Decision number: CCH-D-2114309019-56-01/F Helsinki, 16 October 2015

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

For Oxirane, mono[(C12-14-alkyloxy)methyl] derivs., CAS No 68609-97-2 (EC No 271-846-8), 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 Oxirane, mono[(C12-14-alkyloxy)methyl] derivs., CAS No 68609-97-2 (EC No 271-846-8), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex IX, Sections 9.1.5. and 9.4.2. and Annex X, Sections 9.5.1., 9.4.4. and 9.4.6. of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 11 June 2015, 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.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

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 14 May 2014.

On 19 August 2014 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 25 September 2014 ECHA received comments from the Registrant on the draft decision.

On 27 February 2015 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.

On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 11 June 2015 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 17 July 2015 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.

On 27 July 2015 ECHA referred the draft decision to the Member State Committee.

By 17 August 2015 , in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 31 August 2015 in a written procedure launched on 20 August 2015.

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 IX and X 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. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD 211);

2. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.); using one or more of the following test methods: Sediment-water Chironomid toxicity using spiked sediment, (OECD 218) or Sediment-water Lumbriculus toxicity test using spiked sediment, (OECD 225) or Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233);

3. Effects on terrestrial organisms – Long-term toxicity testing on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD 222), or Enchytraeid reproduction test (OECD 220), or Collembolan reproduction test in soil (OECD 232));

4. Effects on terrestrial organisms – Long-term toxicity testing on plants (Annex X, Section 9.4.6.; test method: Terrestrial plants, growth test, OECD 208, with at

least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030);

5. Effects on terrestrial organisms – Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216).

Requests 2, 3 and 4 are dependent on the outcome of the request 1 and the revised environmental risk assessment and may not need to be conducted if the conditions specified in Section III below are met.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **24 July 2017** an update of the registration dossier containing the information required by this decision. 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 request(s) in this decision, or to fulfil otherwise the information requirement(s) 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 to X of the REACH Regulation.

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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. Column 2 of Annex IX, Section 9.1. specifies that long-term aquatic toxicity testing shall be proposed by the Registrant if the chemical safety

assessment according to Annex I indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.

ECHA notes that the Registrant has made a testing proposal for long-term toxicity testing on Daphnia in the latest dossier submitted ([redacted]). However, as the information requirement for long-term toxicity testing on Daphnia is already subject to the ongoing compliance check, this testing proposal is considered inadmissible and will not be examined separately by ECHA.

ECHA notes that the registration dossier contains two short-term toxicity studies on aquatic invertebrates ([redacted]) and three short-term toxicity studies on fish ([redacted]; [redacted] and a recent study conducted by [redacted]). As explained below, ECHA notes that the available information in the registration dossier indicates that *Daphnia* are substantially more sensitive than fish.

ECHA notes that the registered substance shows acute toxicity to aquatic invertebrates. The key study on short-term toxicity to aquatic invertebrates reported in the registration dossier ([redacted]) was conducted on water accommodated fractions with *Daphnia magna.* The 48-Hour EL50 based on nominal loading rates was 7.2 mg/l loading rate and the 48h NOEC was 1.8 mg/l. This study is assigned as reliability 1 by the Registrant. The other study on short-term toxicity to *Daphnia magna* in the registration dossier ([redacted]) is considered as unreliable by the Registrant since the NOEC and EC50 values were lower than the lowest concentration tested in the study, 10 mg/l.

No long-term studies on aquatic invertebrates are available in the registration dossier. The Registrant does not provide any justification for adapting in accordance with Column 2 of Annex IX, section 9.1, or the general adaptation rules of Annex XI. Furthermore, ECHA notes that the registered substance has a water solubility of 0.483 mg/L and thus can be considered as poorly soluble. Long-term testing is more appropriate for substances which are poorly soluble.

The registration dossier contains three short-term studies on fish. ECHA considers that the two supporting studies are not reliable ([redacted]). In one supporting study ([redacted]) a limit concentration of 5000 mg/L was tested, which is far above the water solubility limit of 0.483 mg/L. In one replicate 100% mortality was observed while in the other two replicates no effects at all were seen. In the other supporting study ([redacted]) 20% mortality was seen at the lowest concentration tested (180 mg/L), whereas no effects were found at higher concentrations. ECHA therefore considers both these studies as not reliable.

