Decision number: CCH-D-0000004930-75-04/F Helsinki, 19 September 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For prop-2-yn-1-ol, CAS No 107-19-7 (EC No 203-471-2), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for prop-2-yn-1-ol, CAS No 107-19-7 (EC No 203-471-2), submitted by [redacted] Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of [redacted]. This decision does not take into account any updates submitted after 6 March 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 8 July 2013.

On 22 November 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 20 December 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision on the requests to conduct an *in vitro* gene mutation study in bacteria, to revise DNELs for workers and the general population, to specify and justify environmental release factors used in the exposure estimation for relevant exposure scenarios, to derive PNEC for marine sediment and PNEC for soil, while he provided comments on the request to conduct a pre-natal developmental toxicity study and a two-generation toxicity study.

On 20 December 2013 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update. On the basis of this information, Section II and III of the draft decision were amended removing the request for a revision of DNELs and for deriving a PNEC for marine sediment. Section II was not amended with respect to the request to conduct an *in vitro* gene mutation study in

bacteria, a pre-natal developmental toxicity study and a two-generation toxicity study, to specify and justify environmental release factors and derive a PNEC for soil based on the integrated testing strategy. The Statement of Reasons (Section III) was changed accordingly to reflect Registrant's comments and latest update.

On 6 March 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposals for amendment to the draft decision were submitted.

On 10 April 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

The present decision relates solely to a compliance check requesting further information in form of *an in vitro* gene mutation study in in bacteria (Annex VIII, 8.4.1.), Pre-natal developmental toxicity study in rats or rabbits by oral route (Annexes IX and X, 8.7.2.), Environmental release factors used in the exposure estimation for relevant exposure scenarios (Annex I, section 5.2.2.), Calculation of Predicted No-Effect Concentration (PNEC) for soil based on the ITS (Annex I, section 3.3.1.), Predicted concentrations in groundwater (Annex I, section 5.2.4.). The other information requirement for a Two-generation reproductive toxicity study is addressed in a separate decision although all requests were initially addressed together in the same draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014 in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 10-13 June 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 12 June 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annexes VIII and IX of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. /OECD 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102, as specified in section III.A.3 below;

2. Pre-natal developmental toxicity study (Annex IX, 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral route.

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Environmental release factors used in the exposure estimation for relevant exposure scenarios (Annex I, section 5.2.2.);

2. Calculation of Predicted No-Effect Concentration (PNEC) for soil based on the Integrated Testing Strategy (Annex I, section 3.3.1.);

3. Predicted concentrations in groundwater. Alternatively, the Registrant is requested to provide justification why information on the concentration(s) of the substance in the groundwater is not relevant to be provided in the CSR. (Annex I, section 5.2.4.).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **28 September 2015**. The timeline has been set to allow for sequential testing as appropriate.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000

tonnes or more per year shall contain as a minimum the information specified in Annexes VII, VIII, IX, and X of the REACH Regulation.

1) *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.)

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

According to paragraph 13 of the current OECD 471 test guideline (updated 1997) at least five strains of bacteria should be used. These should include four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by E.coli WP2 strains or *S. typhimurium* TA102 which have an AT base pair at the primary reversion site.

The Registrant has provided two Bacterial Reverse Mutation Assays with and without methabolic activation according to OECD 471 test guideline conducted with the registered substance in 1979 and 2008 with an assigned reliability score of either 1 or 2. One of the tests used five different strains of S. typhimurium (TA 1535, TA 1537, TA 1538, TA 98 and TA 100) and the other one used three different strains of S. typhimurium (TA1535, TA 98 and TA 100]. However, since those tests were conducted, significant changes have been made to OECD guideline 471 and this means that the study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI.

ECHA concludes that a test using *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 has not been submitted by the Registrant and that the test using one of these is required to conclude on *in vitro* gene mutation in bacteria.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14. / OECD 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

2) Pre-natal developmental toxicity study (Annex IX, 8.7.2.)

