EUROPEAN CHEMICALS AGENCY

Helsinki, 19 December 2016

Addressee: [redacted]

Decision number: TPE-D-2114350585-46-01/F
Substance name: Residues (petroleum), hydrodesulfurized vacuum
EC number: 265-188-0
CAS number: 64742-85-4
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10.06.2016
Registered tonnage band: 1000+T

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rats or rabbits), inhalation route using the analogue substance tank fume condensate derived from Asphalt (EC No 232-490-9, CAS No 8052-42-4).

The present decision relates to the examination of the testing proposal for a pre-natal developmental toxicity study. You also submitted a testing proposal for the two-generation reproductive toxicity study. The testing proposal for the two-generation reproductive toxicity study will be addressed in a separate decision in conjunction of the other Bitumen registrations with the same testing proposal.

You 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 and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **3 January 2018**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Leena Ylä-Mononen, Director of Evaluation

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

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposal(s) submitted by you.

0. Grouping of substances and read-across approach

a. Legal Background on ECHA's assessment of the grouping of substances and read-across hypothesis

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, Section 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

You have submitted a category justification document to support the grouping approach to be applied for the listed bitumen substances. In parellel, you have also submitted a testing proposal document with read-across hypothesis for the reproductive toxicity and developmental toxicity testing applying one-to-one read-across approach. ECHAs analysis of the grouping approach and read-across approach will be discussed under d) and e), respectively.

According to you, 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*'.

You consider 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, you rather justifiy its grouping approach based on the refining processes by which these substances are produced and on two basic physico-chemical properties. More specifically, you define the boundaries of this category as follows:

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

According to you, 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);
3. Residues (petroleum), hydrodesulfurized vacuum; CAS No. 64742-85-4 (EC No. 265-188-0); and
4. Residues (petroleum), thermal cracked vacuum; CAS No. 92062-05-0 (EC No. 295-518-9)

According to you, 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, you assume that the "*category order is not relevant*".

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

You hypothesise 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, you proposed to test one substance as a "*realistic 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 to support the grouping approach and read-across hypothesis

You 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, you 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, you argue 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 you in the form of robust study summaries.

By contrast, you acknowledge 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, you consider 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, you have considered the compositional profiles of the substances (listed above) and proposes to use tank fume condensate derived from Asphalt (EC No 232-490-9, CAS 8052-42-4) as the substance to be tested.

d) ECHAs 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, Section 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: 1.3; February 2014), 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, Section 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 you in the category justification document. 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, Section 1.5., you do not define the category based on the structural similarity of the substances concerned, but you persist in relying exclusively on manufacturing processes and performance characteristics to justify the grouping approach.

Secondly, you do 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, Section 1.5. of 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, Section 1.5. does not affect the possibility for you 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 you 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, Section 1.5.

ECHA has analysed the read-across hypothesis as proposed by you and understands that the selection of the substance to be tested was originally 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). However, you have amended the testing strategy by changing the substance to be tested after contacting all relevant EU manufacturers in 2015 in order "*to obtain and analyse samples to select a representative worst case.*" According to you, based on this analytical survey "*the Bitumen CAS 8052-42-4 is the material to which the vast majority of Bitumen workers in the EU are potentially exposed to*" and should therefore be tested as "*a realistic worst case*". In addition, ECHA notes that the information provided by you 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, according to you the sample proposed to be tested has the highest measured concentration of PAHs among the Bitumen substances causing exposure to workers (containing 4 or more aromatic rings; having high concentration 16 EPA PAHs), and is therefore 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 undermining its actual hazard.

In addition, ECHA notes that you submitted in the category justification document generic compositional data on the substance subject to this decision and on the substance proposed to be tested. 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 for reproductive toxicity and developmental toxicity testing.

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, while ECHA considers that the data you submitted or referred to sufficiently justifies the plausibility of the hypothesis, it considers that the read-across approach still contains deficiencies and uncertainties that have to be addressed by you 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 you that the analogue substance may have a significant variation of composition. As a result, you shall pay specific attention to the principles for selection of the tested sample(s) as established under Appendix 3 of the present decision. ECHA considers that submitting the information as described in Appendix 3 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 the assessment reports, scientific publications and robust study summaries concerning studies invoked by you as part of the testing proposal hypothesis were not submitted in the dossier. ECHA considers that conducting an independent assessment of the proposed read-across approach is not possible in absence of this information. 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.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you argue that "*the references that are referred to by ECHA are used in the testing proposal to support the testing hypothesis and are not intended to support the read-across argument as indicated by ECHA. The references are either peer reviewed papers, which are available in the open literature, or they refer to study reports which are part of dossiers submitted under other categories. For clarification, the latter references will cross-reference to the relevant substance dossiers containing these specific RSSs.*" ECHA notes that the testing proposal hypothesis document attached to the dossier contains read-across justification arguments that suggest selection of Asphalt (EC No 232-490-9, CAS No 8052-42-4) for developmental toxicity testing. ECHA considers that supporting information related to read-across source substance selection is relevant for the read-across assessment and 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 as explained above.