The registration dossier contains also a new short-term fish toxicity study (key study) conducted according to GLP and OECD Guideline 203 (Fish, Acute Toxicity Test) with *Oncorhynchus mykiss*. ECHA considers this new study as reliable although reliability 2 rather than 1 seems more appropriate since there were unexplained concentration losses in the test. This might be due to adsorption to glassware or biodegradation of some components. ECHA further notes that the other two short-term fish tests did not have analytical monitoring and the reliable short-term Daphnia test also had similar concentration losses. This new study tested water accommodated fractions and showed no mortalities, 96-hour nominal LL50 > 100 mg/L and 96h NOELR 100 mg/l. In comparison, the reliable study on short-term Daphnia toxicity gave a 48h-EL50 = 7.2 mg/L nominal loading rate water

accommodated fractions. This indicates that fish are ca. 13 times less sensitive than Daphnia in short-term tests.

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.

As for the test method for the long-term toxicity testing on aquatic invertebrates, ECHA considers the standard recommended test method EU C.20./OECD 211 to be the most appropriate and suitable.

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: Daphnia magna reproduction test (test method: EU C.20./OECD 211).

Notes for consideration by the Registrant

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated (PEC/PNEC>1) (even after further improvements in the exposure information), then long-term fish study needs to be conducted.

2. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.)

"Long-term toxicity to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. 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.

The Registrant has waived testing on sediment organisms using the following justification: "*In accordance with column 2 of REACH Annex X, the long terms toxicity testing to sediment organisms study (required in section 9.5.1) is not required due to the Chemical Safety Assessment according to the Annex I does not indicate the need to investigate further the effects on sediment organisms.*"

In the commenting phase, the Registrant commented that they "*agree to submit the following information derived with the registered substance subject to the present decision: sediment-water Chironomid toxicity test using spiked sediment (test method: OECD 218) or sediment-water Lumbriculus toxicity test using spiked sediment (test method: OECD 225) or Sediment-Water Chironomid life-cycle toxicity test using spiked water or spiked sediment (OECD 233),) if the updated chemical safety assessment indicates the need to further investigates the effects on sediments organisms or an updated argument for an adaptation of the standard information requirements.*"

ECHA notes that an environmental risk assessment is now provided and the Registrant derives the PNEC sediment using the Equilibrium Partitioning Method (EPM). No risks are

identified for the sediment compartment at this stage. However, a long-term aquatic toxicity test is requested in the present decision (request 1) and therefore the PNEC aquatic may change which may result in a change to the PNEC sediment and a potential risk to the sediment compartment cannot be excluded.

Considering the high adsorption potential (log Koc>5.6) of the registered substance, it is not possible to exclude that there is a risk to the sediment organisms due to long-term exposure. The justification for waiving provided by the Registrant is subject to confirmation by the long-term toxicity testing on aquatic invertebrates and subsequent refinement of the environmental risk assessment. If the refined environmental risk assessment confirms that the registered substance does not pose a risk to the sediment compartment, there is no need to conduct the long-term toxicity to sediment organisms.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. 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: sediment-water Chironomid toxicity test using spiked sediment (test method: OECD 218) or sediment-water Lumbriculus toxicity test using spiked sediment (test method: OECD 225) or Sediment-Water Chironomid life-cycle toxicity test using spiked water or spiked sediment (OECD 233).

The Sediment-water Chironomid toxicity using spiked sediment (OECD 218), Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225) and Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233) are each considered capable of generating information appropriate for the fulfilment of the information requirements for sediment long-term toxicity testing. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties. The Registrant has the choice to carry out more than one of the sediment tests defined in Section II above if further testing is required.

Furthermore, both water and sediment exposure scenarios are described in the OECD 233 Test Guideline. The Registrant is advised to consult the OECD 233 Test Guideline and the ECHA Guidance on information requirements and chemical safety assessment (version 2, November 2014), Chapter R7b (Section R.7.8.10.1) for the selection of the appropriate method of spiking.

3., 4. and 5. Effects on terrestrial organisms (Annex IX and X, 9.4.)

