EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002318-75-05/F Helsinki, 17 July 2012

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

For *2,4,6-tris(2,4,6-tribromophenoxy)-1,3,5-triazine*, CAS [redacted] (EC No 426-040-2), 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 testing proposals set out in the registration dossier for ***2,4,6-tris(2,4,6-tribromophenoxy)-1,3,5-triazine***, CAS [redacted] (EC No 426-040-2), submitted by [redacted] (the Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

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

- Annex IX, 8.7.2: Pre-natal developmental toxicity study according to OECD Guideline 414 (Prenatal Developmental Toxicity Study);
- Annex X, 8.7.3: Two-generation reproductive toxicity study according to the OECD Guideline 416 (Two-Generation Reproduction Toxicity Study).

The present decision relates solely to the examination of the testing proposal for a Pre-natal Developmental toxicity study. The testing proposal for the Two-generation reproductive toxicity study is addressed in a separate decision although all testing proposals were initially addressed together in the same draft decision.

The examination of the testing proposal was initiated on 2 May 2011.

ECHA opened a third party consultation for testing proposals including testing on vertebrate animals that was held from 16 June 2011 until 01 August 2011. ECHA did not receive comments from third parties.

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. The draft decision referred to submission number [redacted].

On 24 November 2011 the Registrant provided to ECHA comments on the draft decision and updated his registration dossier (submission number [redacted]) removing eight out of ten previously submitted testing proposals.

ECHA considered the Registrant's comments received and the dossier update and did amend the draft decision accordingly.

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, Competent Authorities of the Member States 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 not to amend the draft decision.

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

The Registrant did not provide comments on the proposals for amendment.

The draft decision was split into two draft decision documents: one relating to the testing proposal for a two-generation reproductive toxicity study and one relating to the testing proposal for a Pre-natal developmental toxicity study.

The Member State Committee reached unanimous agreement on the draft decision relating to the testing proposal for a pre-natal developmental toxicity study 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 the 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)(a) of the REACH Regulation, the Registrant shall carry out the following proposed tests using the indicated test method:

a. Prenatal developmental toxicity study (Annex IX, 8.7.2) in rat by the oral route according to EU Method B.31/OECD Guideline 414;

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **17 July 2013** an update of the registration dossier containing the information required by this decision.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfil this information requirement, he should include in the update of

his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

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.

1) Decisions pursuant to Article 40(3)(a) of the REACH Regulation

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

a. Prenatal developmental toxicity

According to Annex IX, section 8.7.2, of the REACH Regulation Pre-natal developmental toxicity study is required to fulfil the standard information requirements. The information in the registration dossier does not permit an adaptation of this standard information requirement in accordance with the second column of Annex IX and the general rules set out in Annex XI of the REACH Regulation. The Registrant has thus proposed to perform the pre-natal developmental toxicity study to fulfil this information requirement.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the testing proposal is accepted and the Registrant is requested to carry out the following test: Pre-natal developmental toxicity study (Annex IX, section 8.7.2) in the rat by the oral route (EU Method B.31 or OECD 414).

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

2) Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of the adoption of the decision. This period of time took into account the fact that the draft decision contained the request to carry out also the following tests: long-term toxicity testing on aquatic invertebrates, long-term toxicity testing on fish, soil simulation testing, effects on soil micro-organisms, long-term toxicity to sediment organisms, long-term toxicity testing on invertebrates, long-term toxicity testing on plants, as proposed by the Registrant.

ECHA
EUROPEAN CHEMICALS AGENCY

As these testing proposals are no longer present in the updated dossier and therefore no longer requested in the present decision, ECHA considered that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier was 30 months from the date of the adoption of the decision. The decision was therefore modified accordingly.
This period of time (30 months) took into account the fact that the draft decision also requested a reproductive toxicity study according to the standard information requirement of Annex X, 8.7.3 of the REACH Regulation. As the testing request for this study is not addressed in the present draft decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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