Decision number: TPE-D-0000001781-75-05/F 6 February 2012

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

For [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 testing proposal set out in the registration dossier for [redacted] submitted b [redacted] latest submission number [redacted], for [redacted]

In accordance with Articles 10(a)(ix) and 12(1)(d) 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, 9.4.1., column 2: Long-term effects on terrestrial organisms - toxicity to invertebrates (Earthworm Reproduction Test, OECD guideline 222).

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 20 January 2011.

On 15 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, one Competent Authority of the Member States submitted proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received and decided to modify the draft decision accordingly.

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

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

A unanimous agreement of the Member State Committee on the modified draft decision was reached on 18 November 2011 in a written procedure launched on 7 November 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

The Registrant shall carry out either pursuant to Article 40(3)(a) of the REACH Regulation the following test to meet the information requirement of Annex IX, 9.4.1., column 2: Long-term effects on terrestrial organisms – toxicity to invertebrates:

Earthworm reproduction test (OECD guideline 222);

or

pursuant to Article 40(3)(c) of the REACH Regulation one of the following tests:

Enchytraeid reproduction test (OECD guideline 220); or
Collembolan reproduction test (OECD guideline 232)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA 06 February 2013 an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

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

In order to fulfil the standard information requirements set out in Annex IX, section 9.4. of the REACH Regulation, that are currently not available in the registration dossier, the Registrant should normally provide the following studies: (i) short term toxicity to invertebrates (section 9.4.1.), (ii) effects on soil micro-organisms (section 9.4.2.) and (iii) short term toxicity to plants (section 9.4.3.).

Column 2 of section 9.4. allows the Registrant to consider long-term toxicity testing instead of short term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The Registrant considered that due to the properties of the registered substance a long-term toxicity testing is necessary, and proposed an earthworm reproduction test according to OECD guideline 222 in order to fulfil all three standard information requirements in section 9.4. of Annex IX of the REACH Regulation.

As the substance has a high potential to adsorb to soil, the Earthworm reproduction test

(OECD guideline 222), the Enchytraeid reproduction test (OECD guideline 220) or the Collembolan reproduction test (OECD guideline 232) are considered to be appropriate in order to fulfil information requirements of Annex IX, section 9.4.1. (column 2) under REACH. ECHA is not in a position to decide on the most appropriate test protocol, since that depends on species sensitivity and substance properties. Because of the uncertainty with regards to the properties of the substance and species sensitivity the Enchytraeid reproduction test and the Collembolan reproduction test had to be provided as an option to the proposed test. All three test methods are long term studies done with ecological relevant species, and assess the endpoints of survival and reproduction. The Earthworm reproduction test also allows investigating the effects of exposure on growth. Earthworm and enchytraeid are annelid species that live burrowed into the soil and allow investigating both the body wall and ingestion routes of exposure. Collembolans are soil dwelling organisms with a thin exoskeleton highly permeable to air and water, and represent arthropod species with a different route and a different rate of exposure compared to earthworms and enchytraeids.

Therefore based on the above argumentation, and considering that all three tests are recommended OECD test guidelines for generating soil organism toxicity data, ECHA has accepted the Registrant's testing proposal permitting the Registrant to perform the requested Long-term toxicity to invertebrates (Annex IX, 9.4.1.), either by applying OECD guideline 222, OECD guideline 220 or OECD guideline 232. Findings of the required tests may result in a need to investigate further the properties of the registered substance, and hence performance of additional higher tier tests on soil organisms may be requested by ECHA, and/or further testing proposals may need to be submitted by the Registrant depending on the outcome of the terrestrial invertebrate test, as indicated in the REACH Guidance on information requirements and chemical safety assessment, Chapter R7c, Table R.7.11-2, p. 131.

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]

Jukka Malm
Director of Regulatory Affairs