For final decision: TPE-D-2114335411-62-01/F Helsinki, 20 July 2016

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

For octene, EC No 246-920-8 (CAS No 25377-83-7), 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 octene, EC No 246-920-8 (CAS No 25377-83-7), submitted by [redacted] (Registrant).

More specifically, the Registrant has submitted testing proposals in IUCLID sections 7.5.1 and 7.8.2. In addition 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 proposals for the substance subject to the present decision are summarised as follows:

1. Sub-chronic 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 number 112-88-9);
2. Prenatal developmental toxicity study (OECD Guideline 414), species and route of administration not specified, on the analogue substances, hex-1-ene (CAS No. 592-41-6), 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).

This decision is based on the registration 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 10 August 2015, i.e. 30 calendar days after the end of the commenting period.

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 registration at a later stage.

ECHA received the registration dossier containing testing proposals for further examination pursuant to Article 40(1) on 21 May 2013. The registration was subsequently updated on 6 November 2013 and 23 February 2015 containing the above-mentioned testing proposals.

The substance subject to the present decision is a member of the HOPA Higher Olefins category. ECHA held a third party consultation for the testing proposal of that category from 18 June 2012 until 2 August 2012. ECHA did receive information from third parties (see section III below). The substance subject to the present decision was nevertheless not registered at that time. Therefore ECHA held a separate third party consultation for the testing proposals included in the registration of the substance subject to the present decision from 2 June 2014 until 18 July 2014. ECHA did not receive further information from third parties.

On 3 June 2015 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 2 July 2015 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 21 January 2016 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 for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposal(s) for amendment to the draft decision were submitted.

On 26 February 2016 ECHA notified the Registrant of the proposal(s) for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal(s) for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal(s) for amendment received and did not amend the draft decision.

On 7 March 2016 ECHA referred the draft decision to the Member State Committee.

By 29 March 2016 the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 12 April 2016 in a written procedure launched on 1 April 2016.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant has requested to carry out the required tests 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 rats or rabbit, oral route (Annex IX, 8.7.2., test method: EU B.31/OECD 414) on the analogue substances, hex-1-ene (CAS No. 592-41-6), 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).

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.

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.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **27 July 2018** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

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.

In relation to the testing proposals subject to the present decision, 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 all proposed testing relies upon an identical 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 (Section 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", "hexadecene", "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 tests 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. 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) and hex-1-ene ([redacted]% alpha olefin) for pre-natal developmental toxicity and two generation reproductive toxicity. ECHA notes that both substances proposed have a high content of the alpha olefin structural element and stand at the lower boundary with regard to the range of carbon number for the category (for hex-1-ene there is an existing study for sub-chronic toxicity (90-days) by inhalation available).

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), for pre-natal developmental toxicity and two generation reproductive toxicity. In case of negative outcomes of the oral sub-chronic toxicity (90-days) and pre-natal developmental toxicity, the Registrant proposes to test "tetradecene UVCB" ([redacted]% vinylidene, [redacted]% branched) for two generation reproductive toxicity instead of octadec-1-ene. ECHA notes that "octadec-1-ene" contains one of the highest amounts of vinylidene content among the category members and "tetradecene UVCB" contains a high amount for the same structural element while the carbon number is smaller leading to an assumed higher oral absorption.

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), for pre-natal developmental toxicity and two generation reproductive toxicity. In case of negative outcomes of the oral sub-chronic toxicity (90-days) and pre-natal developmental toxicity, the Registrant proposes to test "hexadecene" ([redacted]% di-, [redacted]% tri-substituted) for two generation reproductive toxicity instead of octadecene. ECHA notes that octadecene and hexadecene contain a high amount of di- and tri-substituted content; while the carbon number is smaller in hexadecene leading to an assumed higher oral absorption.

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), for pre-natal developmental toxicity and two generation reproductive toxicity. In case of negative outcomes of the oral sub-chronic toxicity (90-days) and pre-natal developmental toxicity, the Registrant proposes to test "alkenes C8-10, C9 rich" ([redacted]% di-, [redacted]% tri-, [redacted]% tetra-substituted) for two generation reproductive toxicity instead of "hydrocarbons, C12-30, olefin-rich, ethylene polymn. by-product". ECHA notes that "hydrocarbons, C12-30, olefin-rich, ethylene polymn. by-product" contain the highest amount of tetra-substituted content and "alkenes C8-10, C9 rich" contain a high amount of tetra-substituted content and both substances contain a high amount of di-substituted internal olefin content; while the low carbon number in "alkenes C8-10, C9 rich" will lead to a high oral absorption.

