EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003253-82-04/F Helsinki, 25 July 2013

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

For Fatty acids, C18-unsaturated, trimers, CAS No 68937-90-6 (EC No 500-239-5), 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(1)(e) thereof for Fatty acids, C18-unsaturated, trimers, CAS No 68937-90-6 (EC No 500-239-5), by [redacted] (Registrant).

- Long-term toxicity to soil macroorganisms (earthworms, *Eisenia fetida*, OECD 222), proposed to be carried out with the analogue substance Fatty acids, C18-unsaturated, dimers, distillation product (CAS 61788-89-4);
- Long-term toxicity to terrestrial plants (ISO 22030) proposed to be carried out with the analogue substance Fatty acids, C18-unsaturated, dimers, distillation product (CAS 61788-89-4). The test is proposed to be conducted only if effects are observed in the OECD 222 earthworm reproduction test.

This decision is based on the registration dossier 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 after 18 January 2013, 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 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 from initiating a compliance check on the registration at a later stage.

On 14 October 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

On 21 November 2011 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 21 December 2011 and subsequently on 16 January 2012 ECHA received comments from the Registrant indicating a changed testing plan and read-across approach and the commitment to update the dossier within the set deadline. ECHA considered the Registrant's comments received. On the basis of the comments ECHA decided to wait for the Registrant to update the dossier.

Subsequently on 29 March 2012 the Registrant updated his registration dossier with a changed testing plan and an amended read-across approach while maintaining the original testing proposals. On the basis of the comments and the updated registration dossier, Section II below was amended (acceptance of the testing proposals on an analogue substance). The Statement of Reasons (Section III) was changed accordingly.

On 18 January 2013 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, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 21 February 2013 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 4 March 2013 ECHA referred the draft decision to the Member State Committee.

On 25 March 2013, the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 8 April 2013 in a written procedure launched on 27 March 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

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 analogue substance Fatty acids, C18-unsaturated, dimers, distillation product (CAS 61788-89-4):

1. Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222);
2. Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants – ISO 22030).

The Registrant is obliged to ensure and to demonstrate, in accordance with the specific requirements outlined in Sections III and IV below, that the test material is suitable to identify relevant hazards for the substance subject to present decision and that testing of such material does not result in an underestimation of the hazards.

Once results of the requested toxicity test on terrestrial invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. He shall furthermore consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of section 9.4 of Annexes IX and X. If the Registrant concludes that further investigation of effects on terrestrial organisms is required, he shall conduct the requested long-term

toxicity test on plants. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting any information requirement of Annex IX, section 9.4. and Annex X, section 9.4. of the REACH Regulation for which no information has been provided.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **25 January 2015** 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 on the analogue substance Fatty acids, C18-unsaturated, dimers, distillation product (CAS 61788-89-4), the submitted read-across and (sub-)category justification document(s) and the data matrices therein.

In relation to the testing proposals subject to the present decision, the Registrant has proposed to use a read-across and grouping approach, in accordance with Annex XI, 1.5 of the REACH Regulation, and to perform the tests on the analogue substance Fatty acids, C18-unsaturated, dimers, distillation product (CAS 61788-89-4). To the extent that all proposed testing relies upon an identical read-across hypothesis, ECHA has considered first the scientific validity of the proposed read-across and grouping approach (Section 0, below), before assessing the testing proposed (Sections 1 and 2, below).

0. Grouping of substances and read-across approach

Article 13(1) of the REACH Regulation allows that information on intrinsic properties of substances may be generated whenever possible by means other than tests, including information from structurally related substances (grouping or read-across), "*provided that the conditions set out in Annex XI are met*". According to the Registrant, there is a category of *Dimerised fatty acids and its Derivatives*, with two sub-categories (sub-category 1: "predominantly monomers" and sub-category 2 "predominantly oligomers (dimers, trimers)") based on environmental fate properties and that read-across is possible within this category. The substance subject to the present decision has been placed in sub-category 2.

