~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: TPE-D-0000001366-75-06/F Helsinki, 25 July 2011
Date for the decision: 25 July 2011

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

For BDP, CAS [redacted] (EC No 425-220-8), 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 **BDP, CAS [redacted] (EC NO 425-220-8)** submitted by [redacted] (the "Registrant"), latest submission number [redacted] for 100 - 1000 tonnes 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 Annex IX:

a) Annex IX, 9.3.3 Further information on adsorption/desorption depending on the results of the study required in Annex VIII according to OECD Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method)
b) Annex IX, 9.1.5 Long-term toxicity testing on aquatic invertebrates according to OECD Guideline 211 (Daphnia magna Reproduction Test)
c) Annex IX 8.6.2 Sub-chronic toxicity study (90-days): oral according to OECD Guideline 408
d) Annex IX, 9.4.1 (column 2) Effects on terrestrial organisms - toxicity to invertebrates according to OECD Guideline 222 (Earthworm Reproduction Test)

The examination of testing proposals was initiated on 22 June 2010.

ECHA held a public consultation for the testing proposal on Sub-chronic toxicity study (90-days): oral from 1 September 2010 until 15 October 2010. ECHA received 4 comments (see section III).

ECHA examined the testing proposal and the information received from third parties and prepared a draft decision in accordance with Article 40(3) of the REACH Regulation.

On 16 December 2010 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.

By 17 January 2011 ECHA received no comments on the draft decision from the Registrant.

On 18 February 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.

On 23 March 2011 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 within 30 days of the receipt of the notification.

ECHA has reviewed the proposals for amendment of the Member State Competent Authority and decided to amend its draft decision.

On 4 April 2011, the draft decision was referred to the Member State Committee.

On 21 April 2011, the Registrant provided to ECHA comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 25-27 May 2011 a unanimous agreement of the Member State Committee on the amended draft decision was reached on 26 May 2011 and ECHA has taken the decision accordingly pursuant to Article 51(6) 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.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following tests, while taking full account of the obligation to agree on sharing information and costs with other registrants, as set out in section IV of the decision:

a) Annex IX, 9.3.3 Further information on adsorption/desorption depending on the results of the study required in Annex VIII according to OECD Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method)
b) Annex IX, 9.1.5 Long-term toxicity testing on aquatic invertebrates according to OECD Guideline 211 (Daphnia magna Reproduction Test) – this information may also be obtained through data sharing according to Article 27(1)(b) of the REACH Regulation (see section IV below)
c) Annex IX 8.6.2 Sub-chronic toxicity study (90-days): oral according to OECD Guideline 408 – this information must be obtained through data sharing according to Article 27(1)(a) of the REACH Regulation (see section IV below)

Pursuant to Article 40(3)(a) or (b) of the REACH Regulation, the Registrant shall carry out one of the following tests:

d) Annex IX, 9.4.1 (column 2) Effects on terrestrial organisms - toxicity to invertebrates according to relevant OECD Guideline (OECD 222 or OECD 220)

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by 28 January 2013 - 18 months from the date of the decision an update of the registration containing the information required by this decision.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals of the Registrant for the registered substance and the information submitted by the third parties during the public consultation.

The proposed tests (a) to (d) referred to in Section II above are part of the information requirements as laid down in Annex IX of the REACH Regulation. As the information on these endpoints is not included in the technical dossier but need to be present in order to meet the information requirements, it is necessary to generate the data and to perform the tests.

Third party comments with regard to Test (c) referred to in Section II

With regard to the Sub-chronic toxicity study (90-days): oral, third party comments were received during public consultation, stating that read-across from bisphenol A (BPA) and isodecyl diphenyl phosphate (IDP) could be applied to BDP in order to avoid proposed testing.

ECHA has identified several deficiencies in the information provided by the third party with regard to the fulfilment of the conditions laid down under Annex XI section 1.5 of the REACH Regulation, as follows:

- There are structural similarities between BDP and BPA. There is, however, very little specific data on the metabolism of BDP in the dossier, and no data to show that BPA is produced in vivo from BDP. Such data was also not provided by the third party. Moreover the case for toxicological similarity from the point of view of observed toxicological effects or potency of effects has not been adequately demonstrated by the third party.
- Read across from IDP is not acceptable due to structural differences when compared with the registered substance. IDP has a side chain that has no resemblance to the structure of the registered substance. This side chain may have a strong influence on biological activity and makes comparison with the registered substance unreliable. In addition, read-across would also have to take into consideration other potential metabolic break-down products, such as phenols, and any toxicity unique to the parent compound (as opposed to the metabolic breakdown products). These concerns were not adequately addressed in the third party comments.

Based on the observations listed above ECHA concludes that the proposed read-across cannot be accepted as no adequate and reliable documentation has been submitted to

support read-across from BPA or/and IDP to BDP that would allow data gap filling using information from the proposed substances.

Test (d) referred to in Section II

Regarding the Effects on terrestrial invertebrates, as the substance has a high potential to adsorb to soil, either Earthworm reproduction test (OECD 222) or Enchytraeid reproduction test (OECD 220) is considered to be appropriate in order to fulfil information requirements of Annex IX section 9.4.1 (column 2) under REACH. It is however the responsibility of the Registrant to select from those two options the one that uses the most appropriate and the most sensitive species for testing of the registered substance and to conduct the long term toxicity testing accordingly. Moreover, the acceptance of this testing proposal is considered solely in the context of fulfilling the information requirement of Annex IX point 9.4.1 of REACH Regulation.

IV. Obligation to data and cost sharing

Avoidance of unnecessary testing and the duplication of tests is one of the general aims of the REACH Regulation (Article 25).

Following the inquiry process (inquiry number: [redacted]), the Registrant has been informed on the availability of data from other notifiers/registrants of the substance. The registration dossiers of these notifiers/registrants contain data which are relevant to the test (b) referred to in Section II.

Additionally, the information on Sub-chronic toxicity study (90-days): oral for the same substance has already been requested from the notifier/registrant: [redacted] under the Directive 67/548/EEC – now deemed to be an ECHA decision pursuant to Article 135 of the REACH Regulation. Recently [redacted] has submitted this study to ECHA.

Please note that according to Article 26 of the REACH Regulation studies on vertebrate animals shall not be repeated. Therefore, the legal text foresees the sharing of information between registrants. Pursuant to Article 27(1)(a) of the REACH Regulation the Registrant is obliged, with respect to the Sub-chronic toxicity study (90-days) (test (c) referred to in Section II), to request that information from the previous registrant ([redacted]) and make every effort to reach an agreement on the sharing of data and costs.

ECHA reminds that pursuant to Article 27(1)(b) of the REACH Regulation the Registrant, with respect to Long-term toxicity testing on aquatic invertebrates (test (b) referred to in Section II), may request that information from the previous notifier(s)/registrant(s).

V. 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 reads:

> "*Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or*

other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."

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 adapted to the technical progress by Commission Regulation (EC) No 761/2009 and use the applicable test methods to generate the information on the endpoints indicated above.
National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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.

Done at Helsinki,

[redacted]

Geert Dancet
Executive Director