EUROPEAN CHEMICALS AGENCY

Helsinki, 14 October 2016

Addressee: [redacted]

Decision number: CCH-D-2114342397-45-01/F
Substance name: Alcohols, C9-11-branched
EC number: 271-360-6
CAS number: 68551-08-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 12.07.2013
Registered tonnage band: 1000+T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Name or other identifier of the substance (Annex VI, