Decision number: TPE-D-0000004028-78-04/F Helsinki, 19 February 2014

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

For Residues (petroleum), vacuum, CAS No 64741-56-6 (EC No 265-057-8), 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 jointly submitted registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for Residues (petroleum), vacuum, CAS No 64741-56-6 (EC No 265-057-8), by [redacted] (Registrant):

- Prenatal Developmental Toxicity Study (OECD Guideline 414), in rats, inhalation route using tank fume condensate derived from Residues (petroleum), thermal cracked vacuum (CAS No 92062-05-0); and
- Two-Generation Reproduction Toxicity Study (OECD Guideline 416), in rats, inhalation route using Tank fume condensate derived from Residues (petroleum), thermal cracked vacuum (CAS No 92062-05-0).

The present decision relates to the examination of the testing proposal for pre-natal developmental toxicity study. The testing proposal for the two-generation reproductive toxicity study is addressed in a separate decision although both testing proposals 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. In order to follow the procedure outlined in Articles 50(1) and 51 of the REACH Regulation and to allow ECHA complete the necessary administrative practices for the Member States Competent Authorities' referral, ECHA has taken into consideration dossier updates pertinent to the decision received by the deadline of 29 April 2013 agreed between ECHA and the Registrant. Furthermore, ECHA has exceptionally taken into account the data provided by the Registrant, after the deadline, in the informal communication, as Registrant notified it of the incorrectness of some information contained in the relevant update.

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.

On 26 October 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 16 August 2011 until 30 September 2011. ECHA did receive information from third parties (see section III below). On 12 October 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 12 November 2012 ECHA received comments from the Registrant to ECHA's draft decision. In his comments the Registrant indicated his intention to address issues outlined in the draft decision and to submit an updated dossier.

On 29 April 2013 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments received and the updated registration dossier. On that basis, Section II was amended and 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 did not amend the draft decision.

The draft decision was split into two draft decision documents: one relating to the testing proposal for a two-generation reproductive toxicity study and one relating to the testing proposal for pre-natal developmental toxicity study.

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

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 proposal for pre-natal developmental toxicity study as modified at the meeting was reached on 8 November 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation

II. Testing required

The Registrant has proposed to meet the information requirement by testing an analogue substance 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 proposed by the Registrant would be premature at this point in time. The eventual validity of the read-across hypothesis will be re-assessed once the requested studies are submitted. Nevertheless, based on the information currently submitted, ECHA considers that the approach proposed by the Registrant is plausible.

In the light of this assessment, the Registrant shall carry out the following test pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the analogue substance Residues (petroleum), thermal cracked vacuum, CAS No 92062-05-0 (EC No 295-518-9), instead of the substance subject to the present decision:

Pre-natal developmental toxicity study in rat or rabbit, inhalation route (Annex IX, 8.7.2.; test method: EU B.31/OECD 414).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **19 July 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 proposal submitted by the Registrant for the substance subject to the present decision and scientific information submitted by third parties.

In relation to the testing proposal subject to the present decision, the Registrant has proposed to use the grouping of substances and the read-across approach, in accordance with Annex XI, 1.5., and to perform the proposed test using an analogue substance (see Section I) instead of the substance subject to this decision. In its evaluation, ECHA has considered first the scientific validity of the proposed grouping and read-across approach (preliminary considerations; Section III.0), before assessing the testing proposed (Section III.1).

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 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.

The first Recital and the first Article of the REACH Regulation establish the "*promotion of alternative methods for assessment of hazards of substances*" as an objective pursued by the Regulation. In accordance with that objective, ECHA considers whether a prediction of the relevant properties of the substance subject to this decision by using the results of the proposed test 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*".

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

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 for the purpose of read-across in a category that is named '*Bitumens*'.

The Registrant considers that, due to the method of production of crude oils and their complex composition, it is not possible to characterise most petroleum substances in terms of their exact chemical composition, molecular formula or structure. Accordingly, the Registrant rather justifies its grouping approach based on the refining processes by which these substances are produced and on two basic physico-chemical properties. More specifically, the Registrant defines the boundaries of this category as follows:

- Refinery processes: Vacuum distillation;
- Boiling point range: 320°C to >495°C; and
- Carbon number: predominantly >C25.

