Decision number: CCH-D-0000003696-64-03/F Helsinki, 13 February 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For PETIA, CAS No 1245638-61-2 (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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for PETIA, CAS No 1245638-61-2, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex IX, Section 8.7.2. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant 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 5 September 2013, 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 25 April 2013.

On 24 May 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 24 June 2013 ECHA received comments from the Registrant.

The ECHA Secretariat considered the Registrant's comments. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 5 September 2013 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex IX, of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

- Pre-natal developmental toxicity study in rabbits, oral route (Annex IX, 8.7.2.; test method: EU B.31/OECD 414).

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 **13 February 2015.**

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. If the Registrant comes to the conclusion that no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2.

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.

A pre-natal developmental toxicity study is a standard information requirement as laid down in Annex IX, section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier the Registrant provided information with which he sought to fulfil this standard information requirement. The provided information stems from Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD 422). However, this study does not provide the information required by Annex IX, Section 8.7.2., because it lacks, amongst others, sound data on pre- and post-implantation losses, external, soft tissue and skeletal malformations, types and incidences of individual anomalies. The technical dossier neither contained a testing proposal nor an adaptation in accordance with column 2 of Annex IX, Section 8.7.2. or with the general rules of Annex XI for this standard information requirement.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31/OECD 414, the test substance is usually administered orally. ECHA considers this default parameter appropriate and testing should be performed by the oral route.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species. In the draft decision sent to the Registrant pursuant to Article 50(1), ECHA gave the option of testing the rat or the rabbit as a first species.

In the comments to the draft decision (communication number CCH-D-0000003696-64-01/D) the Registrant provided a weight of evidence argument aiming to demonstrate that the registered substance does not cause pre-natal developmental toxicity in rats and that he therefore suggests to perform the Pre-natal developmental toxicity study on rabbits. Furthermore, the Registrant suggested to update his dossier and to include a testing proposal for a Pre-natal developmental toxicity study on rabbits according to EU Method B.31 or OECD testing guideline 414.

ECHA acknowledges that the Registrant intends to update his dossier, but notes that in the draft decision the Registrant was already given the choice for selecting an appropriate species and that a testing proposal for a Pre-natal developmental toxicity study on rabbits is therefore neither required nor requested.

With regard to the Registrant's weight of evidence approach for providing scientific justification that the study in rats is not needed ECHA notes that the dossier currently does not include a valid weight of evidence adaptation for the PNDT in rats. ECHA highlights that in order to justify the weight of evidence, the Registrant would have to provide more information than he provided in the comments. While normally ECHA grants the Registrant the option to choose which species to test first, based on the Registrant's comment that he believes he is able to adapt the information requirement for testing in rats, ECHA has modified the decision specifying that the test shall be carried out in the rabbit. ECHA stresses that this is not to be misunderstood as an approval of the weight-of-evidence argument submitted by the Registrant.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to submit information on Pre-natal developmental toxicity on rabbits, oral route (test method EU B.31/OECD 414) on the registered substance.

<u>Notes for consideration by the Registrant:</u>

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species (Annex X, 8.7.2.), the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species (Annex IX, 8.7.2.) 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. Should the Registrant consider that his weight of evidence arguments for the pre-natal developmental toxicity study in the rat (first brought up in the commenting phase for the present decision) are justified, he should include these arguments and detail them sufficiently in his registration.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted 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 to ensure that his registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In carrying out the study required by the present decision it is important to ensure that the particular sample of substance tested 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(s) registered to enable the relevance of the study 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://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]
Leena Ylä-Mononen
Director of Evaluation