Helsinki, 4 July 2012

Decision number: TPE-D-0000001797-62-10/F

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

**For [redacted] master Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexyl ester, CAS [redacted] (EC No 443-860-6), 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 [redacted] **master Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexyl ester, CAS [redacted] (EC No 443-860-6)**, submitted by [redacted] (Registrant), latest submission number [redacted]

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:

Long-term toxicity testing on fish (Fish, early-life stage toxicity test, OECD 210)

The examination of the testing proposals was initiated upon the date when receipt of the complete registration dossier was confirmed on 30 June 2011.

ECHA opened a third party consultation for the testing proposal including testing on vertebrate animals that was held from 16 August 2011 until 30 September 2011 and received information from a third party (see Section III below).

On 29 November 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.

On 19 December 2011 ECHA received comments from the Registrant. ECHA considered the Registrant's comments received and amended 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. Subsequently, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

ECHA has reviewed the proposal for amendment received and decided not to amend the draft decision.
On 4 April 2012 ECHA notified the Registrant of proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on that proposal within 30 days of the receipt of the notification.

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

On 25 April the Registrant provided comments on the proposed amendment. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 6-8 June 2012, a unanimous agreement of the Member State Committee on the draft decision as referred to MSC was reached on 7 June 2012.

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

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following test using the indicated test method:

- Long-term toxicity testing on fish: Fish, early-life stage toxicity test (Annex IX, 9.6.1.2., test method: OECD 210)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA **by 31 May 2014** an update of the registration dossier containing the information required by this decision.

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 and scientific information submitted by a third party.

a) Examination of the testing proposals

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

Long-term toxicity testing on fish is part of the standard information requirements as laid down in Annex IX, section 9.6.1. of the REACH Regulation.

Initially the Registrant had waived the need to do this study on the basis of the *Daphnia* study in which no effects at water solubility limit were observed and the BCF study in which no mortality was observed.

Following a compliance check of the dossier with submission number [redacted] ECHA issued a communication letter CCH-C-0000001656-70-02/F to the Registrant indicating that

the waiver submitted for this endpoint appeared not to be acceptable since it was unclear what the actual concentrations throughout the exposure in the BCF study were. No evidence was presented in the dossier that fish would be less sensitive than daphnids or algae, for which long-term studies were available. ECHA therefore invited the Registrant in its letter to either improve the waiver or to submit a testing proposal. On this basis the Registrant decided to submit a testing proposal to fulfil the requirements of this end-point.

Given that the information on this endpoint is not available for the registered substance ECHA has therefore decided pursuant to Article 40(3)(a) of the REACH Regulation, to require the Registrant to carry out the proposed study: Long-term toxicity testing on fish: Fish, early-life stage toxicity test (test method: OECD 210).

b) Consideration of the third party information

The third party has proposed to use a quantitative structure-activity relationship (QSAR) model for fish, early life stage toxicity, before further tests on animals are requested. The third party has indicated that their information is confidential and therefore this information is not provided to the registrant.

ECHA concludes that on this occasion, the information submitted does not meet the conditions for the adaptation on the basis of QSAR models set out in Annex XI, Section 1.3. Therefore, it cannot constitute an acceptable adaptation to standard information requirements.

c) Deadline to submit the (required) information

In its comments, the Registrant requested to prolong the timeline proposed in the draft decision for submission of the requested information from 12 to 28 months. The Registrant based its request on issues related to the laboratory capacity and on the time frame for the scheduling of the test. ECHA took the information provided by the Registrant into account, but concluded that 28 months for finalising the study is not justified when compared with the time needed for method development of similar difficult-to-test substances. ECHA concludes that in this case, the following time schedule is justified:

- GLP substance evaluation: 5 months
- Develop analytical method in test media: 5 months
- Scale-up of testing design for fish, saturation of exposure system, experimental conduct and reporting: 6 months
- Re-characterisation: 4 months
- Preparation of the REACH update registration dossier: 2 months

Therefore, ECHA concludes that the timeline can be prolonged from 12 months to 22 months.

## 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 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 as adapted to technical progress 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.

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