EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003991-68-04/F Helsinki, 5 September 2014

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

For hex-1-ene, CAS No. 592-41-6 (EC No. 209-753-1), 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 hex-1-ene, CAS No. 592-41-6 (EC No. 209-753-1) referred to as "substance subject to this decision" below, by [redacted] (Registrant).

More specifically, the dossier encloses a document "Higher Olefins Testing Proposal", which contains a testing plan to "*provide information that will meet the higher tier testing requirements of REACH*" for a group of substances, including the substance subject to this decision. The testing plan is summarised as follows:

1. Subchronic repeated dose toxicity study (OECD Guideline 408, oral route), species not specified, on the analogue substances, oct-1-ene (CAS No. 111-66-0), nonene, branched (CAS No. 97280-95-0), octadecene (CAS No. 27070-58-2), hydrocarbons C12-30, olefin-rich, ethylene polymn. by-product (CAS No. 68911-05-7) and octadec-1-ene (CAS No. 112-88-9)
2. Prenatal developmental toxicity study (OECD Guideline 414), in the rat by the oral route, on the substance subject to this decision
3. Two-generation reproduction toxicity study (OECD Guideline 416), in the rat by the oral route, on the substance subject to this decision.

The present decision relates only to the examination of the testing proposals 1 and 2.

The testing proposal 3, for fulfilling the information requirement for a reproductive toxicity study (Annex X, 8.7.3.), is addressed in a separate decision although all these were initially addressed together in the same draft decision.

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 1 August 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 from initiating a compliance check on the present dossier at a later stage.

On 15 September 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals on prenatal developmental toxicity and two-generation reproduction toxicity 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 not receive information from third parties.

On 3 January 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 25 January 2012, ECHA received comments from the Registrant indicating a changed testing strategy proposing additional tests for subchronic toxicity (90-day). Subsequently, on 6 March 2012 ECHA received an update of the registration dossier including a testing proposal for subchronic repeated dose toxicity.

The examination of the testing proposals for sub-chronic toxicity (90-day) was initiated upon the date when receipt of the complete registration dossier was confirmed on 7 March 2012.

ECHA held a third party consultation for the testing proposal on sub-chronic toxicity (90-day) from 25 June 2012 until 09 August 2012. ECHA did not receive information from third parties.

ECHA considered the Registrant's comments received and the information included in the updated dossier. On that occasion, ECHA noted that the draft decision initially sent to the Registrant did not address all the defects present in the testing strategy initially proposed by him. ECHA considered that the omitted issues were significant and must therefore be considered in the final decision to be sent to the Registrant. Nevertheless, ECHA was mindful to give useful effect to the right to comment on arguments omitted in the previous draft decision, in accordance with Article 50(1) of the Regulation. In order to allow the Registrant to comment on grounds that should have been initially notified to him, ECHA decided to notify him, for comment, a modified draft decision including the grounds omitted in the previous draft decision. ECHA has also taken this opportunity to include in its assessment a testing proposal on a new endpoint included by the Registrant in its testing strategy, following its update of the dossier.

On 10 September 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 10 October 2012 ECHA received comments from the Registrant indicating a now substantially changed category and read-across approach requesting additional time to develop a full new testing plan. Subsequently, on 08 March 2013 ECHA received an update of the registration dossier including a new test plan.

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

On 1 August 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, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 6 September 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 not to amend the draft decision.

On 16 September 2013 ECHA referred the draft decision to the Member State Committee.

The draft decision was split into two draft decision documents: one relating to the testing proposal for a two-generation reproduction toxicity study (Annex X, 8.7.3.), and one relating to the testing proposals for subchronic repeated dose toxicity and prenatal developmental toxicity.

