EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002091-87-05/F Helsinki, 29 July 2013

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

For climbazole, CAS No 38083-17-9 (EC No 253-775-4), 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)(d) thereof for climbazole, CAS No 38083-17-9 (EC No 253-775-4), by [redacted] (Registrant).

- Dissociation Constants in Water (OECD 112)
- Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test (OECD 208)

This decision is based on the registration dossier as submitted with submission number [redacted] for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 18 January 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 decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

On 9 December 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

On 15 June 2012 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 9 July 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision but requesting a second option of guideline for one of the requested tests.

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

On 18 January 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, one Competent Authority of a Member State submitted proposals for amendment to the draft decision.

On 21 February 2013 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 amended the draft decision accordingly.

The Registrant did not provide any comments on the proposed amendment.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

A unanimous agreement of the Member State Committee on the draft decision was reached on 8 April 2013 in a written procedure launched on 27 March 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

The Registrant shall carry out the following proposed test 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. Dissociation constant (Annex IX, 7.16.; test method: OECD 112).

The Registrant shall carry out the following modified test pursuant to Article 40(3)(b) of the REACH Regulation using one of the indicated test methods and the registered substance subject to the present decision:

2. Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

The Registrant shall carry out the following additional tests pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

3. Effects on terrestrial organisms (Annex IX, 9.4.; Test on toxicity to soil micro-organisms: EU Method C.21 or OECD 216); and
4. Effects on terrestrial organisms (Annex IX, 9.4.; Test on toxicity to invertebrates: OECD 222, OECD 220, or OECD 232).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **29 April 2014** 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 proposals submitted by the Registrant for the registered substance

1. Dissociation constant

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

A dissociation constant study is a standard information requirement as laid down in Annex IX, section 7.16. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to to provide information for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Dissociation constants in water (test method: OECD 112) using the registered substance.

2. Effects on terrestrial organisms (Ref. Section II, tests 2-4)

Pursuant to Article 40(3)(b) and (c) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test under modified conditions and to carry out additional tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

The Registrant must address the standard information requirements set out in Annex IX, section 9.4., for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), and short-term toxicity testing on plants (Annex IX, section 9.4.3.). Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on the endpoint 'effects on terrestrial organisms' is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

a) Terrestrial Plants (Annex IX, 9.4.3. and Column 2 of Annex IX, 9.4.)

The Registrant proposed a long-term toxicity test on terrestrial plants (OECD 208), with the following justification: As the registered substance is stable and the use of the EPM method provides only an uncertain assessment of risk, it cannot alone be used to obviate the need for further information. The Registrant further states that a single test on soil organisms is adequate to meet the standard information requirements and that this test should be a long-term text because the substance has to be assumed to be very persistent in the absence of specific soil data. The Registrant proposes to perform a toxicity test on plants as algae was found to be the most sensitive test organism in the short-term toxicity tests on aquatic organisms. As the substance is likely to be very persistent, ECHA agrees that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX). The proposed test is suitable to address the information requirement of Annex IX, section 9.4.3.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. The long-term toxicity testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208

guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

In his comments submitted to ECHA on 9 July 2012, the Registrant indicated that he would wish to be given the ISO 22030 standard as an option to the OECD 208 guideline with at least six species tested for the testing of long-term toxicity to plants. ECHA agrees that the ISO 22030 standard is appropriate for the generation of data to fulfil the information requirement for long-term toxicity to plants and has accordingly included this option in Section II of the present decision.

Therefore pursuant to Article 40(3)(b) of the REACH Regulation, the Registrant is required to carry out the proposed study under modified conditions: Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) using the registered substance.

b) Terrestrial Invertebrates (Annex IX, 9.4.1. and Column 2 of Annex IX, 9.4.)

The proposed test accepted by ECHA under subsection (a) above is not sufficient by itself to address the standard information requirements of Annex IX, section 9.4.1. ECHA notes that the registration dossier does not contain data for this endpoint.

Based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), ECHA considers that the substance would fall into soil hazard category 4. For such substances it is not possible to adapt the present standard information requirement depending on the results of the other long-term study for soil requested by the present decision and an initial screening assessment based upon the Equilibrium Partitioning Method (EPM). The Guidance foresees that long-term toxicity tests according to the information requirements of Annex X should be carried out and that the lowest value obtained should be used to derive the PNEC soil.

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. ECHA notes that, according to the evidence presented within the Registration dossier, the substance is likely to be very persistent (1% biodegradation in water after 28 days).

Furthermore, by proposing a long-term toxicity test (accepted by ECHA under subsection (a) above) ECHA considers that the Registrant has concluded on the need for long-term toxicity testing to be performed instead of short-term, on the basis that the substance meets the column 2 adaptation criteria of Annex IX, section 9.4. On this basis, ECHA considers that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX). Moreover, section R.10.6.2., Chapter R10 of the abovementioned Guidance allows the potential application of a lower AF if information on additional long-term terrestrial toxicity test of two trophic levels were available. In contrast, the Guidance does not allow for a lower AF to be applied if information on a short-term study were to become available in addition to the long-term plant study.

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out one of the following additional studies: Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232, using the registered substance.

c) Soil microorganisms (Annex IX, section 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation. ECHA notes that the registration dossier does not contain data for this endpoint and that the proposed test that ECHA accepted under subsection (a) above is not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test (test method: EU C.21 or OECD 216).

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216), using the registered substance.

IV. Adequate identification of the composition of the tested material

It is important to ensure that the particular sample of substance tested in the new studies 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 studies must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade registered to enable the relevance of the studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA 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).

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.

VI. 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.

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Geert Dancet
Executive Director