Thirdly, with regard to robust study summaries submitted by you in support to your 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 your claim that other constituents do not contribute to reproductive toxicity. ECHA stresses that the read-across justifications ultimately submitted by you 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 Appendix 3 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 you, this outcome shall not alter your obligation to meet the standard information requirements. Should the read-across approach be inadequate, it is your responsibility 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, as proposed by you. 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.

ECHA also points out that future information may become available that could justify the selection of a more representative substance 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 your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you further explained that the testing hypothesis is subsequently applied to select "*a realistic worst case*" test sample via the decision tree as described in the testing proposal. In any case, ECHA may re-assess the read-across based adaptation to the information requirements, which could lead to request testing another substance instead of the one that is currently regarded to represent "a realistic 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.

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

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.

You have submitted a testing proposal for a pre-natal developmental toxicity study in rats according to EU B.31/OECD TG 414 by the inhalation route with the analogue substance tank fume condensate derived from Asphalt (EC No 232-490-9, CAS 8052-42-4).

ECHA has evaluated your proposal to perform the test with the analogue substance tank fume condensate derived from Asphalt (EC No 232-490-9, CAS 8052-42-4) (see section 0). In light of the provided information, ECHA considers that testing via the inhalation route of the condensate of vapours produced by the heating of the substance as described in your 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.

ECHA considers that the proposed study performed with the analogue substance tank fume condensate derived from Asphalt (EC No 232-490-9, CAS 8052-42-4) is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

EUROPEAN CHEMICALS AGENCY

You proposed testing with rats. According to the test method EU B.31/OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent. On the basis of this default consideration, ECHA considers testing should be performed with rat or rabbit as a first species.

ECHA considers that the oral route is usually the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. ECHA notes that the substance is not a gas. However, you 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 provided information, ECHA considers that testing via the inhalation route of the condensate of vapours produced by the heating of the substance as described in your 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. Thus ECHA considers that the study should be performed by the inhalation route.

In your comment(s) on the draft decision according to Article 50(1) of the REACH Regulation you noted that the requested study is already ongoing based on the ECHA decisions communicated in TPE-D-0000004024-86-04/F, TPE-D-0000004028-78-04/F and TPE-D-0000004027-80-04/F. Furthermore, you communicated your intention to update the dossier(s) with the requested information and the relevant data to support the read-across arguments. ECHA acknowledges the comments to the draft decision and your intention to update the registration dossier(s) accordingly.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the analogue substance tank fume condensate derived from Asphalt (EC No 232-490-9, CAS 8052-42-4): Pre-natal developmental toxicity study in a first species (rat or rabbit), inhalation route (test method: EU B.31/OECD TG 414). The sample of the substance to be tested shall be chosen and reported on in accordance with the specific requirements outlined In Appendix 3 below.

Notes for your consideration

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, you 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 you consider that the conditions for adaptations are not fulfilled, you should include in the update of your dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If you come to the conclusion that the conditions for these adaptations can be fulfilled, you should update your 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.

For the selection of the appropriate species you are advised to consult ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015), Chapter R.7a, section R.7.6.2.3.2.

Appendix 2: Procedural history

ECHA received your registration containing a testing proposal for a pre-natal developmental toxicity study for examination pursuant to Article 40(1) on 7 May 2013. On 19 February 2016 you updated your registration and changed the testing proposal, in particular by changing the analogue substance to be tested. Furthermore, on 10 June 2016 you updated your dossier with a status report of the ongoing developmental toxicity testing of the related bitumen registrations.

ECHA held a third party consultation concerning the registered substance and the hazard endpoint concerned from 4 April 2014 until 19 May 2014. ECHA did not receive information from third parties.

This decision does not take into account any updates after **21 September 2016**, 30 calendar days after the end of the commenting period.

ECHA notified you of the draft decision on 15 July 2016 and invited you to provide comments

On 19 August 2016, ECHA received your comments agreeing to the draft decision and editorial clarification regarding the supporting documentation for read-across justifications and arguments.

The ECHA Secretariat considered your comments. Editorial clarification was included in the Appendix 1 (Reasons) whereas the information required was not amended.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your 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.

2. 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.

3. In carrying out the test(s) required by the present decision it is important to ensure that the particular sample of substance tested 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 or imported. If the registration of the substance covers different grades, the sample used for the new test(s) must be suitable to assess these. Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.

   More specifically, ECHA notes that 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 your 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 you did not propose to test the complete manufactured substance, but a condensate from the fumes that are generated by heating the substance, you 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 the hazard.

Based on the analytical information currently provided by you, 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 48 mg/kg. In addition, the sample selected for testing shall also contain the highest concentration of other aromatic hydrocarbons.

4. Since the required test(s) will be conducted with an analogue substance in the context of a read-across approach, the identity of the test material used to perform the test should be specified in line with the ECHA's Practical Guide 6 "How to report on read-across". This is required to demonstrate that the test material is representative of the analogue substance identified in the read-across approach and used to predict the properties of the registered substance.