EUROPEAN CHEMICALS AGENCY

Helsinki, 5 November 2012

Decision number: TPE-D-0000002720-82-03/F

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

For pentane-2,4-dione, CAS No 123-54-6 (EC No 204-634-0), 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 pentane-2,4-dione, CAS No 123-54-6 (EC No 204-634-0), by [redacted] (Registrant), latest submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year:

- Long-term toxicity testing on aquatic invertebrates (*Daphnia magna* reproduction test, OECD 211)
- Long-term toxicity testing on fish (Fish, prolonged toxicity test: 14-day study, OECD 204)

On 29 November 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.

ECHA held a third party consultation for the testing proposals from 15 July 2011 until 29 August 2011, during which no scientifically valid information relating to the above-mentioned testing proposals was received.

On 8 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 28 June 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision. On 28 June 2012 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments and updated dossier received and did not amend the draft decision.

On 19 July 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 of the receipt of the notification.

Subsequently, one Competent Authority of a Member State submitted proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received

and decided to modify section III of the draft decision.

On 22 August 2012 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 within 30 days of the receipt of the notification.

On 3 September 2012 ECHA referred the draft decision to the Member State Committee.

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

A unanimous agreement of the Member State Committee on the draft decision was reached on 8 October 2012 in a written procedure launched on 26 September 2012 and ECHA took the decision 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

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

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

2. Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210);

while the originally proposed test for a Long-term toxicity testing on fish (test method: OECD 204) proposed to be carried out using the registered substance is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **5 August 2014** an update of the registration dossier containing the information required by this decision.

Before conducting any of the tests mentioned above in points 1 and 2 the Registrant shall consult the ECHA *Guidance on information requirements and chemical safety assessment (version 1.1., August 2008)*, Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

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. Long-term toxicity testing on aquatic invertebrates

a) Examination of the testing proposal

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 invertebrates is a standard information requirement as laid down in Annex IX, 9.1.5. of the REACH Regulation. Column 2 of Section 9.1 of Annex IX further indicates that this information requirement must be fulfilled unless the chemical safety assessment leads to the conclusion that the test is not needed. 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 provide information for this endpoint.

In the dossier, the Registrant referred to a long-term study on aquatic invertebrates (Klimisch score 4) and provided the following justification for conducting the proposed test: "As there is only little information available the studies are not assignable as to the validity criteria. Therefore a testing proposal has been filed".

There was no indication in the available short-term toxicity studies on aquatic species that fish would be substantially more sensitive than *Daphnia*.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7b, Figure R.7.8-4 page 53, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted.

b) Outcome

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) using the registered substance.

2. Long-term toxicity testing on fish

a) Examination of the testing proposal

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may take a decision rejecting the proposed test in accordance with Article 40(3)(d), but requiring the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

According to column 1, Section 9.1.6 of Annex IX of the REACH Regulation, long-term toxicity testing on fish is required to fulfil the standard information requirements. 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 provide information for this endpoint.

The Registrant proposed testing according to the OECD Guideline 204 (Fish, prolonged toxicity test: 14-day study). ECHA notes that the proposed test method does not correspond

to the test methods enumerated in Annex IX 9.1.6. More specifically, Annex IX, 9.1.6 establishes that the information shall be provided for one of the Sections 9.1.6.1 (OECD Guideline 210: Fish early-life stage (FELS) toxicity test), 9.1.6.2 (OECD Guideline 212: Fish short-term toxicity test on embryo and sac-fry stages) or 9.1.6.3 (OECD Guideline 215: Fish, juvenile growth test). Furthermore, the Guidance on Information requirements and Chemical Safety Assessment (R.7.8.4.1, page 25) states, that "*only such studies can be regarded as long-term fish test, in which sensitive life-stages (juveniles, eggs, larvae) are exposed". Thus, tests performed according to OECD 204 (Fish, Prolonged Toxicity Test: 14-Day Study (OECD 1984)) or similar guidelines cannot be considered suitable long-term tests. They are, in effect, prolonged acute studies with fish mortality as the major endpoint examined*".

ECHA notes that the preferred test method is the OECD Guideline 210 (FELS) in accordance with Annex IX, 9.1.6.1. as this method is the one that can be applied for any substance type, it has a longer test duration (depending on the species but usually 28 days post-hatch compared to 14 days) and it thus accounts better for long-term environmental exposures. The FELS is internationally considered to be the most sensitive method covering the most critical life-stages and events for fish (embryos, larvae and juveniles) and it is the preferred and most widely used method for predicting chronic toxicity to fish within different regulatory frameworks (OECD Fish Testing Guidance document c.f. "Series on Testing and Assessment No. 171: Fish Toxicity Framework Test at http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/seriesontestinganassessmentpublicationsbynumber.htm). Performing the long-term toxicity test according to the most sensitive test (OECD Guideline 210) is particularly relevant for the registered substance, as the Registrant has identified the need to refine the hazard assessment due to the poor quality of the acute fish toxicity data being outdated and not having been performed in accordance with good laboratory practice.

Therefore, the Registrant is requested to carry out the long-term toxicity on fish according to OECD guideline 210 with the registered substance, while the proposed test according to OECD 204 is rejected pursuant to Article 40(3)(d).

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7b, Figure R.7.8-4 page 53, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted.

b) Outcome

Therefore, pursuant to Article 40(3)(c)of the REACH Regulation, the Registrant is required to carry out the additional study: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210); using the registered substance while the proposed test Fish, prolonged toxicity test: 14-day study (OECD 204) is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

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.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the

Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In addition, 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.

Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the study/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.

[redacted]
Jukka Malm
Director of Regulatory Affairs