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), for pre-natal developmental toxicity and two generation reproductive toxicity. 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 Registrant 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", "hexadecene", "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 screening 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, pre-natal developmental toxicity and two-generation reproduction 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 to be submitted 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. 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 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.

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 received no third party comments for the registered substance, but ECHA did receive third party information concerning the testing proposal during the third party consultation of other members of the HOPA Higher Olefins category. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

Third party information:

The third Party proposed ECHA to take into account a weight-of-evidence approach before further tests on vertebrate animals are required. As part of this approach, the third party referred to existing data from repeated dose toxicity studies in rodents with substances others than the one registered. ECHA has taken the information provided into account and concluded that it is insufficient for demonstrating that the conditions of Annex XI, Section 1.2. of the REACH Regulation are met. ECHA notes that the information provided by the third party is not sufficient for concluding that the "human health" properties of the registered substance could be reliably predicted with tests performed with the read across substances shown. More specifically, the proposed weight-of-evidence approach is not sufficient to assume that the substance has or has not a particular dangerous property and that the standard information requirements for "90-day repeated dose toxicity, pre-natal developmental toxicity or reproductive toxicity studies" could be adapted. Although ECHA recognises that the information as provided by the third party might be scientifically valid, it does not fulfil Annex XI requirements and is therefore not sufficient to allow ECHA to reject the testing proposal.

In addition, the third party has explicitly mentioned that alkenes have been considered in the OECD SIDS higher olefin category. However, the existence of this category, or its consideration by the OECD, is not in itself a valid basis for adaptation of the information requirement.

Furthermore, insofar as these third party comments address read-across, ECHA notes that the testing plan for the higher olefins category is consistent with the third parties considerations and uses supporting data in a weight-of-evidence approach for consolidating the category.

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 received no third party comments for the registered substance, but ECHA did receive third party information concerning the testing proposal during the third party consultation of other members of the HOPA Higher Olefins category. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

Third party information:

The third Party proposed ECHA to take into account a weight-of-evidence approach before further tests on vertebrate animals are required. As part of this approach, the third party referred to existing data from repeated dose toxicity studies in rodents with substances others than the one registered. ECHA has taken the information provided into account and concluded that it is insufficient for demonstrating that the conditions of Annex XI, Section 1.2. of the REACH Regulation are met. ECHA notes that the information provided by the third party is not sufficient for concluding that the "human health" properties of the registered substance could be reliably predicted with tests performed with the read across substances shown. More specifically, the proposed weight-of-evidence approach is not sufficient to assume that the substance has or has not a particular dangerous property and that the standard information requirements for "90-day repeated dose toxicity, pre-natal developmental toxicity or reproductive toxicity studies" could be adapted. Although ECHA recognises that the information as provided by the third party might be scientifically valid, it does not fulfil Annex XI requirements and is therefore not sufficient to allow ECHA to reject the testing proposal.

In addition, the third party has explicitly mentioned that alkenes have been considered in the OECD SIDS higher olefin category. However, the existence of this category, or its consideration by the OECD, is not in itself a valid basis for adaptation of the information requirement.

Furthermore, insofar as these third party comments address read-across, ECHA notes that the testing plan for the higher olefins category is consistent with the third parties considerations and uses supporting data in a weight-of-evidence approach for consolidating the category.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the following studies: Pre-natal developmental toxicity study in rat or rabbit, oral route (test method: EU B.31/OECD 414) using the analoge substances hex-1-ene (CAS No. 592-41-6), 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).

Notes for consideration by the Registrant

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, Section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

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, Section 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. If the Registrant considers that the conditions for adaptations are not fulfilled, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that the conditions for these adaptations can be fulfilled, he should update his technical dossier by clearly stating the reasons for proposing to adapt the standard information requirement of Annex X, Section 8.7.2. of the REACH Regulation.

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 proposals. 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. 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.

Authorised[2] by Ofelia Bercaru, Head of Unit, Evaluation

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.