"Effects on terrestrial organisms" are standard information requirements as laid down in Annex IX and X, Sections 9.4. of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, Section 9.4.2.), short-term and long-term toxicity to invertebrates (Annex IX, Section 9.4.1. and Annex X, Section 9.4.4.) and short-term and long-term toxicity to plants (Annex IX, Section 9.4.3. and Annex X, Section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

3. Toxicity testing on terrestrial invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

The Registrant has waived testing on terrestrial invertebrates using the following justification: "*In accordance with section 3 of REACH Annex XI, the study does not need to be conducted as the manufacturer and/or importer fulfill all the conditions under Annex XI Section 3.2(a).*"

ECHA points out the justification for waiving provided by the Registrant does not meet the criteria of the general adaptation rules of Annex XI or Column 2 of Annex IX and X, Section 9.4. of the REACH Regulation.

More specifically, Annex XI, Section 3, states that testing in accordance with Annex IX and X may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report and that in all cases adequate justification and documentation shall be provided. ECHA notes that based on the information provided in section 3.5 of the technical dossier of the Registrant there are wide dispersive uses of the substance, e.g. exposure release categories (ERCs) 8c, 8e and 8f, which indicate exposure to this compartment.

In the commenting phase, the Registrant commented that they "*will consider the Integrated Testing Strategy as recommended in Section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and Chemical Safety Assessment (version 1.1., November 2012) and determine the need of further testing on terrestrial organisms. Additionally, if* [redacted] *conclude that no further investigation of effects on terrestrial invertebrates is required,* [redacted] *agree to update the technical dossier by clearly stating the reasons of adapting the information requirements of section 9.4.1. of Annex IX and section 9.4.4. of Annex X.*"

ECHA notes that an environmental risk assessment is now provided and the Registrant derives the PNEC soil using EPM. No risks are identified for the soil compartment at this stage. However, a long-term aquatic toxicity test is requested in the present decision (request 1) and therefore the PNEC aquatic may change which may result in a change to the PNEC soil and a potential risk to the soil compartment cannot be excluded.

Considering the high adsorption potential (log Koc>5.6) of the registered substance, it is not possible to exclude that there is a risk to the soil due to long-term exposure. The justification for waiving and comments provided by the Registrant are subject to confirmation by the long-term toxicity testing on aquatic invertebrates and subsequent refinement of the environmental risk assessment. If the refined environmental risk assessment confirms that the registered substance does not pose a risk to the soil compartment, there is no need to conduct the toxicity testing on terrestrial invertebrates as further specified on the 'Notes for consideration by the Registrant' at the end of Section III.A.

Furthermore, column 2 of Annex IX and X, Section 9.4. provides that the studies do not need to be conducted if direct or indirect exposure to the soil compartment is unlikely. For the reasons outlined above and considering also the high adsorption potential (log Koc>5.6) of the registered substance, it is not possible to exclude that there is a risk to terrestrial organism due to long-term exposure.

Hence, the justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX and X, Section 9.4., or the general adaptation rules of Annex XI. Therefore, the adaptations 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 requirements. 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: Earthworm reproduction test (Eisenia fetida/Eisenia andrei) (test method: OECD 222), or Enchytraeid reproduction test (test method: OECD 220), or Collembolan reproduction test in soil (test method: OECD 232).

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

4. Toxicity testing on terrestrial plants (Annex IX, 9.4.3. and Annex X, 9.4.6.)

The Registrant has waived testing on terrestrial plants using the following justification: "*In accordance with column 2 of REACH Annex X, the long-term toxicity to plants study (required in section 9.4.6) does not need to be conducted as the results of the Chemical Safety Assessment according to Annex I does not indicate the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms.*"

In the commenting phase, the Registrant commented that they "*will consider the Integrated Testing Strategy as recommended in Section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and Chemical Safety Assessment (version 1.1., November 2012) and determine the need of further testing on terrestrial organisms. Additionally, if* [redacted] *conclude that no further investigation of effects on terrestrial invertebrates is required,* [redacted] *agree to update the technical dossier by clearly stating the reasons of adapting the information requirements of section 9.4.3. of Annex IX and section 9.4.6. of Annex X).*"

ECHA notes that an environmental risk assessment is now provided and the Registrant derives the PNEC soil using EPM. No risks are identified for the soil compartment at this stage. However, a long-term aquatic toxicity test is requested in the present decision (request 1) and therefore the PNEC aquatic may change which may result in a change to the PNEC soil and a potential risk to the soil compartment cannot be excluded.