A "pre-natal developmental toxicity study" for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier the Registrant has provided a study record for a "pre-natal developmental toxicity study" (test method: OECD 414) conducted on the analogue substance 2-butyne-1,4-diol in rat. In the Chemical Safety Report the Registrant provided the following arguments for using this study to fulfil the information requirement: "*Both substances are structurally very similar alkine alcohols with a short C-chain and a triple bond in beta position to the primary alcohol moiety. The water solubility and log Pow of both substances are similar. Both are metabolized by alcohol dehydrogenases and presumably have a very similar reactive metabolite*".

Article 13(1) of the REACH Regulation requires information on intrinsic properties of substances on human toxicity to be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping or read-across), "*provided that the conditions set out in Annex XI are met*".

More specifically, Section 1.5. of Annex XI provides that grouping of substances and read-across approach may be used if the following conditions are met:
- adequacy for the purpose of classification and labelling and/or risk assessment;
- adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
- exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
- adequate and reliable documentation of the study is provided.

Additionally, Annex XI, 1.5. requires a structural similarity among the substances within a group or category and this similarity may be based on:
(1) a common functional group;
(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or
(3) a constant pattern in the changing of the potency of the properties accross the category.

ECHA notes that in the Chemical Safety Report, concerning developmental toxicity, the Registrant refers to the result of a "reproduction/ developmental toxicity screening test" (test method: OECD 421) conducted on the registered substance, prop-2-yn-1-ol in rat. However, this study does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations.

ECHA notes further that, concerning the OECD 414 study on the analogue substance, the Registrant has supported the read-across approach stating that the results obtained from

the pre-natal developmental toxicity study performed with the analogue substance are in line with the results obtained from the reproduction/developmental toxicity screening test performed with the registered substance. However, while the oral gavage dosing in the pre-natal developmental toxicity study was possible up to 80 mg/kg bw/day with only one death observed after 10 days treatment, in the screening test three animals died and the remaining animals were sacrified due to extensive weight loss at the dose 45 mg/kg bw/day, administered via oral gavage, within a week. Therefore, ECHA notes that the registered substance seems to be more toxic than the analogue substance.

Moreover, ECHA notes that the Registrant has not supported the read-across argument with any quantitative comparison of the physico-chemical properties of the two substances nor with a systematic comparison of the toxicological properties of the two substances, including a consideration of the above-mentioned indications of a higher toxicity of the registered substance than the analogue substance. As a result, ECHA concludes that the conditions provided in Annex XI, section 1.5. are not met.

Therefore, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used. ECHA notes that there might be considerations to prefer one species over the other to be tested as the first species. It is up to the Registrant to decide which is the most appropriate species to investigate first.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation, provided a read across justification document which is also included in the updated dossier. The document provides further scientific arguments that according to the Registrant allow fulfilling the standard information requirement for a pre-natal developmental toxicity study with the above-described read across approach. ECHA's assessment of these arguments is described in the paragraphs below.

ECHA notes that the Registrant provided a comparison of the toxicological and physico-chemical properties of prop-2-yn-1-ol and 2-butyne-1,4-diol in the read-across justification attached to Section 13 of the updated IUCLID dossier. The Registrant explained, in the above mentioned document, that prop-2-yn-1-ol and 2-butyne-1,4-diol show similar toxicological characteristic indicating that they can be grouped in a read-across approach as laid down in REACH Regulation, Annex XI Section 1.5. and challenged ECHA's interpretation that the registered substance seems to be more toxic than the analogue substance.

ECHA acknowledges the Registrant's assessment but is of the opinion that based on the findings of the OECD 421 study on the registered substance and the OECD 414 study on the analogue substance, there is a concern that the registered substance could be more toxic than the analogue substance. Firstly, ECHA notes that, from the table comparing the toxicological profiles of the two substance, it is not clear whether liver, kidney and spleen/blood cell toxicity occurs at the same dose levels with the same severity for both substances in repeated dose toxicity studies, thus allowing to conclude that the potency

would be about the same related to the systemic toxicity organ by organ. Secondly, ECHA observes that the Registrant's argument that the two substances would have similar metabolism and have a very similar reactive metabolite is not substantiated with comparison of any metabolic or toxicokinetic data available on the two substances.

