EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002462-80-05/F Helsinki, 17 September 2013

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

For heptanoic acid, CAS No 111-14-8 (EC No 203-838-7), 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)(e) thereof for heptanoic acid, CAS No 111-14-8 (EC No 203-838-7), by [redacted] (Registrant).

- Long-term toxicity to aquatic invertebrates, OECD guideline 211 (*Daphnia magna* reproduction test);
- Short-term toxicity to invertebrates, OECD guideline 207 (Earthworm, acute toxicity tests);
- Effects on soil micro-organisms, OECD guideline 216 (Soil micro-organisms: nitrogen transformation test);
- Short-term toxicity to plants, OECD guideline 208 (Terrestrial plants test: seedling emergence and seedling growth test);
- Sub-chronic toxicity study (90-day), in rats, oral route, OECD guideline 408; and
- Pre-natal developmental toxicity study, in rabbits, OECD guideline 414.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more 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.

On 26 August 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 31 May 2011 until 15 July 2011. ECHA did receive information from third parties (see section III below).

On 17 August 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 13 September 2012 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received. The comments are reflected in the Statement of Reasons (Section III) whereas no amendments to the Testing Required (Section II) were made.

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 decided to amend the draft decision.

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

The Registrant provided comments on the proposals for amendment on 15 March 2013. The Member State Committee took the comments of the Registrant into account.

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.

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 tests 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. Long-term toxicity testing to aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211)
2. Short-term toxicity to invertebrates (Annex IX, 9.4.1.); test method: Earthworm acute toxicity test (*Eisenia fetida/Eisenia andrei*), (OECD 207), or, if long-term testing is considered appropriate, Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2 and Annex X, 9.4.4.); 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);
3. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216); and
4. Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2.; test method: EU B.26/OECD 408).
5. Pre-natal developmental toxicity study in rabbits, oral route (Annex X, 8.7.2.; test method: EU B.31/OECD 414)

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

6. Short-term toxicity testing on plants (Annex IX, 9.4.6) test method: Terrestrial plants, growth test (OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species), or, if long-term testing is considered appropriate, Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2 and Annex X, 9.4.6); 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 determine the appropriate order of the studies taking into account the possible outcome and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **17 September 2015** an update of the registration dossier containing the information required by this decision.

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant should submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If the Registrant comes to the conclusion that no further investigation of effects on aquatic organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

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 and scientific information submitted by third parties.

1. Long-term toxicity testing to 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

According to column 1 of Section 9.1.5. of Annex IX of the REACH Regulation, long-term toxicity testing on invertebrates 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 provided the following justification for conducting the proposed test: "According to claimed uses of heptanoic acid aquatic compartment exposure is likely. At the moment no data is available for characterizing heptanoic acid long term effects on organisms inhabiting aquatic compartment. Even if the risk assessment demonstrates that there is no risk for those organisms using the PNEC derived with short term data, a test is proposed for covering this question."

There were no indications in the dossier from the short-term toxicity studies on aquatic species that the 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. Effects on terrestrial organisms (information requirements 2, 3 and 6 of Section II of the present decision)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out proposed tests and pursuant to Article 40(3)(b) of the REACH Regulation, ECHA may require the Registrant to carry out a proposed test under modified conditions.

The Registrant must address the standard information requirements set out in Annexes IX and X, 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.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, Section 9.4.3.) and long-term toxicity testing on plants (Annex X, Section 9.4.6.).

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 invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

The Registrant proposed a short-term toxicity test on terrestrial invertebrates (OECD 207) with the following justification:
"According to claimed uses of heptanoic acid terrestrial exposure is likely. At the moment no data is available for characterizing heptanoic acid effects on organisms inhabiting terrestrial compartment. Even if the risk assessment demonstrated that there little risk for those organisms using the PNEC derived through equilibrium partitioning method, tests are proposed for covering this question.
Indeed, the RCR for Grassland at the level of the manufacturing site is higher than 1. However, the 0.02 release factor to wastewater is a worst case that is ten times higher than

the actual release factor to wastewater of the manufacturing site. The releases to soil in general, including to grassland, are directly related to the amount of substance entering the STP. Thus we can assume that the Grassland PEC will be in fact ten times lower and thus the PEC/PNEC ration will be below 1. However we propose tests to refine the PNEC soil."