The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. More specifically, Section 1.5 of Annex XI of the REACH Regulation sets out the conditions to be met by alternative methods so that equivalent results to the prescribed test may be obtained. To this end, it is necessary to consider whether programmes of testing proposed by registrants are appropriate to fulfil the relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting wherever possible the use of alternative means, as long as equivalent results to the prescribed test are provided on health and environmental hazards.

The Registrant has proposed to test Fatty acids, C18-unsaturated, dimers, distillation product (CAS 61788-89-4) on the basis that this substance can be regarded as a representative worst case test substance for the proposed sub-category 2 "predominantly oligomers" of Dimerised fatty acids and its derivatives. The Registrant has indicated that in the proposed read-across and grouping approach for the Dimerised fatty acids and its derivatives all substances covered show similarity in regard to their composition containing common or closely related constituents.

ECHA notes that in the registration dossier the Registrant has provided a category definition, a justification for the category and the required respective documentation. The category justification contains a similarity assessment detailing the common origin and associated similar structure characteristics with typical molecular structures of the category members. The similarity of the source and target substances has been assessed and the decision process for the selection of the source substance has been detailed and documented. The category and read-across based classification has been explained based on available data. The Registrant has provided a detailed overview of ecotoxicological, environmental fate and toxicological data and addressed metabolic pathways and toxicokinetics. With regards to environmental fate and ecotoxicology endpoints the category has been further divided into two sub-categories based on physichochemical properties and environmental fate. The category hypothesis and scientific basis for the read-across given by the Registrant is the absence of (environmental) toxicity for all category members which the Registrant seeks to confirm by the testing proposed.

ECHA considers that the category hypothesis as currently documented is plausible. The target and source substances have been appropriately selected and their similarity with regards to chemical structures, environmental fate, and ecotoxicology and physicohemical properties has been satisfactorily presented. The obvious datagaps for the category members with regards to environmental endpoints may be covered with the testing addressed in this decision. However, ECHA notes that for the assessment of the relevance of the studies requested for the category justification in relation to the substance subject to present decision there must be adequate information on the identity of the sample tested and the substance registered (Fatty acids, C18-unsaturated, trimers). In particular, given the intrinsic compositional variability of the registered substances of the sub-category and the intended read-across, information as specified below has to be provided:

a) The identity and concentration of all known constituents and structural elements (aromatic and aliphatic rings, degree of unsaturation, branching, molecular size and carbon chain length distribution). Constituents, which have a common functionality or belong to the same class, shall be grouped as far as possible. In particular constituents or groups of constituents with hazards must be reported separately together with their concentration values;

b) An explanation based on factual evidence present in the dossier of why the composition of the sample tested represents a worst case scenario for the applicability domain of the sub-category and how it relates to the substance subject to this decision. More specifically, the data supporting the notion that in general constituents bearing double bond functionalities pose a higher risk than saturated carboxylic acids must be present in the dossier in form of robust study summaries in IUCLID endpoint study records.

Despite the need to provide this further information and explanation, ECHA considers that the justification given and the documentation provided demonstrates to a sufficient level the plausibility of the read-across approach. I.e. the requirements of Annex XI, Section 1.5 in conjunction with Article 13(1) and Annexes IX/X, third introductory paragraph, of the REACH Regulation may be met. However, a final conclusion on the validity of the suggested approach to adapt the standard information requirement will only be possible when it has been demonstrated and further documented on the basis of test results from the experimental studies proposed by the Registrant and required by the present decision that the conditions set out in Annex XI, Section 1.5 are met for these specific endpoints.

ECHA emphasises that it is the Registrant's responsibility to amend and substantiate the read-across and category justification according to Annex XI, 1.5. and to use all relevant available data.

Following the update of the dossier based on the present decision, ECHA will determine whether the documentation provided is ultimately sufficient to satisfactorily address the ecotoxicological information requirements of Annexes IX and X for the substance subject to this decision as proposed by the Registrant. If, upon further consideration, the proposed approach does not satisfy the conditions set out in Annex XI, 1.5. including the adequacy of the results for the purpose of classification and labelling and/or risk assessment, ECHA reserves the right to request the information necessary to fulfil the information requirements.