The Registrant also argues that as *"propargyl alcohol is characterized by a potent systemic toxic behavior following repeated administration, it can be excluded that a NOAEL from further animal studies would contribute to the overall risk assessment."* ECHA notes that the REACH Regulation does not contain generic provision to adapt the standard information requirement of pre-natal developmental toxicity study if the substance shows *"a potent systemic toxic behaviour following repeated administration".*

Therefore, for the reasons explained above, ECHA concludes that the read-across approach is not adequately justified and does not allow establishing that the pre-natal developmental toxicity properties of the registered substance can be predicted from those of the analogue substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the oral route.

Notes for consideration by the Registrant

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, Section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if weight of evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that testing is necessary to fulfill this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2.

B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

1) Environmental release factors used in the environmental exposure estimation (Annex I, section 5.2.2)

Pursuant to sections 0.6.2 and 0.6.3 of Annex I of the REACH Regulation a CSA performed by a Registrant shall include an exposure assessment according to section 5 of Annex I when the substance fulfills the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 and listed under section 0.6.3 of Annex I or is assessed to be a PBT or vPvB. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards. Pursuant to the Annex I, section 5.2.1 of the REACH Regulation the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Pursuant to the Annex I, section 5.2.2 of the REACH Regulation emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions (OCs) described in the exposure scenario (ES) have been implemented.

ECHA's Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) indicates the default release factors recommended for the corresponding environmental release categories (ERC) which shall be used for the generation of the exposure estimation. According to this Guidance the exposure scenario should contain information (about operational conditions (OCs) and risk management measures (RMMs)) based on which the assumed release factors and daily use rates can be justified. ECHA notes that if other than default ERC release factors were used for emission estimation (for example the ones based on A/B Tables from TGD, 2003), this should be clearly explained in the chemical safety assessment and these release factors have to be well justified.

ECHA notes that the Registrant has included 10 exposure scenarios (ESs) in his Chemical Safety Report (CSR): 1. Manufacture and distribution of substance, 2. Formulation & (re)packing of substances and mixtures, 3. Use as an intermediate, 4. Use in laboratories, 5. Use in laboratories, 6. Corrosion inhibitor for surface treatment and in cleaning agents, 7. Corrosion inhibitor for surface treatment and in cleaning agents, 8. Corrosion inhibitor for surface treatment and in cleaning agents, 9. Corrosion inhibitor for surface treatment and in cleaning agents and 10. Corrosion inhibitor for surface treatment and in cleaning agents.

Exposure scenarios 1, 3, 6, 7, 8 and 9

ECHA notes that release factors applied to ES 1 (manufacture) are supported by the Registrant only with an indication of manufacture site. Furthermore, ECHA notes that release factors applied in the exposure estimation of ESs 3, 6, 7, 8 and 9 are substantiated by the Registrant with the following statement "*this release is regarded as typical for the customer use/downstream users*". However, ECHA notes that no further details and/or documented evidence are provided in the CSR to fully justify these release factors.

ECHA considers that a clear and detailed explanation (e.g. based on RMMs and/or OCs and/or substance properties and/or site(s) specific measurements) shall be provided in the CSR in order to justify the use of non-default ERC release factors in the exposure estimation of the above mentioned ESs. ECHA notes that, in the event site(s) specific measurements of releases are available, the results of these measurements shall be provided in the form of a summary. This summary shall be detailed enough for ECHA to understand whether it covers all possible releases from the substance processing according to the relevant ESs.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation, indicated his willingness to provide an explanation for the use of non-default ERC release factor and submitted an updated registration dossier including a revised CSR.