This test is suitable to address the information requirement of Annex IX, section 9.4.1. However, ECHA considers that presently it is not possible to determine whether results obtained from the proposed short-term test (Annex IX, 9.4.1.) could be used to adequately justify an adaptation of the standard information requirement of Annex X, 9.4.4. for long-term testing. Additionally, ECHA notes that long-term tests are suitable to simultaneously address the information requirement of Annex X, Section 9.4.4. and Annex IX, Section 9.4.1. Therefore, the Registrant is granted the option to carry out a long-term test as an alternative to the short-term test on terrestrial invertebrates that the Registrant proposed.

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)(a) of the REACH Regulation the Registrant is required to carry out the proposed study Short-term toxicity to invertebrates (Annex IX, 9.4.1.); test method: Earthworm acute toxicity test (*Eisenia fetida/Eisenia andrei*), (OECD 207) or may, as alternative to the short-term test, opt to carry out one of the following studies: Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.); 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.

b) Terrestrial Plants (Annex IX, 9.4.3. and Annex X, 9.4.6.)

The Registrant proposed a short-term toxicity test on terrestrial plants with the following justification: "
According to claimed uses of heptanoic acid terrestrial exposure is likely. At the moment no data is available for characterizing heptanoic acid effects on organisms inhabiting terrestrial compartment. Even if the risk assessment demonstrated that there little risk for those organisms using the PNEC derived through equilibrium partitioning method, tests are proposed for covering this question.
Indeed, the RCR for Grassland at the level of the manufacturing site is higher than 1. However, the 0.02 release factor to wastewater is a worst case that is ten times higher than the actual release factor to wastewater of the manufacturing site. The releases to soil in general, including to grassland, are directly related to the amount of substance entering the STP. Thus we can assume that the Grassland PEC will be in fact ten times lower and thus the PEC/PNEC ration will be below 1. However we propose tests to refine the PNEC soil."

This test is suitable to address the information requirement of Annex IX, section 9.4.3. However, ECHA considers that presently it is not possible to determine whether results obtained from the proposed short-term test (Annex IX, 9.4.3.) could be used to adequately justify an adaptation of the standard information requirement of Annex X, 9.4.6. for long-term testing. Additionally, ECHA notes that long-term tests are suitable to simultaneously address the information requirement of Annex X, Section 9.4.6. and Annex IX,

Section 9.4.3. Therefore, the Registrant is granted the option to carry out a long-term test as an alternative to the short-term test on terrestrial plants that the Registrant proposed.

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 short-term toxicity testing, ECHA considers three species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with one monocotyledonous species and two dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. Alternatively, for long-term toxicity testing, ECHA considers six species as the minimum and testing shall be conducted, as a minimum with two monocotyledonous species and four dicotyledonous species. The Registrant should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 40(3)(b) of the REACH Regulation, the Registrant is required to carry out one of the following studies: Short-term toxicity testing on plants (Annex IX, 9.4.3.) test method: Terrestrial plants, growth test (OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species), or, if long-term testing is considered appropriate, Long-term toxicity testing on plants (Annex X, 9.4.6.); 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.

c) Effects on soil micro-organisms (Annex IX, 9.4.2.)

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

The Registrant provided the following justification for conducting the proposed test:
"A short-term toxicity study on terrestrial invertebrates is a standard information requirement as laid down in Annex IX, section 9.4.1., column 1 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 generate the data for this endpoint. According to claimed uses of heptanoic acid terrestrial exposure is likely. At the moment no data is available for characterizing heptanoic acid effects on organisms inhabiting terrestrial compartment. Even if the risk assessment demonstrated that there little risk for those organisms using the PNEC derived through equilibrium partitioning method, tests are proposed for covering this question.
Indeed, the RCR for Grassland at the level of the manufacturing site is higher than 1. However, the 0.02 release factor to wastewater is a worst case that is ten times higher than the actual release factor to wastewater of the manufacturing site. The releases to soil in general, including to grassland, are directly related to the amount of substance entering the STP. Thus we can assume that the Grassland PEC will be in fact ten times lower and thus the PEC/PNEC ration will be below 1. However we propose tests to refine the PNEC soil."

