

Decision number: CCH-D-0000004322-84-03/F

Helsinki, 16 September 2014

**DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006****For Soybean oil, epoxidized, CAS No 8013-07-8 (EC No 232-391-0), 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 Soybean oil, epoxidized, CAS No 8013-07-8 (EC No 232-391-0), submitted by [REDACTED] (Registrant). The scope of this compliance check is limited to the standard information requirements of Sections 9.4 of Annexes IX and X of the REACH Regulation relating to terrestrial toxicity, and the related environmental hazard assessment. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

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 12 June 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 16 August 2013.

On 29 October 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.

On 27 November 2013 ECHA received comments from the Registrant.

The ECHA secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 12 June 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

## II. Information required

Pursuant to Articles 41(1)(b), 41(3), 10(a) (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 to terrestrial invertebrates (Annex X, 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;
2. Long-term toxicity testing on plants (Annex X, 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 test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030);
3. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

Pursuant to Articles 41(1)(c), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above long-term terrestrial studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including derivation of the terrestrial PNEC.

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.

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 **23 June 2015**.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

## 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.

Pursuant to Articles 10(a)(vi) and (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.

Therefore, the Registrant must address the standard information requirements set out in Annexes IX and X, section 9.4., for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.).

### 1. Terrestrial Invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

The Registrant did not provide information fulfilling the information requirements of Annex IX, 9.4.1. and Annex X, 9.4.4. Instead he proposed to adapt the standard information requirements using the following justification: "In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary. Consequently, in accordance with Column 2 of REACH Annex X, the study does not need to be conducted as all identified uses of the substance are assessed as safe for the environment."

ECHA notes that the Registrant has proposed to adapt the standard information requirements of Annex IX, 9.4.1. and Annex X, 9.4.4. on basis of the chemical safety assessment (CSA) indicating no hazard. However, the Chemical Safety Report (CSR) submitted by the Registrant as part of the technical dossier does not contain the Exposure Assessment (EA) and the subsequent Risk Characterisation (RC) sections, whilst in section 3.5 of the IUCLID technical dossier it is indicated that the substance has both wide dispersive outdoor and indoor uses by professional users and consumers (ERCs 8f, 10a and 10b and ERCs 8c and 11a). ECHA considers that as neither an Exposure assessment nor a Risk characterisation have been submitted and the substance has wide dispersive outdoor/indoor uses the claim of all identified uses being assessed as safe for the environment is not valid. Thus, ECHA considers that the Registrant has not proven that soil exposure is unlikely.

The Registrant in his comment indicates that the above mentioned ERCs were chosen by the Registrant as a conservative approach not to miss any applications of the substance. The Registrant states that even when it is certain that these uses occur, it is questionable whether high volumes are used in these applications. The Registrant states further that he is in the process of assessing these applications and their respective volumes. ECHA notes that based on the information currently available in the registration dossier and as explained above, in his comments the Registrant has not proven that soil exposure is unlikely and that soil testing is not required.

Furthermore, according to ECHA Guidance R7C (version 1.1., November 2012) as the water solubility of the substance is less than 1 mg/l, the absence of acute aquatic toxicity is not a reliable indicator for potential effects on soil organism due to the low exposure in the aquatic test. Therefore ECHA concludes further that the lack of effects in acute aquatic studies alone cannot be used to adapt the standard information requirement for terrestrial testing.

The Registrant in his comment states further that he believes that the substance and its breakdown products, due to its natural source and similarity with naturally occurring epoxidized oils, do not represent any harm to the terrestrial environment. The Registrant further claims that the substance would fit under the category of epoxidized oils and derivatives, and that data from the other substances in the category can be used to assess potential hazards. ECHA notes that as no data on terrestrial endpoints are presented for any of the substances that according to the Registrant belong to the category, these arguments cannot be considered to be adequate adaptation arguments according to Annex XI. Consequently, there is no need for ECHA to assess the validity of the proposed category approach further.