By 7 October 2013 the Registrant provided 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 4-8 November 2013, a unanimous agreement of the Member State Committee on the draft decision relating to the testing proposals for subchronic repeated dose toxicity and prenatal developmental toxicity, as modified at the meeting, was reached on 7 November 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

In parallel, following a compliance check on the identity of the substance "nonene (CAS No. 27215-95-8)", the multiple registrants of that substance jointly requested a change of the substance's identifiers to "nonene, branched (CAS No. 97280-95-0)", which reflects the substance actually manufactured and imported. After verifying that this modification had no consequence on the selection of that substance for the proposed testing strategy, ECHA adapted the present decision *mutatis mutandis*.

II. Testing required

The Registrant has requested to carry out the required sub-chronic repeated dose toxicity test using analogue substances as part of a read-across and grouping approach, in accordance with Annex XI, 1.5. ECHA emphasises that any final determination on the validity of the read-across, including the grouping approach proposed by the Registrant, would be premature at this point in time. The eventual validity of the read-across hypothesis and grouping approach will be reassessed once the requested information is submitted. In the meantime, based on the information currently submitted, ECHA considers that the approach proposed by the Registrant is plausible. In the light of this assessment ECHA has taken the following decision.

The Registrant shall carry out the following tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and substances:

1. Sub-chronic repeated dose toxicity study in rats, oral route (Annex IX, 8.6.2., test method: EU B. 26/OECD 408) on the analogue substances, oct-1-ene (CAS No. 111-66-0), nonene, branched (CAS No. 97280-95-0), octadecene (CAS No. 27070-58-2), hydrocarbons C12-30, olefin-rich, ethylene polymn. by-product (CAS No. 68911-05-7) and octadec-1-ene (CAS number 112-88-9); and

2. Pre-natal developmental toxicity study in rat or rabbit, oral route (Annex IX, 8.7.2., test method: EU B.31/OECD 414) on the on the substance subject to this decision.

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 **12 September 2016** an update of the registration dossier containing the information required by this decision.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfill this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

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 proposals submitted by the Registrant for the registered substance.

In relation to the testing proposal for sub-chronic repeated dose toxicity, the Registrant has proposed to use a read-across and grouping approach, in accordance with Annex XI, 1.5, and to perform the proposed tests on several analogue substances as outlined below. To the extent that some of the proposed testing relies upon a read-across hypothesis, ECHA has considered first the scientific validity of the proposed read-across and grouping approach (preliminary considerations; Section 0, below), before assessing the testing proposed (Sections 1 and 2, below).

0. Grouping of substances and read-across approach (preliminary considerations)

a) Legal Background on ECHA's assessment of the grouping of substances and read-across hypothesis brought forward by the Registrant

The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. To this end, it is necessary to consider whether programmes of testing proposed by registrants are appropriate to fulfil the relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting wherever possible the use of alternative means, where equivalent results to the prescribed test are provided on health and environmental hazards. In accordance with these objectives, ECHA shall assess whether a prediction of the relevant properties of the substance subject to this decision by using the results of the proposed tests is sufficiently plausible based on the information currently available.

Article 13(1) of the REACH Regulation requires information on intrinsic properties of substances on human toxicity to be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping or read-across), "*provided that the conditions set out in Annex XI are met*".

According to Annex XI, 1.5 there needs to be structural similarity among the substances within a group or a category such that the relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation.

The Registrant has submitted testing proposals, based on a grouping and read-across approach, intended to fulfil information requirements for oral sub-chronic toxicity (90-days; Annex IX 8.6.2.), pre-natal developmental toxicity (Annexes IX and X, 8.7.2.), and toxicity to reproduction (Annex X, 8.7.3.). It is noteworthy that under the evaluation of the testing proposals, ECHA has not performed a compliance check on other endpoints such as mutagenicity, carcinogenicity and repeated dose toxicity and may do so at any time at its own discretion.

b) Introduction of the grouping approach and read-across hypothesis proposed by the Registrant

According to the Registrant, the substance subject to this decision can be grouped with other substances in a category for the purpose of read-across. The grouping is based on the fact that all substances that are members of the category share a structural similarity; i.e. they have the same functional group (one carbon-carbon double bond). The Registrant considers substances that fulfil the following criteria as member of the category:

- the number of carbon atoms between C6 and C30;
- the presence of structures with even or odd numbers of carbon atoms;
- the location of the carbon-carbon double bond (i.e. alpha olefin, vinylidene olefin and internal olefins);
- the presence of linear and branched structures.