ECHA points out that effects on soil micro-organisms is a standard information requirement as laid down in Annex IX, section 9.4.2 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 generate the data for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed 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.

3. Sub-chronic toxicity study (90-day)

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.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, section 8.6.2. 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 generate the data for this endpoint.

The Registrant proposed testing by the oral route. In the light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is appropriate.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

Third party information 1:
ECHA has examined the information submitted by a third party. The third party presented a quantitative structure-activity relationship model (QSAR) for repeated dose 90-day oral toxicity study in rodents. The third party has indicated that their information is confidential and this information is thus not provided to the Registrant.

ECHA notes that the compliance with the Annex XI section 1.3 requirements could not be established as the required information concerning the validity, adequacy for risk assessment and/or classification and labelling and documentation of the model was found insufficient. The submitted documents provide evidence that the descriptors of the predicted substance fall within the ranges of the individual descriptors, used for development of the model.

The Q(SAR) Model Reporting Format QMRF does not provide sufficient information to deduce whether the training set was constructed from studies that cover the information requirements of the OECD 408 guideline, or important study aspects, such as the uniform selection of species, dose selection and number of animals used. In addition, the submitted QPRF does not contain any indication on the adequacy in relation to a defined regulatory purpose of the Testing Proposal.

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.

Third party information 2a
A third party has indicated that due to the corrosive property of the substance, *in vivo* testing should be prevented based on animal welfare reasons (Directive 2010/63/EC) and on Annex XI (testing technically not possible).

ECHA notes that under certain conditions *in vivo* testing with corrosive substances is technically possible. As specified in the general part of Annexes VII-X "in vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided". The test methods for repeated dose toxicity and reproductive toxicity specify that the highest dose level should induce "toxicity but not death or severe suffering". It is the Registrant's responsibility to ensure that appropriate dose/exposure levels are used. Therefore, the information submitted does not provide a sufficient basis on which to reject the proposed test.

Third party information 2b
A third party has proposed to consider existing data. In particular, the third party suggested considering data from subacute toxicity studies on rodents and data from a chronic study on pigs. The proposed studies do not meet the any of the criteria laid down in column 2 of the Annex IX 8.6.2. of the REACH Regulation and therefore, ECHA concludes that this is not a sufficient basis to fulfil the data/information requirement.

Third party information 2c
The third Party has proposed to take into account results from repeated dose studies by using the read-across substances octanoic acid (CAS No.124-07-2) and 2-ethylhexanoic acid (CAS No. 149-57-5). The third party refers to the category justification provided in the attached review paper (US EPA Initial Risk-Based Prioritization of High Production Volume Chemicals for the C7-C9 Aliphatic Aldehydes and Carboxylic Acids Category (2009)).

ECHA acknowledges the information provided by the third party but notes that it is the responsibility of the Registrant to use read across. Furthermore, the Registrant has to justify that the criteria set out in Annex XI, 1.5. of the REACH Regulation, respectively, are met and that the information is a sufficient basis to fulfil the data/information requirements.

c) Outcome

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408) using the registered substance.

4. Pre-natal developmental toxicity study

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.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, section 8.7.2. of the REACH Regulation. According to section 8.7.2. of Annex X subject to the Annex IX, 8.7.2. column 2 requirements of the REACH Regulation, a further pre-natal developmental toxicity study performed in a second species is required to fulfil the standard information requirements. The information available on this endpoint for the registered substance in the technical dossier does not meet these information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant has provided information from a pre-natal developmental toxicity study in which no adverse effects on development (NOAEL > 1000 mg/kg bw/day) were observed in rats.