1. Long-term toxicity on 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 to terrestrial invertebrates is a standard information requirement as laid down in Annex X, Section 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. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant provided the following justification for conducting the proposed test: "Due to the fact that the sub-category 2 members of the Dimerised Fatty Acids and its derivatives have the general estimated logkow >4 and logKoc > 5 (i.e. adsorption to organic carbon in soils is expected) and considering that a direct and indirect exposure of the soil compartment cannot be ruled out, data on terrestrial toxicity is required for the chemical safety assessment. No data available on the effects of the category members Dimerised Fatty Acids and its Derivatives (sub-category "predominantly oligomers") on terrestrial organisms are available, thus in order to fulfil the standard information required according to Regulation (EC) No. 1907/2006, Annex X, Column I (9.4) a long-term toxicity test with soil macroorganisms (earthworms, OECD 222) is proposed for the category member Fatty acids, C18-unsatd., dimers (CAS No. 61788-89-4). A long-term test is considered in order to take the potential persistence of the category members into account, as well as the low water solubility. Testing of the toxicity on earthworm evaluates the exposure to the test substance via soil pore water, surface contact as well as by ingestion of soil particles. In the case of observed effects in the proposed test, additionally a long-term toxicity test with higher plants will be conducted according to ISO 22030 with the same substance. Otherwise it is assumed, that due to the lack of effects in long-term toxicity tests with soil invertebrates, as well as in a long-term toxicity test with fish within the solubility limit of the tested substance (CAS 68783-41-5) and their low bioaccumulation potential, toxicity to

plants cannot be expected. Therefore an additional long-term toxicity test with higher plants would not be reasonable." ECHA notes that the test on long-term toxicity to terrestrial invertebrates is suitable to address the information requirement of Annex X, section 9.4.4. and at the same time that of Annex IX, section 9.4.1.

As pointed out above in Section 0, ECHA considers the proposal for testing the analogue substance Fatty acids, C18-unsaturated, dimers (CAS 61788-89-4), to meet this endpoint requirement plausible. Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia Andrei*), OECD 222) using the analogue substance Fatty acids, C18-unsaturated, dimers, distillation product (CAS 61788-89-4).

2. Long-term toxicity testing on plants

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

The proposed test that ECHA accepted under subsection 1. above is not sufficient by itself to address the standard information requirements of Annex IX, section 9.4.3. and Annex X, section 9.4.6. ECHA notes that the registration dossier does not contain data for this endpoint.

The Registrant provided the following justification for conducting the proposed test: "In the case of observed effects in the proposed test, additionally a long-term toxicity test with higher plants will be conducted according to ISO 22030 with the same substance. Otherwise it is assumed, that due to the lack of effects in long-term toxicity tests with soil invertebrates, as well as in a long-term toxicity test with fish within the solubility limit of the tested substance (CAS 68783-41-5) and their low bioaccumulation potential, toxicity to plants cannot be expected. Therefore an additional long-term toxicity test with higher plants would not be reasonable."

Based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test.

As the Guidance advocates performing an initial screening assessment based upon the EPM, together with a confirmatory long-term soil toxicity test (the long-term toxicity to terrestrial invertebrates test, specified in 1. above), which the Registrant is requested to carry out by the present decision, ECHA considers that at this stage it is not possible to determine whether a test will be required to fulfil the standard information requirements of Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation.

The Registrant shall determine the need to perform further terrestrial toxicity tests on plants based on the outcome of the requested toxicity test on terrestrial invertebrates and the considerations set out in Table R.7.11.-2, section R7.C. of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008).

As pointed out above in Section 0, ECHA considers the proposal for testing the analogue substance Fatty acids, C18-unsaturated, dimers, distillation product (CAS 61788-89-4), to meet this endpoint requirement plausible. Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the proposed test: Soil Quality –Biological Methods – Chronic toxicity in higher plants – ISO 22030 using the substance Fatty acids, C18-unsaturated, dimers, distillation product (CAS 61788-89-4), if the outcome of the test specified in 1. above indicates the need for further testing. In any case the Registrant needs to state the reasons for his decision to perform or waive the experimental testing.

IV. Adequate identification of the composition of the tested material

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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

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

ECHA 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).

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.

VI. 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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