AHL (AHL = urea ammonium nitrate): In summary preparation contains 10 % pure cyanamide	Acute	LC_{50} > 1000 mg product/kg dry soil NOEC = 500 mg product/kg dry soil LC_{50} > 111.56 mg a.s./kg dry soil NOEC = 55.7 mg a.s./kg dry soil
	Preparation	Chronic	No data – data needed for final risk assessment
Other soil macro-organisms – not required			
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡	42 d	+ 27 % effect at day 28 at 4.8 mg a.s./kg d.w.soil (mg a.s./ha) + 5 % effect at day 42 at 4.8 mg a.s./kg d.w.soil (mg a.s./ha)
Carbon mineralisation	a.s. ‡	28 d	+ 5 % effect at day 28 at 4.8 mg a.s./kg d.w.soil
Field studies[2] - not required			

[1] No correction of end point has been necessary, since due to log Pow <2.0

[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Grapes 1 x 9360 g a.s./ha (covers also kiwi)

Test organism	Test substance	Time scale	Soil PEC_{ini}	TER	Trigger
Earthworms					
Eisenia fetida	Cyanamide L500 + AHL	Acute	7.488 mg a.s. per kg soil	> 14.9	10

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Screening test: (Trigger at maximum field rate (9.36 kg a.s./ha) according to SANCO/10329/2002 (European Commission, 2002b): 50 %)

In a screening test on seedlings emergence of cyanamide L500 (20 kg a.s./ha) on 10 different non-target species, following species were the most sensitive: *Allium cepa* (57 %) - emergence; *Brassica oleracea* (89%) and *Allium cepa* (86 %) - dry weight; *Brassica oleracea* and *Allium cepa* - mean height (41 %).

In a screening test on vegetative vigour and early growth of cyanamide L500 (20 kg a.s./ha) on 10 different non-target species, following species were the most sensitive: *Cucumis sativus* (84 %) and *Lycopersicum lycopersicum* (88 %) - dry weight; *Cucumis sativus* (90 %) - mean height.

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure[1] (g/ha)	TER	Trigger[2]
Allium cepa	Cyanamide L 500		871 (a.s.)	9360 (a.s.)	5.4 (3 m)	5
Lycopersicum lycopersicum	Cyanamide L 500	3540 (a.s.)		9360 (a.s.)	10.8 (3 m)	5

[1] based on Ganzelmeier drift data and deposition after volatilisation

[2] according to SANCO/10329/2002 (European Commission, 2002b)

Additional studies (e.g. semi-field or field studies)

Not required

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	End point
Activated sludge	No data
Microbial activity in water/*Pseudomonas putida*	Hydrogen cyanamide, 49 - 491 mg a.s./L Duration 19 h; growth NOEC 88 mg a.s./L EC_{10} 157 mg a.s./L EC_{50} 283 mg a.s./L

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

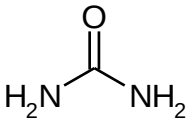
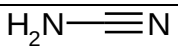
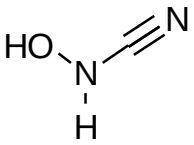
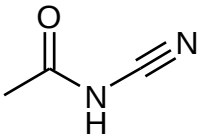
Compartment	
soil	Parent (cyanamide)
water	Parent (cyanamide)
sediment	Parent (cyanamide)
groundwater	Parent (cyanamide)

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	R 50/53, N, dangerous for the environment

	RMS/peer review proposal
Preparation	-

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
Urea	Carbamide	
Hydrogen cyanamide	Cyanamide	
Hydroxycyanamide	N-hydroxy-cyanamide	
N-acetylcyanamide	N-acetyl-cyanamide	

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
ATP	Adaptation to Technical Progress of classification, labelling and packaging (CLP) regulation
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAD	diode array detector
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
ELPOS	Environmental Lon-range Transport and Persistence of Organic Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ETE	estimated theoretical exposure
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery

FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FOMC	first-order multi-compartment
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-DAD	high pressure liquid chromatography with diode array detector
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPLC-MS/MS	high pressure liquid chromatography with tandem mass spectrometry
HPLC-UV	high pressure liquid chromatography with ultraviolet detector
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	inter-laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
i.v.	intravenous
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
LRTP	long-range transport potential
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level

MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RP-HPLC-UV	reversed phase high pressure liquid chromatography with ultraviolet detector
RPE	respiratory protective equipment
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
SL	soluble concentrate
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
T3	tri-iodothyroxine
T4	thyroxine
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet

vdf	vegetation distribution factor
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WHO	World Health Organisation
wk	week
yr	year