According to the Registrant, the category justification document covers the substances that are listed below:

1. Asphalt; CAS No. 8052-42-4 (EC No. 232-490-9);
2. Residues (petroleum),vacuum; CAS No. 64741-56-6 (EC No. 265-057-8); and
3. Residues (petroleum), thermal cracked vacuum; CAS No. 92062-05-0 (EC No. 295-518-9).

Besides of these three substances, the Registrant indicated that there will be, in the future, more substances to be considered as members of this category. However, only the above listed substances are considered for the present assessment of the grouping and read-across approach.

According to the Registrant, the carbon number distribution and the hydrocarbon class profiles are sufficiently similar for all substances that are currently members of the category. Based on that similarity and the broad composition of the substances, as indicated above, the Registrant assumes that the "*category order is not relevant*", i.e. the differences among category members do not influence their hazardous properties.

Furthermore, the Registrant claims that substances covered by the category have similar physical-chemical and technical characteristics and present similar health, safety and environmental hazards.

The Registrant hypothesises that one hydrocarbon class (polycyclic aromatic hydrocarbons containing 4 or more aromatic rings) is the only putative reproductive toxicant among the hydrocarbon constituents in this category. Therefore, the Registrant has proposed to test one substance as a "*reasonable worst case*" to cover the standard information requirements for developmental toxicity and toxicity to reproduction (Annex X, 8.7.2. and 8.7.3.) and, subsequently, use the results of this study by means of read-across for all the other substances listed above.

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

Concerning the grouping approach, ECHA requested in its draft decision notified to the Registrant according to Article 50(1) of the REACH Regulation justifications of the claim of the structural similarity of these substances. This draft decision also pointed out the need to demonstrate similar effects with respect to the endpoint under consideration. In the updated dossier, the Registrant provided a generic compilation of compositional information of these three substances from measurements using chromatographic techniques (i.e. average carbon number distribution and average relative mass (%) of four major hydrocarbon classes named saturates, aromatics, resins and asphaltenes.

Concerning the read-across approach, the Registrant has provided information to support the read-across hypothesis that "*if reproductive or developmental effects were to occur following exposure to emissions from hot bitumen then this would most likely be caused by the PAH fraction in the emissions*". This information consists of references to national and international assessment reports, scientific publications and supporting studies conducted on petroleum substances, which address some of the hydrocarbon classes present in the substance subject to this decision.

More specifically, the Registrant argues that several studies on sub-chronic toxicity, pre-natal developmental toxicity, and toxicity to reproduction conducted on substances that are claimed to be predominantly aliphatic in composition (paraffins, iso-paraffins and naphthenics) did not demonstrate reproductive toxicity effects. Some of these studies have been submitted by the Registrant in the form of robust study summaries.

By contrast, the Registrant acknowledges that other studies performed with substances with a high content in polycyclic aromatic hydrocarbons showed developmental toxicity. ECHA notes that some of these substances are already classified as reproductive toxicants.

Consequently, the Registrant considers that a substance that contains the highest concentration of "*polycyclic aromatics, containing 4 or more aromatic rings*" would be representative of the reproductive toxicity potential of the category members without underestimating the actual hazards of these substances. "*As a conservative approach, the testing proposal is based on maximizing the sum of the 4 to 7 ring PACs content in emissions derived from bitumen to represent a reasonable worse case for worker exposure. The sum of 4 to 7 ring PACs is not measurable in bitumen due to limitations in the analytical methodology. The reasonable worse case will instead be reflected by the selection of a bitumen substance having high sum of 16 EPA PAHs.*"

In that line, the Registrant has considered the compositional profiles of the substances (listed above) and proposes to use Residues (petroleum), thermal cracked vacuum (CAS No 92062-05-0) as the substance to be tested.

d) ECHA's analysis of the grouping approach in light of the requirements of Annex XI, 1.5

ECHA understands that the grouping approach is based on the refining processes by which these substances are produced and on two basic physico-chemical properties.

The REACH Regulation allows for the adaptation of the standard testing regime by means of grouping and read-across as outlined in Annex XI, 1.5: "*Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or category of substances*".

ECHA notes that "petroleum substances" are specifically addressed in ECHA's Guidance for identification and naming of substances under REACH and CLP (version: 1.2; March 2012), Section 4.3.2.2 Substances obtained from oil and oil like sources. This Guidance document acknowledges that UVCB (*substances of Unknown or Variable composition, Complex reaction products or Biological materials*) petroleum substances, such as the substance subject to the present decision, may have a considerable intrinsic compositional variability, which may exceed the compositional variability normally observed for other UVCBs.