Considering the high adsorption potential (log Koc>5.6) of the registered substance, it is not possible to exclude that there is a risk to the soil due to long-term exposure. The justification for waiving and comments provided by the Registrant are subject to confirmation by the long-term toxicity testing on aquatic invertebrates and subsequent refinement of the environmental risk assessment. If the refined environmental risk assessment confirms that the registered substance does not pose a risk to the soil compartment, there is no need to conduct the toxicity testing on terrestrial plants as further specified on the 'Notes for consideration by the Registrant' at the end of Section III.A.

Furthermore, column 2 of Annex IX and X, Section 9.4. provides that the studies do not need to be conducted if direct or indirect exposure to the soil compartment is unlikely. For the reasons outlined above and considering also the high adsorption potential (log Koc>5.6)

of the registered substance, it is not possible to exclude that there is a risk to terrestrial organism due to long-term exposure.

Hence, the justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX and X, Section 9.4., or the general adaptation rules of Annex XI. Therefore, the adaptations 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 requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

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: Terrestrial plants, growth test (test method: OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030).

5. Effects on soil micro-organisms (Annex IX, 9.4.2.)

The Registrant has waived testing on effects on soil microorganisms using the following justification: "*In accordance with column 2 of REACH Annex IX, the effects on soil micro-organisms study (required in section 9.4.2) does not need to be conducted as the results of the Chemical Safety Assessment does not indicate this choice of test to be appropriate.*"

ECHA points out the justification for waiving provided by the Registrant does not meet the criteria of the general adaptation rules of Annex XI or Column 2 of Annex IX, Section 9.4. to the REACH Regulation.

More specifically, Annex XI, Section 3, states that testing in accordance with Annex IX may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report and that in all cases adequate justification and documentation shall be provided. ECHA notes that based on the information provided in section 3.5 of the technical dossier of the Registrant there are wide dispersive uses of the substance, e.g. ERCs 8c, 8e and 8f, which indicate exposure to this compartment.

Furthermore, column 2 of Annex IX, Section 9.4. provides that the studies do not need to be conducted if direct or indirect exposure to the soil compartment is unlikely. For the reasons outlined above and considering also the high adsorption potential (log Koc>5.6) of the registered substance, it is not possible to exclude that there is a risk to terrestrial organism due to long-term exposure.

Hence, the justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, Section 9.4., or the general adaptation rules of Annex XI. Therefore, the adaptations cannot be accepted.

Moreover, ECHA considers that the effects on soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

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

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2, November 2014), Chapter R.7C, Section R.7.11.3.1., p115, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

In the commenting phase, the Registrant commented that they "*agree with ECHA regarding the fact that effects on soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint. Consequently* [redacted] *agree to conduct the study: Soil microorganisms: nitrogen transformation test according to EU C.21./OECD 216.*"

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: soil microorganisms: nitrogen transformation test (test method : EU C.21./OECD 216).

Notes for consideration by the Registrant

ECHA notes that the results from the toxicity test on aquatic invertebrates requested under subsection A.1 of the present Decision may allow the subsequent refinement of the PNECwater. Consequently, the Registrant may consider the integrated testing strategy (ITS) as recommended in section R.7.11.6. and Table R.7.11-2, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), and determine the need for further testing on terrestrial organisms. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the information requirements of section 9.4. of Annexes IX and X, of the REACH Regulation.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 31 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested information other than the one requested in the present decision. ECHA considers that a reasonable time period for providing the information on long-term toxicity testing on aquatic invertebrates

(Annex IX, Section 9.1.5.), long-term toxicity to sediment organisms (Annex X, Section 9.5.1.), long-term toxicity testing on terrestrial invertebrates (Annex X, Section 9.4.4.), long-term toxicity testing on plants (Annex X, Section 9.4.6.) and effects on soil micro-organisms (Annex IX, Section 9.4.2.) required in the present decision, in the form of an updated registration, is 21 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

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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Leena Ylä-Mononen, Director of Evaluation

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.