ECHA notes that the Registrant proposes to conduct the pre-natal developmental toxicity study in rabbits. The rabbit is considered an acceptable option as the second species for a pre-natal developmental toxicity.

The Registrant did not specify the route to be used in the pre-natal developmental toxicity study that he proposed. According to the test method EU B.31/OECD 414, the test substance is usually administered orally. ECHA considers this default parameter appropriate and testing should be performed by the oral route.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

Third party information 1a

A third party has indicated that consideration should be given to the corrosive property of the substance. ECHA notes that under certain conditions *in vivo* testing with corrosive substances is technically possible. As specified in the general part of Annexes VII-X "in vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided". The test methods for repeated dose toxicity and reproductive toxicity specify that the highest dose level should induce "toxicity but not death or severe suffering". It is the Registrant's responsibility to ensure that appropriate dose/exposure levels are used. Therefore, the information submitted does not provide a sufficient basis on which to reject the proposed test.

Third party information 1b

The third party further proposed to consider existing data and refered to results from an oral reproduction/developmental toxicity screening study and a developmental toxicity limit test conducted on the registered substance. ECHA notes that the screening study does not fulfil the information requirements for the prenatal developmental toxicity study. Regarding the developmental toxicity limit test, ECHA acknowledges the information provided by the third party but notes that it is the responsibility of the Registrant to evaluate the quality of data and to ensure that the information is a sufficient basis to fulfil the data/information requirements.

Third party information 1c
The third party also proposed to consider CAESAR QSAR model for prenatal developmental toxicity. The result from the QSAR model (i.e. "toxic" or "non-toxic") is not suitable for the purposes for classification and labelling and/or risk assessment for the endpoint for which testing has been proposed to meet the information requirement (Annex X, 8.7). The documentation provided is inadequate and it has not been shown if the scientific validity of the model has been established or not. Therefore, the conditions specified in Annex XI, 1.3 of the REACH Regulation are not met and the results cannot be used instead of testing. The submitted documents also indicate that the substance might be outside of the applicability domain of the model.
Therefore, 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, 1.3 and it cannot constitute an acceptable adaptation to standard information requirements.

Third party information 1d
The third party further refered to the results from repeated dose studies by using the read-across substances octanoic acid (CAS No.124-07-2), nonanoic acid (CAS No. 124-07-2), and 2-ethylhexanoic acid (CAS No. 149-57-5). The third party refers to the category justification provided in the attached review paper (US EPA Initial Risk-Based Prioritization of High Production Volume Chemicals for the C7-C9 Aliphatic Aldehydes and Carboxylic Acids Category (2009)).

ECHA acknowledges the information provided by the third party but notes that it is the responsibility of the Registrant to use read across. Furthermore, the Registrant has to justify that the criteria set out in Annex XI, 1.5. of the REACH Regulation, respectively, are met and that the information is a sufficient basis to fulfil the data/information requirements.

c) Outcome

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is thus required to carry out the proposed study: Pre-natal developmental toxicity study in rabbits, oral route (test method: EU B.31/OECD 414) using the registered substance.

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.

5. Deadline for submitting the studies

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the fact that the Registrant shall determine the appropriate order of the studies taking into account the possible outcome and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation.
In his comments, the Registrant requested to prolong the timeline proposed in the draft decision for submission of the requested information from 24 to 30 months. The Registrant based his request on issues related to the laboratory capacity and on time needed for the "step-by-step" testing. However, the Registrant did not substantiate the laboratory capacity with relevant documentation as requested by ECHA and did not justify the additional time needed for the "step-by-step" testing. Further, it is noted that the Registrant did also not claim any substance-specific technical difficulties in carrying out the proposed tests.

Therefore, ECHA considered the request of the Registrant, but concluded that extension of the deadline to 30 months for finalising the studies is not justified. ECHA concludes that the timeline of 24 months is appropriate.

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, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed tests, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade 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). 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.

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