Nevertheless, ECHA stresses that the requirements for grouping set out in Annex XI 1.5 pursue the objective of identifying hazards of the substances concerned. For that specific objective, the intrinsic compositional variability between substances shall be taken into account by any registrant relying upon a category, because it may influence the outcome of the hazard assessment. This would imply at least that this registrant qualifies the compositional variability in order to justify the relevance of the category.

In relation to the present category, ECHA took note of the generic compilation of compositional information that was submitted by the Registrant in the updated category justification document, following the request of ECHA within the draft decision previously notified. However, while this generic data reveals structural similarity to some degree among the category members, ECHA stresses several deficiencies.

Firstly, contrary to the explicit requirement of Annex XI, 1.5, the Registrant does not define the category based on the structural similarity of the substances concerned, but persists in relying exclusively on manufacturing processes and performance characteristics to justify the grouping approach.

Secondly, the Registrant does not sufficiently qualify the compositional variability of the substances concerned by the category in order to justify that the compositional variability would not be such as to affect the determination of the actual hazard of the substances concerned.

Thirdly, the generic compositional data submitted only refers to the average carbon number distribution and average relative mass (%) of four major hydrocarbon classes. However, in the absence of detailed compositional information on the substances concerned by the category, including representative ranges of hydrocarbon classes content, ECHA considers that the respective hazards of these substances cannot be identified in a representative way which does not underestimate the hazard.

Consequently, ECHA considers that the category '*Bitumens*' does not fulfil the requirement defined in Annex XI, 1.5. and does not allow the Registrant to meet the objective pursued by the REACH Regulation. As a result and based on the information analysed by ECHA, these substances cannot be considered as a group, or category of substances under the REACH Regulation, irrespective of the status of these substances under other legal systems.

Nevertheless, the determination that these substances cannot be considered as a group in accordance with Annex XI, 1.5 does not affect the possibility for the Registrant to invoke a read-across approach in order to predict human health effects of these substances individually. Irrespective of the unsuitability of the grouping approach, it is therefore necessary for ECHA to consider the proposal from the Registrant to predict the reproductive toxicity potential of the substance subject to this decision from a test to be performed on an analogue substance.

e) ECHA's analysis of the read-across hypothesis in light of the requirements of Annex XI, 1.5

ECHA has analysed the read-across hypothesis as proposed by the Registrant and understands that the selection of the substance to be tested is entirely determined by the concentrations of polycyclic aromatic hydrocarbons with 4 or more rings, having high concentration of 16 US Environment Protection Agency (EPA) polycyclic aromatic hydrocarbons (PAHs). In addition, ECHA notes that the information provided by the Registrant indicates the existence of a correlation between toxicological effects (systemic toxicity, foetotoxicity and increased resorptions) and the concentrations of polycyclic aromatic hydrocarbons with 4 or more rings.

More specifically, the substance proposed to be tested has a relatively high concentration of polycyclic aromatic hydrocarbons (containing 4 or more aromatic rings; having high concentration 16 EPA PAHs), in line with the read-across hypothesis which could allow a representative determination of the reproductive and developmental toxicity potential of the substance subject to this decision without underestimating its actual hazard.

In addition, ECHA notes that the Registrant only submitted in the updated category justification document generic compositional data on the substance subject to this decision and on the substance proposed to be tested. Nevertheless, ECHA considers that this data provides indication that these substances are likely to have sufficient compositional relationship to justify that a one-to-one read-across approach may eventually be acceptable.

Based on the above, ECHA considers that the proposed read-across hypothesis based on the relationship between concentrations in polycyclic aromatic hydrocarbons with 4 or more rings and the investigated toxicological effects is plausible. However, ECHA considers that the proposed hypothesis and a read-across approach still contains deficiencies and uncertainties that have to be addressed by the Registrant in order to ensure compliance of the approach with the requirements set out in section 1.5 of Annex XI.

Firstly, ECHA notes from the generic compositional information submitted by the Registrant that the analogue substance may have a significant variation of composition. As a result, the Registrant shall pay specific attention to the principles for selection of the tested sample(s) as established under Section IV of the present decision. ECHA considers that submitting the information as described in Section IV of the present decision is a minimum condition for the ultimate compliance of the read-across approach with the requirements set out in section 1.5 of Annex XI.

