EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002575-71-05/F Helsinki, 19 December 2012

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

For [redacted], CAS No [redacted] (EC No [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 proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12 (1)(d) thereof for [redacted], CAS No [redacted] (EC No [redacted]), by [redacted] (Registrant), latest submission number [redacted] for the tonnage band of 100 to 1000 tonnes per year:

- Long-term toxicity testing on aquatic invertebrates (test method: *Daphnia magna* reproduction test, OECD 211).

This decision is based on the registration dossier as submitted with submission number [redacted], for tonnage band of 100 to 1000 tonnes per year.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 23 January 2012. This decision does not take into account any updates after 6 September 2012, 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.

On 5 June 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 5 July 2012 ECHA received comments from the Registrant, confirming his intention to perform the Daphnia magna reproduction test.

ECHA considered the Registrant's comments received. On basis of the comments, only the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 6 September 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 a proposal for amendment to the draft decision.

On 10 October 2012 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on that proposal for amendment within 30 days of the receipt of the notification.

ECHA has reviewed the proposal for amendment received and decided to amend the draft decision.

On 22 October 2012 ECHA referred the draft decision to the Member State Committee.

The Registrant did not provide any comments on the proposed amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 November 2012 in a written procedure launched on 14 November 2012. ECHA took the decision pursuant to Article 51(6) 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 to initiate a compliance check on the present dossier at a later stage.

II. Testing required

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

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

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **19 December 2013** an update of the registration dossier containing the information required by this decision.

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant shall consider submitting a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If the Registrant comes to the conclusion that no further investigation of effects on aquatic organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

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

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

1. Long-term toxicity on aquatic invertebrates

a) Examination of the testing proposal

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. Column 2 of Section 9.1 of Annex IX further indicates that this information requirement must be fulfilled unless the chemical safety assessment leads to the conclusion that the test is not needed. 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 provide information for this endpoint.

The Registrant provided the following justification for conducting the proposed test:

"Available studies on fish, algae and microorganisms did not reveleal any toxic effect in the range of water solubility of the compound. The study on daphnia is not regarded as valid due to the limited exposure time of only 24 hours instead of 48 hours. Furthermore, undissolved parts of the test compound could be detected. Due to the low water solubility of the test compound a long-term toxicity study on daphnia is proposed to adequately assess the toxicity towards aquatic invertebrates."

"In Annex VII of Regulation (EC) No 1907/2006, it is laid down that in case of short-term toxicity on invertebrates (preferred species Daphnia) the registrant may consider long-term toxicity testing instead of short-term. An available short-term study on daphnia is disregarded due to the limited exposure time of only 24 hours. Furthermore, in Annex VII, column 2 of the above mentioned regulation the long-term toxicity study on Daphnia shall be considered if the substance is poorly water soluble. Therefore, a long-term toxicity test according to OECD guideline 211 instead of the short-term study is proposed."

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7b, Figure R.7.8-4 page 53, 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. 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 an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted. However, if a risk is indicated when applying an assessment factor of 50, 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: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) using the registered substance.

b) Deadline of the decision

In its comments, the Registrant requested to prolong the timeline for submission of the requested information. The Registrant based its request on issues related to the laboratory capacity and on the time frame for scheduling the test of a difficult-to-test substance. Under Article 40(4), ECHA is required to set a deadline for the required test. ECHA took the information provided by the Registrant into account and extended the timeline by 3 months, from 9 months to 12 months.

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 study 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 study must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade registered to enable the relevance of the study to be assessed.

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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Director of Regulatory Affairs