The following explanation is included in the latest dossier update to justify the release factors used in the exposure estimation: *"Customer use. No data available from downstream users regarding RMMs. Hence, generic assumptions were made. Via eSDS every user has to make sure he fulfils the requirements set in this scenario for safe use."*

In this respect, ECHA notes that pursuant to Article 14(6) and Section 0.7. of Annex I of the REACH Regulation, it is indicated that an exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These sets of conditions contain a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users. s. Furthermore, pursuant to section 5.2.2 of Annex I of the REACH Regulation *"the emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented"*. Finally, according to Annex I, section 5.1.1 of the REACH Regulation *"The exposure scenario, resulting from the final iteration (a final exposure scenario), shall be included in the chemical safety report and attached to the safety data sheet in accordance with Article 31"*.

ECHA does not consider release factors alone as sufficient information to replace the set of conditions which shall be recommended by the Registrant to downstream users. Additionally, ECHA notes that it is not clear which "generic assumptions" were made by the Registrant for exposure estimation. Thus, ECHA considers that the justification provided in order to justify the use of non-default release factors in the exposure estimation is not satisfactory.

In his comments on the proposals for amendments submitted by the Competent Authorities of the Member States, the Registrant indicated that he cannot justify the non-default ERC release factors used in the exposure estimation since no data is available on RMMs/OCs and/or site specific information and/or substance properties. He indicated that there are no information available also from customer uses and that the assumptions made are realistic and leading to the safe use of the substance. Finally, he indicated that it is the responsability of the subsequent users of the substance to ensure that their respective use are safe e.g. by scaling.

ECHA notes that, as reported above, the assumptions made by the Registrant to justify the safe use of the substance are not clear. The Registrant is referring to "generic assumptions" which are not satisfactory enough to justify the non-default ERC release factors used in their exposure estimation. These generic assumptions presumably include a set of RMMs/OCs and/or site specific measurement and/or substance properties and should be clearly explained/listed by the Registrant in the CSR.

Therefore, pursuant to Article 41(1)(c) and 41(3) of the REACH Regulation the Registrant is requested to provide a clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties and/or site(s) specific measurements) for the use of non-default ERC release factors in the exposure estimation of ESs 1, 3, 6, 7, 8 and 9. ECHA notes that exposure scenarios shall contain information on operational conditions (OCs) and risk management measures (RMMs) applied. Alternatively, the Registrant may decide to use ERCs' default release factors for his exposure estimation. The chemical safety report shall be amended accordingly.

2) Calculation of Predicted No-Effect Concentration (PNEC) for soil based on the Integrated Testing Strategy

Pursuant to Annex I, section 3.3.1 and 3.3.2 of the REACH Regulation, based on the available information, the PNEC for each environmental sphere shall be established. Moreover, according to Article 14(4) of the REACH Regulation, if the substance fulfils the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 which are listed in Article 14(4)(a-d) of the REACH Regulation or is assessed to be a PBT or vPvB, the chemical safety assessment (CSA) shall include an exposure assessment and risk characterisation. Annex I, section 6.2 of the REACH Regulation specifies that the risk characterisation shall consider the environmental spheres for which exposure to the substance is known or reasanobly foreseeable.

ECHA notes that exposure of soil is likely to occur, since the exposure estimation provided by the Registrant in the CSR indicates exposure of the soil in a number of developed ESs. ECHA observes that the Registrant derived the PNEC for the soil compartment on the basis of the only available toxicity study with soil microorganisms. The Guidance on information requirements and chemical safety assessment, Chapter R.10 (p. 41) (ECHA, 2008) states that: "*If results from short-term tests with a producer, a consumer and/or decomposer are available, the result is divided by a factor of 1000 to calculate the* $PNEC_{soil}$*. If only one terrestrial test result is available (earthworms or plants), the risk assessment should be performed both of this test result and on the basis of the outcome of the aquatic toxicity data to provide an indicator of the risk.*"

