EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002353-81-04/F Helsinki, 2 July 2012

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

For p-phenylenediamine, CAS No 106-50-3 (EC No 203-404-7), 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 p-phenylenediamine, CAS No 106-50-3 (EC No 203-404-7), by [redacted] (Registrant), latest submission number [redacted], for the tonnage band of 1000 tonnes or more per year:

- Long-term toxicity testing on invertebrates (OECD Guideline 211);
- Long-term toxicity testing on fish (OECD Guideline 210).

On 31 August 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposal for "Long-term toxicity testing on fish (OECD Guideline 210)", which at that time was the only testing proposal set out by the Registrant in the registration dossier for the substance mentioned above (at that time the latest submission number was [redacted]).

ECHA held a third party consultation for the testing proposal including testing on vertebrate animals from 26 January 2011 until 12 March 2011. ECHA did receive comments from a third party (see Section III below).

On 27 October 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 24 November 2011, ECHA received comments from the Registrant, and on 28 November and 30 December 2011, ECHA received further communications in follow-up to the comments of 24 November. On 16 January 2012 the Registrant updated his registration dossier (submission number [redacted]), by adding the testing proposal "Long-term toxicity testing on invertebrates (OECD Guideline 211)", which was not included in the dossier before that time, and by indicating a testing strategy.

ECHA considered the Registrant's comments received and the new information in the updated dossier and did modify 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 to amend the draft decision accordingly.

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

On 4 May 2012 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

Unanimous agreement of the Member State Committee on the 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 requirements of the REACH Regulation. 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. Long-term toxicity testing on invertebrates (*Daphnia* sp.) (Annex IX, 9.1.5.; test method: EU C.20/OECD 211);
2. Long-term toxicity testing on fish (Fish Early-Life Stage, FELS, Toxicity Test) (Annex IX, 9.1.6.2.; test method: OECD 210).

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 1 and 2 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.

As degradation products may be formed under test conditions (reported half-life of 6 hours), the Registrant is required to ensure that the test substance's concentration is adequately maintained and quantified during the long-term toxicity testing. To this end an appropriate analytical test method should be available before the initiation of the definitive tests, the nominal test concentrations should be confirmed by analytical measurements and the results should be adequately documented in the robust study summaries. When performing the OECD 211 and 210 tests, the registrant is recommended to perform a continuous flow-through experiment as the initial concentrations are expected to decline by more than 90% over 24 hours.

In addition, based on the recommendations provided in the OECD Series on testing and assessment Number 23, for substances with a half-life between less than 3 days and more than 1 hour, the Registrant is advised assessing the adverse effects of the degradation products of the substance for these aquatic endpoints.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **2 January 2014** an update of the registration dossier containing the information required by this decision.

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 proposals submitted by the Registrant for the registered substance and scientific information submitted by a third party.

1. Long-term toxicity testing 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. As in previous testing the concentrations of the test material (the registered substance) had not been well maintained, no reliable information on this endpoint is available for the registered substance, but needs to be present in the technical dossier to meet the information requirement. Consequently, there is an information gap and it is necessary to generate the data for the endpoint.

Due to problems in maintaining substance concentrations within the required 80% in the acute aquatic studies reported by the Registrant, ECHA reminds the Registrant of the need for analytical monitoring in the long-term studies to be conducted. Furthermore, the Registrant is reminded to take into account the short half-life of the substance and to follow the correct procedure for difficult substances as defined in the OECD Guidance document No. 23 on aquatic toxicity testing of difficult substance and mixtures (ENV/JM/MONO(2000)6) when performing the tests and interpreting the results.

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

2. Long-term toxicity testing on fish

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 fish is a standard information requirement as laid down in Annex IX, 9.1.6. of the REACH Regulation. As in previous testing the concentrations of the test material (the registered substance) had not been well maintained, no reliable information on this endpoint is available for the registered substance, but needs to be

present in the technical dossier to meet the information requirement. Consequently, there is an information gap and it is necessary to generate the data for the endpoint.

Due to the problems in maintaining substance concentrations within the required 80% in the acute aquatic studies reported by the Registrant, ECHA reminds the Registrant of the need for analytical monitoring in the long-term studies to be conducted. Furthermore, the Registrant is reminded to take account of the short half-life of the substance and to follow the correct procedure for difficult substances as defined in the OECD Guidance document No. 23 on aquatic toxicity testing of difficult substance and mixtures (ENV/JM/MONO(2000)6) when performing the tests and interpreting the results.

In response to ECHA's draft decision, the Registrant proposed a testing strategy for aquatic toxicity and submitted in an updated dossier an additional proposal for long-term toxicity testing on invertebrates. According to the Registrant's testing strategy should the invertebrate and the algae be clearly the most sensitive species in the acute toxicity tests, the fish early life stage test would be waived on the basis that new information will not be scientifically relevant. ECHA concludes that the testing strategy is in line with the ECHA Guidance. According to the ECHA Guidance on information requirements and chemical safety assessment (Chapter R7b (version 1.1., August 2008) p. 51 and Figure R.7.8-4 p. 53) if based on acute aquatic toxicity there would be compelling evidence to suggest that fish is substantially (by at least a factor of 10) 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* 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, the long-term fish testing on fish 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.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation.

The third party has proposed considering the physical-chemical properties relevant for the exposure (e.g. low potential for bioaccumulation) when evaluating the testing proposal. The third party suggested further considering the stability of the substance under environmentally relevant conditions (e.g. photodegradation) before undertaking the test. However, the substance shows high acute toxicity in target organisms despite the low bioaccumulation potential and the information concerning photodegradation does not fulfil the information requirements of REACH Article 10 (a)(vi) concerning study summaries or of Article 10 (a)(vii) concerning robust study summaries.

The Registrant has considered the low stability of the substance under test conditions and concluded that the available information for the hazard assessment for the aquatic environment is not reliable. The substance has shown a high toxicity to aquatic organisms in short-term tests. Further, the Registrant did not present data demonstrating negligible exposure and risk. Therefore, it can not be assessed whether exposure and risk might be negligible.

On the basis of the considerations set out above ECHA does therefore not see a reason to reject the testing proposed by the Registrant.

c) Outcome

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is thus requested to carry out the following test: Fish, Early-life Stage Toxicity Test (Annex IX, 9.1.6.2, test method: OECD 210) using the registered substance.

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.

[redacted]
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