Decision number: TPE-D-0000002006-86-04/F/RECT Helsinki, 30 May 2012

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

For Aziridine, CAS No 151-56-4 (EC No 205-793-9), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has adopted the following decision initially taken on 7 February 2012 with decision number TPE-D-0000002006-86-03/F and appealed on 30 April 2012 in accordance with Article 93(1) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation). The initial decision had been taken pursuant to the procedure set out in Articles 50 and 51 of the REACH Regulation.

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined a testing proposal set out in the registration dossier for Aziridine, CAS No 151-56-4 (EC No 205-793-9), submitted by [redacted] (Registrant).

This decision is based on the registration dossier as submitted with submission number [redacted]. This decision does not take into account any updates submitted after 2 September 2011, the date upon which ECHA notified its draft decision to the the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposal as part of the registration dossier to fulfil the information requirements set out in Annex IX:

Annex IX, 9.1.6.2: Fish short-term toxicity test on embryo and sac-fry stages

The examination of the testing proposal was initiated on 9 August 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 26 January until 14 March 2011. ECHA received the following comments from third parties:

- ECEA 2011 Comments on "Testing proposals involving vertebrate animals: request for information from third parties"

ECHA examined the testing proposal and the information received from third parties and drafted a decision in accordance with Article 40 of REACH.

On 8 July 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

The Registrant did not provide any comments on the draft decision.

On 2 September 2011 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. Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received and did not modify the draft decision. On 5 October 2011 ECHA notified the Registrant of the 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.

On 17 October 2011 ECHA referred the draft decision to the Member State Committee.

On 4 November 2011 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 7-9 December 2011, the Member State Committee modified the draft decision and a unanimous agreement of the Member State Committee on the modified draft decision was reached on 9 December 2011.

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

Pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant shall carry out the following test using the indicated test method:

Fish early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1, long-term toxicity testing on fish, test method: OECD 210)

while the originally proposed Fish short-term toxicity test on embryo and sac-fry stages according to test method OECD 212 for provision of Annex IX, 9.1.6; is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA **by 30 May 2013** 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 proposal of the Registrant for the registered substance and scientific information submitted by third parties.

(i) Examination of the testing proposal

Pursuant to Article 40(3)(d) of the REACH Regulation, ECHA may reject a proposed test. Furthermore, 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 and XI of the REACH Regulation.

The proposed test forms part of the standard information requirements for substances registered for [redacted] according to Annex IX, 9.1.6.2 to the REACH Regulation if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms.

The Registrant, during the commenting period within the decision making phase, has brought forward arguments showing that the chemical safety assessment according to Annex I does not indicate the need to investigate further the effects on aquatic organisms. Whilst ECHA has considered these arguments, no conclusion could be made on their scientific validity because the registration dossier as submitted for the examination of the testing proposal with the submission number referenced above did not contain a valid adaptation statement based on Annex IX, 9.1., column 2 of the REACH Regulation.

The proposed OECD 212 guideline does not appear to be the most appropriate test to be performed in order to fulfil the requirements of this endpoint. ECHA notes that OECD 210 is generally considered more sensitive than OECD 212. Currently, OECD 210 is the most widely used method for industrial chemicals for predicting chronic toxicity to fish according to the findings of the draft OECD workshop paper on fish toxicity testing framework (http://www.oecd.org/dataoecd/58/37/48699063.pdf, September 2010). In addition, in the technical dossier there is no available information on the mode of action of the substance. Therefore, it is difficult to establish whether the OECD 212 test method is sufficiently sensitive to determine the chronic effect on fish for this substance.

For the above reasons, pursuant to Article 40(3)(c) the Registrant is requested to carry out the following test: Long-term toxicity testing on fish (Annex IX, 9.1.6.1., OECD 210 (Fish, Early-life Stage Toxicity Test)). The originally proposed test OECD 212 for provision of Annex IX, 9.1.6.2.; is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

(ii) Consideration of third party information

Information submitted by the third party suggests considering the following alternative testing strategies before conducting the study:

1. Degradation of the substance
2. OECD 212 test guideline

ECHA has examined the scientific information submitted by the third parties as follows:

1. It is proposed by the third party to take into consideration whether the registered substance can be degraded, biotically or abiotically, to give stable and/or toxic degradation

products, before further tests on animals are requested. The third party indicated that the registered substance is ready biodegradable, it hydrolyzes and it is highly volatile, thus the need to test long-term toxicity to fish should be carefully evaluated in light of expected degradation of the substance occurring in aquatic environment.

ECHA notes that the substance is not readily biodegradable, as it does not fulfil the 10-day window, and that hydrolysis is not fast. Despite the high vapour pressure, the substance has a low Henry constant which indicates that the substance would preferably stay in water. Also the Level III MacKay model indicates that 40% of the substance would partition to water.

Therefore, the third party proposal does not provide a sufficient basis on which to reject the testing proposal.

2. It is proposed by the third party to consider the new OECD guideline under development called Fish embryo test (FET), if the results of the preliminary validation results are available by the time of the ECHA decision. According to the third party, this test is considered to be superior to the OECD 212 in part because it gives a clear definition of fish life stages and when to stop the test, in order to avoid the risk of starvation of the fish fry.

ECHA notes that the proposed FET is still under validation and has not been officially adopted by OECD. At present, it cannot fulfil the information requirements of REACH for long-term toxicity testing. Therefore, ECHA concludes that the FET OECD guideline under development cannot be used in place of the Fish short-term toxicity test on embryo and sac-fry stages.

ECHA is of the opinion that the third party comments do not provide a sufficient basis for rejecting the testing proposal.

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]

Geert Dancet
Executive Director