Decision number: TPE-D-0000002295-75-05/F Helsinki, 13 June 2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For [redacted] 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(e) thereof for [redacted], by [redacted] (Registrant), latest submission number [redacted] for the tonnage band of 1000 tonnes or more per year:

- Viscosity (OECD Guideline 114);
- Long-term toxicity testing on aquatic invertebrates (OECD guideline 211); Long-term toxicity study on fish (OECD Guideline 210, Fish early-life stage toxicity test);
- Long term toxicity on soil macro-organisms (OECD Guideline 222);
- Long-term toxicity to terrestrial plants (ISO 22030). The test is proposed to be conducted in case of effects are observed in the proposed earthworm reproduction test;
- Developmental toxicity / teratogenicity study (OECD 414) in rats, oral route.

On 25 October 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated an examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a third party consultation for the testing proposals from 29 July 2011 until 12 September 2011. ECHA did not receive information from third parties.

On 26 January 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 13 February 2012 ECHA received comments from the Registrant and considered the Registrant's comments received and did not amend the draft decision.

On 2 March 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, one Competent Authority of a Member State submitted proposals for

amendment to the draft decision.

On 4 April 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided not to amend the draft decision.

On 16 April 2012 ECHA referred the draft decision to the Member State Committee.

On 30 April 2012 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account and modified the draft decision.

A unanimous agreement of the Member State Committee on the modified draft decision was reached on 21 May 2012 in a written procedure launched on 10 May 2012.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Viscosity (Annex IX, 7.17., test method: OECD 114);
2. Pre-natal developmental toxicity study in rats, oral route (Annex IX, 8.7.2., test method: EU B.31/OECD 414);
3. Long-term toxicity on invertebrates (*Daphnia sp.*) (Annex IX, 9.1.5., test method: EU C.20/OECD 211);
4. Long-term toxicity testing on fish (Annex IX, 9.1.6.1., test method: OECD 210);
5. Long-term toxicity to terrestrial invertebrates (Annex X, 9.4.4., test method: OECD 222);
6. Long-term toxicity testing to terrestrial plants (Annex X, 9.4.6., test method: ISO 22030).

The Registrant shall carry out the following additional test pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

7. Effects on soil micro-organisms (Annex IX, 9.4.2., test method: EU C.21/OECD 216).

The Registrant shall determine the appropriate order of the studies taking into account the possible outcomes and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation. More specifically, prior to conducting the tests 3 and 4 above, the Registrant shall take into account the guidance related to integrated testing strategy for aquatic toxicity testing to determine the sequence in which the tests are to be conducted.

Data from a second pre-natal developmental toxicity study on another species is a standard

information requirement according to Annex X, 8.7.2. of the REACH Regulation. 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. 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.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **13 June 2014** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

1. Viscosity

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Information on viscosity is a standard information requirement as laid down in Annex IX, section 7.17. of the REACH Regulation. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed test: Viscosity of liquids (test method: OECD 114) using the registered substance.

2. Pre-natal developmental toxicity study

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

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. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant proposed testing by the oral route on rats. In the light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route on rats is appropriate.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed test: pre-natal developmental toxicity study on rats (test method: OECD 414) using the registered substance.

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all 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.

3. Long-term toxicity on invertebrates

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Long-term toxicity testing on invertebrates is a standard information requirement as laid down in Annex IX, 9.1.5. of the REACH regulation. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements following the substance properties and the need to investigate further the effects of the substance as indicated in the Chemical Safety Assessment (CSA). Consequently, there is an information gap and it is necessary to generate the data for this endpoint.
The Registrant notes that there are no experimental data available on the effects of [redacted] on aquatic organisms but only estimated data. However, no data at all is available for characterising long-term effects of the substance on aquatic organisms. Moreover, the Registrant has proposed the test to refine the predicted no effect concentration (PNEC) value as indicated in the Chemical Safety Report (CSR). ECHA considers this justification appropriate for the testing of the registered substance.

According to ECHA Guidance (Chapter R7b (version 1.1., August 2008) Figure R.7.8-4 p. 53) if based on acute data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the daphnia study is to be conducted first. If based on the results of the long-term *Daphnia sp*. study and an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: *Daphnia sp*. reproduction test (test method: EU C.20/OECD 211) using the registered substance.

4. Long-term toxicity testing on fish

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Long-term toxicity testing on fish is part of the standard information requirements as laid down in Annex IX, section 9.1.6. of the REACH Regulation. The information needs to be present in the technical dossier to meet the information requirements following the substance properties and the need to investigate further the effects of the substance as indicated in the CSA. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

As for test 3 above, the Registrant notes that there are no experimental data available on the effects of [redacted] on aquatic organisms but only estimated data. However, no data at all is available for characterising long-term effects of the substance on aquatic organisms. Moreover, the Registrant has proposed the test to refine the PNEC value as indicated in the CSR. ECHA considers this justification appropriate for the testing of the registered substance.

According to ECHA Guidance (Chapter R7b (version 1.1., August 2008), p. 51 and Figure R.7.8-4 p. 53) if based on acute aquatic toxicity data there would be compelling evidence to suggest that fish is substantially less sensitive than invertebrates or algae no further fish test would be necessary. In case neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies are required on both. According to the integrated testing strategy, the *Daphnia sp.* study is to be conducted first. If based on the results of the long-term *Daphnia sp.* study and an applied assessment factor of 50 no risks are indicated, the long-term fish testing may no longer be necessary to be conducted. Therefore, prior to initiating the long-term fish study, the Registrant is to take account of this guidance related to the sequence of testing to determine whether testing on vertebrate animals is required.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Fish early-life stage toxicity test (test method: OECD 210) using the registered substance.