Secondly, ECHA points out that all the assessment reports and some scientific publications and robust study summaries concerning studies invoked by the Registrant were not submitted in the updated dossier. ECHA also considers that submitting this information is a minimum condition for the ultimate compliance of the read-across approach with the requirements set out in section 1.5 of Annex XI.

Thirdly, with regard to robust study summaries submitted by the Registrant in support to its hypothesis, ECHA stresses that, although the test material is identified by CAS No. and/or chemical name, its composition is either not described at all or not sufficiently described. This information is of a particular importance to substantiate the claim of the Registrant that other constituents do not contribute to reproductive toxicity. ECHA stresses that the read-across justifications ultimately submitted by the Registrant shall guarantee that there is no significant uncertainty whether the observed toxicity may be caused by other constituents present in the test material and/or present in the substance subject to the present decision. With respect to robust study summaries already submitted, ECHA considers that submitting the information on the test material as described in Section IV of the present decision is a minimum condition for the ultimate compliance of the read-across approach with the requirements set out in section 1.5 of Annex XI.

In the case where the test performed in accordance with the present decision would not confirm the 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 approach be inadequate, it is the responsibility of the Registrant to ultimately submit reliable information or adaptations which are used in a way that does not underestimate hazards of the registered substance in relation to the relevant endpoint.

Moreover, the read-across adaptation based on the results of the proposed test 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, 8.7.2., 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.

Finally, ECHA also points out that future information may become available that could justify the selection of a more representative substance(s) than the one that is currently regarded to represent "the worst-case". ECHA stresses that, in such circumstance, it is the primary responsibility of the Registrant "*on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency*", in accordance with Article 22 of the REACH Regulation. In any case, ECHA may re-assess the read-across based adaptation to the information requirements, which could lead to request testing another substance(s) instead of the one that is currently regarded to represent "the worst-case". Information that could affect the validity of the selected test substance may come from data submitted in the context of other REACH registrations for comparable substances.

1. 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. 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 has therefore submitted a testing proposal for pre-natal developmental toxicity study (test method EU B.31/OECD 414) to fulfil the information requirements. The Registrant proposes that the test is to be performed on rat with tank fume condensate derived from the analogue substance residues (petroleum), thermal cracked vacuum (CAS No 92062-05-0), by the inhalation route.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species. ECHA considers this default parameter appropriate and testing should be performed with the rat or the rabbit as a first species to be used. The Registrant did not propose to test the complete substance. Instead, he proposed to test a condensate from the fumes that are produced by heating the substance. The condensates are then to be tested via inhalation, because human exposure to the compounds in these condensates occurs mostly through inhalation of emissions from hot bitumen. Moreover, the Registrant points out that it is technically not feasible to test the complete substance via the oral or the dermal route or via inhalation, due to it physicochemical properties. The Registrant states: *"Substances within the bitumen category are only soluble in a limited range of hydrocarbon solvents. Their physical form, high molecular weight (predominantly >C25) and insoluble nature means it is technically infeasible to test bitumen as such by the oral, dermal or inhalation routes. For use and application, bitumen is generally heated to temperatures in the range 140-180°C, at which small amounts of lower molecular weight constituents are released to atmosphere, forming a mix of hydrocarbon vapour and condensation aerosol droplets. Published industry guidance in Europe (www.Eurobitume.eu) specifies a maximum safe handling and storage temperature of 200°C for paving grade bitumen."*

The Registrant proposed conducting the studies by inhalation, *"since exposure to emissions from hot bitumen is the major route of occupational exposure. Emissions contain a large number of organic constituents. The boiling point (10-90%) range of condensed emissions from asphalt collected at work sites has been reported to be in the range 196 - 400°C, indicating potential for exposure to emissions of hydrocarbons with carbon numbers in the range of C10 to C25. The emissions are known to comprise approximately 70% of straight and branched chain aliphatics, monocycloparaffins, and alkylbenzenes, the remaining 30% comprising a mixture of polycyclic aromatic hydrocarbons (PAHs), with the majority being alkylated 2 and 3 ring compounds."*

In light of the information provided by the Registrant, ECHA considers that testing via the inhalation route of the condensate of vapours produced by the heating of the substance as described in the Registrant's proposal is appropriate. ECHA points out that the composition of the condensates tested should reflect the composition of the fumes that are produced under the conditions of practical use, in such a way that an underestimation of hazard is prevented.