Therefore, the adaptation proposed by the Registrant to cover the information requirement of Annex IX, 9.4.1. and Annex X 9.4.4. cannot be accepted.

As explained above, the information requirements are not met. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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 (Annex X, 9.4.4.) and at the same time to fulfil the information requirement of Annex IX, 9.4.1. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance: Long-term toxicity to terrestrial invertebrates (Annex X, 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.

## 2. Terrestrial Plants (Annex IX, 9.4.3. and Annex X, 9.4.6.)

The Registrant did not provide information fulfilling the information requirements of Annex IX, 9.4.3. and Annex X, 9.4.6. Instead he proposed to adapt the standard information requirements using the following statement: "In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary. Consequently, in accordance with Column 2 of REACH Annex X, the study does not need to be conducted as all identified uses of the substance are assessed as safe for the environment."

ECHA notes that, as fully explained in Section III 1. above, whilst wide dispersive outdoor and indoor uses have been identified in IUCLID section 3.5 and no Exposure Assessment or Risk Characterisation sections have been submitted as part of the CSR, it is not justified to state that all uses have been assessed as safe for the environment.

Furthermore, as also fully explained in section III 1. above, absence of acute aquatic toxicity is not a reliable indicator for potential effects on soil organism for a low water solubility substance. Therefore ECHA concludes further that lack of effects in acute aquatic studies alone cannot be used to adapt the standard information requirement for terrestrial testing.

Moreover, as also fully explained in section III 1. above, the information provided by the Registrant in his comment to the draft decision did not prove that the criteria of either the specific adaptation rules of Column 2 of Annex X, Section 9.4, or the general adaptation rules of Annex XI could be fulfilled and soil testing is, thus, required.

Therefore, the adaptation proposed by the Registrant to cover the information requirement of Annex IX, 9.4.3 and Annex X, 9.4.6 cannot be accepted.

As explained above, the information requirements are not met. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Terrestrial plants growth test (OECD 208), (subject to the conditions outlined below) and the Soil Quality – Biological Methods – Chronic toxicity in higher plants test (ISO 22030) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing on plants (Annex X, 9.4.6.) and at the same time to fulfil the information requirement of Annex IX, 9.4.3.

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. The long-term toxicity 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(3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance: long-term toxicity to plants (Annex X, 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 test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

### 3. Soil microorganisms (Annex IX, section 9.4.2.)

The Registrant did not provide information fulfilling the information requirement of Annex IX, 9.4.2. Instead he proposed to adapt the standard information requirement using the following justification: "In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary. Consequently, in accordance with Column 2 of REACH Annex X, the study does not need to be conducted as all identified uses of the substance are assessed as safe for the environment."

ECHA notes that, as fully explained in Section III 1. above, whilst wide dispersive outdoor and indoor uses have been identified in IUCLID section 3.5 and no Exposure Assessment or Risk Characterisation sections have been submitted as part of the CSR, it is not justified to state that all uses have been assessed as safe for the environment.

Furthermore, as also fully explained in section III 1. above, absence of acute aquatic toxicity is not a reliable indicator for potential effects on soil organism for a low water solubility substance. Therefore ECHA concludes further that lack of effects in acute aquatic studies alone cannot be used to adapt the standard information requirement for terrestrial testing.

Moreover, as also fully explained in section III 1. above, the information provided by the Registrant in his comment to the draft decision did not prove that the criteria of either the specific adaptation rules of Column 2 of Annex X, Section 9.4, or the general adaptation rules of Annex XI could be fulfilled and soil testing is, thus, required.

Therefore, the adaptation proposed by the Registrant to cover the information requirement of Annex IX, 9.4.2 cannot be accepted.

As explained above, the information requirement is not met. Consequently there is an information gap and it is necessary to provide information for this endpoint. Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

#### IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and 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. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 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://www.echa.europa.eu/web/guest/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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