In ECHA's understanding the read-across hypothesis, as presented by the Registrant, is based on the fact that all substances within this category can be assumed not to produce significant systemic toxicity. Furthermore, according to the Registrant a trend of decreasing oral absorption is expected within the category (as the molecular weight increases). The Registrant predicts based on this assumption that the higher molecular weight members will exhibit low absorption and consequently not display significant toxicity. However, ECHA notes that the Registrant has not defined the term "low absorption".

c) Information submitted by the Registrant to support the grouping approach and read-across hypothesis

In order to support its testing proposal, the Registrant has provided information based on scientific publications on *in vitro* hepatic metabolism of olefins. From this information, the Registrant points out that the olefin structures "*are metabolized to diols via an epoxide intermediate by hepatic microsomal enzymes*" and that "*the position of the double bond as well as the degree of substitution influences this metabolism, with alpha olefins appearing more biologically reactive relative to internal and/or branched olefins.*" Based on this information the Registrant concludes that all different olefin structures (i.e. alpha, internal, branched, even numbered, odd numbered) should be included in the testing programme.

Furthermore, the Registrant has provided seven oral combined repeated dose toxicity and reproduction/developmental toxicity screening (OECD 422), sub-acute repeated dose toxicity (OECD 407), and sub-chronic toxicity (OECD 408) studies on the substances "hexene", "tetradecene", "alkenes, C16-C18", "alkenes C20-C24". ECHA notes that four of the studies show no effects at the limit dose (1000 mg/kg bw/day), and that this supports the Registrant's assumption of no significant toxicity. However, while data from two studies perfomed using "hexene" show minor toxicological effects (OECD 407 and 408; *e.g.* decreased body weight), the OECD 422 study performed using "tetradecene" shows effects at the lowest dose tested (LOEL 100 mg/kg bw/day; *e.g.* hydrocarbon nephropathy, haematology, organ weights). As a result, the Registrant acknowledges that his assumption of no toxicity for all substances in the category is not fully supported by all available information. In order to address this issue, the Registrant commits in the testing programme to further strengthen the category with an additional seven "Combined repeated dose toxicity study with the reproduction/developmental toxicity screening tests" (OECD guideline 422) on the substances: "oct-1-ene", "nonene, branched", "decene", "hexadecane", "octadec-1-ene – UVCB" and one substance with a carbon number above C20 ("alkenes, C20-C24", "hydrocarbons, C12-30, olefin-rich, ethylene polymn. by-product" or "alkenes, C24-28" are indicated as candidate test substances).

In addition, the Registrant has initiated a test programme that aims at generating information on oral absorption properties for the category members. This includes two steps, first *in vitro* absorption data using a "Gut-sac model" for all category members (studies are on-going) and, subsequently, *in vivo* validation of the *in vitro* model by testing representative samples (using four to six ^{14}C-labeled substances) in order to confirm the relationship and trends observed above. ECHA notes that the preliminary data of the "Gut-sac model" already included in the justification document indicates a decrease in absorption with the carbon number of the olefin members with an apparent thresfold for low absorption at a carbon number of 14 (C14).

d) The selection of substances to be tested

The Registrant has proposed to test five substances with the intention to cover the structural variability of the category for the information requirement subchronic toxicity (90-days). ECHA has considered each substance proposed to be tested in the light of the corresponding structural element(s).

i. The substances in the category can contain up to 99% of the alpha olefin structural element. The Registrant proposes to test oct-1-ene ([redacted]% alpha olefin) for oral sub-chronic toxicity (90-days). ECHA notes that the substance proposed has a high content of the alpha olefin structural element and stands at the lower boundary with regard to the range of carbon number for the category.