5. Long-term toxicity to terrestrial invertebrates

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Long-term toxicity testing on terrestrial invertebrates is a standard information requirement as laid down in Annex X, 9.4.4. of the REACH Regulation. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements following the substance properties and the need to investigate further the effects of the substance as indicated in the Chemical Safety Assessment (CSA). Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant notes that there are no data available on the effects of [redacted] on terrestrial organisms but data only from a read across substance. The registrant considers as a result of the CSA that in addition to this screening risk assessment, a confirmatory long-term soil toxicity test, the earthworm reproduction test according to OECD 222, is needed. ECHA considers this justification appropriate for the testing of the registered substance. A long-term earthworm test allows uptake via all possible exposure routes, via surface contact, soil particle ingestion and the pore-water. As such earthworms are highly exposed to toxicants in soil and may be sensitive to the potential adverse effects of a substance.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Earthworm reproduction test (*Eisenia fetida/Eisenia Andrei*) (test method: OECD 222) using the registered substance.

6. Long-term toxicity testing to terrestrial plants

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Long-term toxicity testing on terrestrial plants is a standard information requirement as laid down in Annex X, 9.4.6. of the REACH Regulation. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements following the substance properties and the need to investigate further the effects of the substance as indicated in the Chemical Safety Assessment (CSA). Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

As a result of the CSA, the Registrant is proposing to conduct the test only if effects are observed in the OECD 222 earthworm reproduction test. If adverse effects were observed in the earthworm reproduction test, the chronic testing in plants would be needed to refine the hazard assessment of the substance. However, when a substance is not readily biodegradable and no further information on biodegradation is available, due to the potential persistence and high adsorption on soil combined with its toxicity, testing on both terrestrial plants and terrestrial invertebrates is necessary to identify the toxicity of the substance on soil compartment. ECHA concludes from the distribution modeling data and estimated adsorption and biodegradation properties, that soil compartment exposure is high and condequently the substance is provisionally classified as the most hazardous for the soil compartment: not readily biodegradable, high absorption coefficient to soil. Therefore, the registered substance falls in Hazard Category 4 as explained in the guidance and such category confirms that the tiered testing strategy cannot be applied in the present case (Chapter R7c, version 1.1., August 2008, Table R.7.11-2, p. 131).

Therefore, the study long-term toxicity testing on terrestrial plants is to be conducted pursuant to Article 40(3)(a) regardless of the results received from carrying out long-term toxicity testing on terrestrial invertebrates requested above under 5 (Earthworm reproduction test).

7. Soil Microorganisms: Nitrogen Transformation Test

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

In order to fulfill the standard information requirements set out in Annex IX, section 9.4., the Registrant has to provide normally the following information on: (i) short term toxicity to invertebrates (section 9.4.1), (ii) effects on soil micro-organisms (section 9.4.2.) and (iii) short term toxicity to plants (section 9.4.3.). According to Column 2 of Annex X 9.4., the choice of the appropriate terrestrial toxicity tests depends on the outcome of the CSA. Furthermore, as indicated in ECHA Guidance R.7 C and Table R.7.11-2 (version 1.1, August 2008, p131-132) for substances in Hazard Category 4 and in order to refine PNEC soil an additional study on soil micro-organisms, preferably on the nitrogen cycle, has to be considered.

The Registrant waived the study on soil micro-organisms with reference to the proposed earthworm reproduction test as indicated in relation to test 5 above. The registrant also proposes a toxicity test on plants as indicated in point 6 above. However, these tests proposed by the Registrant individually or jointly are not sufficient to fulfill all the information requirements outlined in Annex IX, 9.4. The proposed tests do not address the third trophic level requested for this tonnage band (i.e. the information requirement in section 9.4.2.) for soil microorganism. The registration dossier does not contain any valid justification for waiving the study in section 9.4.2 in accordance with the specific rules for adaptation indicated in column 2 of Annex 9.4 or the general rules for adaptation under Annex XI. This justification for omitting this data requirement by using the result of the Earthworm reproduction test is not covered by column two or Annex adapatation options. In addition, the guidance and hazard soil category indicate clearly that three chronic or long-term soil organisms toxicity tests have to be performed (Chapter R7. C, version 1.1, August 2008, R.7.11.5.3, p121) due to the potential persistence and high adsorption on soil combined with the toxicity of the registered substance. ECHA concludes from the distribution modeling data and estimated adsorption and biodegradation properties, that soil compartment exposure is high and justifies the testing on soil micro-organisms. The testing proposed by the Registrant for terrestrial plants and invertebrates is therefore to be considered non-compliant with Annex IX, 9.4 and it is necessary to require the remaining

study for micro-organisms to ensure that the information requirement for this endpoint is met.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out as additional study: Soil Microorganisms: Nitrogen Transformation Test (test method: EU C.21/OECD 216) using the registered substance.

Deadline for submitting the required information

In the draft decision, ECHA indicated that the Registrant should submit the required information to ECHA in an updated registration dossier within 18 months from the date of the final decision. During the commenting period on the proposals for amendment, the Registrant indicated that 24 months would be more appropriate deadline to submit the required information when considering the estimated time to plan, conduct and analyse the studies, and provided requested evidence. Taking this into account, ECHA is requesting the Registrant to submit an update of the registration dossier containing the required information within 24 months of the date of the final decision.

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

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 appeal shall be lodged within three months of receiving notification of this decision.
Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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