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.

A third party acting on behalf of the Registrant provided clarification on the substance to be tested and noted that only a single test is intended to be undertaken for this category of substances. This third party also noted that this information would be corrected in updated registration dossiers. On 29 April 2013 ECHA received an updated registration dossier on the substance subject to the present decision including sufficiently detailed explanations on the choice of the test substance. ECHA considered the information provided and amended the draft decision accordingly.

In addition, the third party proposed an alternative testing strategy under which this endpoint is suggested to be covered by an extension of the two generation reproductive toxicity study to include additional groups of animals addressing the developmental toxicity endpoint. In response ECHA notes, that the third party has proposed a strategy for ECHA to consider before further tests on animals are requested. However, third parties were invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". As the proposal for a strategy as such cannot be regarded information or studies, ECHA concludes that this is not a sufficient basis to fulfil the data/information requirement.

Additionally, ECHA notes that an extension of the two generation reproductive toxicity study to include additional group of animals addressing the developmental toxicity may give further information on developmental toxicity but might not fulfil the requirement for a pre-natal developmental toxicity study (test method: B.31/OECD 414). For example different dose levels in the two-generation study and the pre-natal developmental toxicity study might be required, dosing before mating (as performed in the two-generation study) might have an impact on the findings in the pre-natal developmental toxicity study and additional group to address developmental toxicity would not save animals. Therefore, ECHA sees no benefit to combine these studies.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Pre-natal developmental toxicity study in rat or rabbit, inhalation route (test method: EU B.31/OECD 414) using the analogue substance residues (petroleum), thermal cracked vacuum (CAS No 92062-05-0). The sample of the substance to be tested shall be chosen and reported on in accordance with the specific requirements outlined in Section IV below.

d) 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, 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, 8.7.2. of the REACH Regulation.

2. Deadline for submitting the information

In the updated dossier the Registrant asked for an extension of the deadline for submitting the requested information. The Registrant's justification for this request was that firstly, 24 months would be needed in order to perform a pre-natal developmental toxicity study (OECD 414) and a reproductive toxicity study (OECD 416) and secondly, an additional 17 months period would be needed for sample selection and characterization; workplace exposure monitoring; and emission condensate collection and validation. ECHA evaluated the justification provided and decided to change the deadline from 30 months to 41 months.

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 41 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 draft decision, ECHA considers that a reasonable time period for performing the required test is 12 months. Therefore, ECHA changed the deadline from 41 months to 29 months. ECHA amended the decision 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 study meets 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 test, the sample of substance used for the new study 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 test 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 study is appropriate to assess the properties of the substance subject to the present decision and does not lead to an underestimation of the hazards, 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 study must be suitable to assess these grades.

Finally there must be adequate and detailed information on substance identity for the sample tested and the substance subject to the present decision to enable the assessment of the relevance of the study. In particular, given the intrinsic compositional variability of the test substance and of the substance subject to the present decision, information as specified below has to be provided:

a) Detailed information on the composition of the sample tested and of the substance subject to the present decision, using best available analytical techniques such as, for instance, two dimensional gas chromatography (GC-GC): this must include information on the identity and concentration of the constituents. In reporting, the chemical composition, both individual constituents of relevance for the study as well as "major hydrocarbon classes" should be presented. Regarding the characterisation of the PAH, a detailed analysis of the PAH chemical identities and concentrations in the test material and the substance subject to the present decision shall be provided to allow substantiation of the Registrant's hypothesis that the types of PAHs suggested to cause reproductive toxicity are indeed likely to cause reproductive toxicity as observed in the proposed test;

b) An explanation why the composition of the sample tested represents the composition of the substance subject to the present decision;

c) As the Registrant did not propose to test the complete manufactured substance, but a condensate from the fumes that are generated by heating the substance, he should demonstrate based on the detailed analytical composition on the test material and the intrinsic variability of the substance subject to the present decision that the sample selected for testing does not result in an underestimation of hazard the proposed UVCB testing approach and putative read-across theory of the Registrant.

Based on the analytical information currently provided by the Registrant, ECHA concludes that the sample selected for testing shall contain the highest concentration of 16 EPA PAHs. The highest concentration currently reported in the testing proposal justification document is [redacted] mg/kg. In addition, the sample selected for testing shall also contain the highest concentration of other aromatic hydrocarbons.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Leena Ylä-Mononen
Director of Evaluation