ii. The substances in the category can contain up to 36% of the vinylidene and 69% of the branched structural elements. The Registrant proposes to test "octadec-1-ene UVCB" ([redacted]% vinylidene, [redacted]% branched) for oral sub-chronic toxicity (90-days. ECHA notes that the substance proposed contains one of the highest amounts of vinylidene content among the category members.

iii. The substances in the category can contain up to 95% of the di- and 65% of the tri-substituted internal structural element. The Registrant proposes to test octadecene ([redacted]% di-, [redacted]% tri-substituted) for oral sub-chronic toxicity (90-days). ECHA notes that octadecene contains a high amount of di- and tri-substituted content.

iv. The substances in the category can contain up to 8% of the tetra-substituted internal structural element. The Registrant proposes to test "hydrocarbons, C12-30, olefin-rich, ethylene polymn. by-product" ([redacted]% di-, [redacted]% tetra-substituted) for oral sub-chronic toxicity (90-days). ECHA notes that "hydrocarbons, C12-30, olefin-rich, ethylene polymn. by-product" contain the highest amount of tetra-substituted content among the category members and a high amount of di-substituted internal olefin content.

v. The substances in the category can contain up to 90% of the odd carbon number structural element. The Registrant proposes to test "nonene, branched" ([redacted]% odd carbon number) for oral sub-chronic toxicity (90-days) ECHA notes that "nonene, branched" contains the highest amount of odd carbon number content.

ECHA notes that the substances proposed to be tested cover the structural diversity within category as defined by the Registrant. However, ECHA notes further that the category is defined by carbon number (i.e. C6 to C30) and that the substances proposed to be tested cover only the range between C6 and C23, and that the absorption of individual substances, as well as their toxicological properties, are currently identified as key parameters in the selection of substances to be tested.

e) ECHA analysis of the grouping approach and the read-across hypothesis of the Registrant in light of the requirements of Annex XI, 1.5

ECHA understands that the grouping approach is based on a common structural element (i.e. one double carbon-carbon bond) within well-defined boundaries and that the read-across hypothesis assumes that all substances within the category exhibit no or low toxicity. ECHA has analysed the grouping approach as proposed by the Registrant and considers that the criteria for category membership and the boundraries of the category have been sufficiently defined.

Accordingly, ECHA considers the read-across hypothesis plausible based on the supportive available toxicological information. The preliminary information on oral absorption and data from available repeated dose toxicity studies suggest that it may be possible to predict the properties of a member-substance of the category based on information available for other substances in that category.

However, while data from two studies performed according to OECD 407 and 408 test guidelines using "hexene" show minor toxicological effects (*e.g.* decreased body weight), the OECD 422 study performed using "tetradecene" shows effects at the lowest dose tested (LOEL 100 mg/kg bw/day; *e.g.* hydrocarbon nephropathy, haematology, organ weights). ECHA concludes that the Registant's assumption of no toxicity for all substances in the category is not supported by the currently available information. These uncertainties must be addressed by the Registrant when implementing the testing program in order to meet the conditions set out in Annex XI, section 1.5 of the REACH Regulation.

Firstly, the Registrants committed to further strengthen the category with an additional seven "Combined repeated dose toxicity study with the reproduction/developmental toxicity screening tests" (OECD guideline 422) on the substances: "oct-1-ene", "nonene, branched", "decene", "hexadecane", "octadec-1-ene – UVCB" and one substance with a carbon number above C20 ("alkenes, C20-C24", "hydrocarbons, C12-30, olefin-rich, ethylene polymn. by-product" or "alkenes, C24-28" are indicated as candidate test substances). ECHA considers that generating this additional information is a minimum condition for the ultimate compliance of the category with regard to sceening level repeated dose toxicity and toxicity to reproduction, where currently only limited information is available.