ECHA therefore concludes that the PNEC for soil cannot be derived solely on the basis of the toxicity test with soil microorganisms, when this study is the only available on soil toxicity. In such a case, an Integrated testing strategy (ITS) for Effects on Terrestrial Organisms as summarised in the Guidance on information requirements and chemical safety assessment, Chapter R.7c (ECHA, 2012, version 1.1) shall be followed by the Registrant in deriving the PNEC soil and in performing the risk assessment of the soil compartment. ECHA notes that based on fate and aquatic toxicity properties, the substance can be assigned to the soil hazard category 1 (according to Table R.7.11-2 contained in the above mentioned Guidance R.7c). Consequently, ECHA underlines that for such type of substances the equilibrium partitioning method (EPM) can be applied to aquatic data to identify a PNEC for soil organisms. However, this method should only be considered as a screening assessment for identifying substances requiring further testing. Therefore, as illustrated in the above mentioned Guidance R.7c, if the $PEC_{soil}/PNEC_{soil}$ ratio calculated using the EPM method is greater than 1, tests with soil organisms should be considered as an essential requirement for a refined effects assessment. In that case the Registrant shall therefore submit to ECHA testing proposals for short-term toxicity testing with soil invertebrates and with soil plants in order to fulfil the standard information requirements of Annex IX, 9.4.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation, indicated his willingness to establish a more stringent PNEC for soil and submitted an updated registration dossier including a revised CSR.

ECHA observes that an old value of PNEC for soil (obtained from toxicity tests on soil microorganisms) is provided in Section 6 of the IUCLID registration dossier and Section 7.6 of the CSR. However, ECHA notes that in section 9 and 10 of the CSR the Registrant has introduced a newly derived value of PNEC for soil (corresponding to 0.00244 mg/kg dw) used to calculate the risk characterisation ratios (RCRs) for the terrestrial compartment. ECHA underlines that the Registrant has failed to explain how this new value of PNEC for soil was estimated and presumes that it was done through the EPM method.

Additionally, ECHA calculated the PNEC for soil following the Integrated Testing Strategy described in ECHA Guidance R.10 by application of the EPM method and obtained a value (0.000244 mg/kg dw) which is 10 times lower than the one used by the Registrant in the risk characterisation.

Finally, ECHA underlines that by application of the value estimated by ECHA in the derivation of RCRs, at least one RCR for soil would become above 1, indicating a risk for soil in the use of the substance. Thus, ECHA considers that based on the information provided the risk for the terrestrial compartment is not sufficiently controlled.

Therefore, pursuant to Article 41(1)(c) and 41(3) of the REACH Regulation the Registrant shall establish the PNEC for soil using the EPM method, as described in Section R.10.6. of the Guidance on information requirements and chemical safety assessment, Chapter R.10 (ECHA, 2008). The derived PNEC for soil shall be further used in the CSA as described in the integrated testing strategy (ITS) for Effects on Terrestrial Organisms in Figure R.7.11-3 Scheme B and Table R.7.11-2 of the above mentioned Guidance, Chapter R.7c. The IUCLID registration dossier and CSR shall be amended accordingly.

3) Predicted concentrations in groundwater

Pursuant to the Annex I, section 5.2.4. of the REACH Regulation an estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment). Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed.

The Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 2.1, October 2012) report that "*indirect exposure of humans via the environment may occur by consumption of food (fish, crops, meat and milk) and drinking water, inhalation of air and ingestion of soil. [...] The indirect exposure is assessed by estimating the total daily intake of a substance based on the predicted environmental concentrations for (surface) water, groundwater, soil and air.*"

ECHA notes that the Registrant has not reported in the CSR any information on the concentration(s) of the substance in the groundwater. ECHA considers that this information is relevant and necessary for the assessment of humans exposed indirectly via the environment.

Therefore, pursuant to Article 41(1)(c) and 41(3) of the REACH Regulation the Registrant is requested to provide information on the concentration(s) of the substance in the groundwater and take account of it in the assessment of indirect exposure of humans via environment. Alternatively, the Registrant is requested to provide a justification as to why information on the concentration(s) of the substance in the groundwater is not relevant to be provided in the CSR. The CSR shall be amended accordingly.

C. Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a two-generation reproductive toxicity study (Annex X, 8.7.3.). As this endpoint is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required

information in the form of an updated IUCLID5 dossier is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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