Secondly, as pointed out in section d) above, the Registrant has proposed to test five substances for sub-chronic (90-day) toxicity to address Annex IX and X requirements taking into account the structural variability within the category. ECHA considers it plausible that the substances selected by the Registrant cover the structural variability within the category and that the grouping will ultimately be acceptable for ECHA.

However, the category is defined by carbon number (i.e. C6 to C30) and that the substances proposed to be tested cover the range between C6 and C23. As a result, the read-across proposed involves extrapolation rather than interpolation for substances with a carbon number of >C23. The Registrant therefore committed himself to verify the assumption of no absorption above the carbon number of C23 using information generated by verification of the "Gut-Sac-Model" with adequate *in vivo* absorption studies.

ECHA considers that generating reliable information on oral absorption for all category members is also a minimum condition for the ultimate compliance of the grouping and read-across approach proposed by the Registrant. However, ECHA cannot conclude on this aspect as the validation of the data generated with the "Gut-sac model" is still to be completed.

Thirdly, remaining uncertainties, which must be addressed by the Registrant, include the missing definition of the terms "low/no absorption", especially as the OECD 407 and OECD 408 studies with tetradecene show clear systemic effects when the "Gut-sac model" predicts no significant absorption for the corresponding carbon number (*i.e.* C14).

In the case where the tests performed in accordance with the present decision would not confirm the grouping and read-across hypothesis relied upon by the Registrant, this outcome shall not alter the obligation of the Registrant to meet the standard information requirements. Should the read-across strategy be inadequate, it is the responsibility of the Registrant to ultimately submit reliable information or adaptations which is used in a way that does not underestimate hazards of the registered substance in relation to the relevant endpoints.

Finally, the read-across adaptation based on the results of the proposed tests shall ensure that any remaining uncertainties, including results of any existing studies which might give rise to concern, are analysed, minimized, and taken into account for the purpose of classification and labelling and/or risk assessment.

In any case, following the update of the dossier submitting the information required in the present decision, ECHA will determine whether the documentation provided is sufficient to satisfactorily address the information requirement of Annex X for the entire category as proposed by the Registrant. If, upon further consideration, the proposed approach does not satisfy the conditions set out in Annex XI, ECHA reserves the right to request the information necessary to fulfil the information requirements for the substance subject to the present decision.

1. Repeated dose 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 tests.
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. Although information on this endpoint (via inhalation route) is available for the substance subject to this decision, ECHA recognises the need to address the present testing proposal in the broader context of the category concerning higher olefins. In that respect, ECHA considers that the testing is required in any case on the analogue substances referred to by the Registrant. As a result, ECHA sees no reasons not to accept the testing proposed by the Registrant on these analogue substances.

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

The Registrant did not specify the species to be used for testing. According to the test method EU B. 26/OECD 408, the rat is the preferred species. ECHA considers the default parameter appropriate and testing should be performed with the rat as species to be used.

b) Consideration of the information received during third party consultation

ECHA did not receive information from third parties.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the following study: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408) using the analogue substances oct-1-ene (CAS No. 111-66-0), nonene, branched (CAS No. 97280-95-0), octadecene (CAS No. 27070-58-2), hydrocarbons C12-30, olefin-rich, ethylene polymn. by-product (CAS No. 68911-05-7) and octadec-1-ene (CAS No. 112-88-9).

2. 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 tests.

Pre-natal developmental toxicity studies are part of the standard information requirements as laid down in Annexes IX and X, section 8.7.2. 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 did not specify the species and route to be used for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or rabbit as a first species to be used.

b) Consideration of the information received during third party consultation

ECHA did not receive information from third parties.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out a pre-natal developmental toxicity study in rat or rabbit, oral route (test method: EU B.31/OECD 414) with the substance subject to this decision.

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

3. Timeline for providing the requested information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a reproductive toxicity study according to the standard information requirement of Annex X, 8.7.3 of the REACH Regulation. As the testing proposal for this study is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 24 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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. 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 grades 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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Leena Ylä-Mononen
Director of Evaluation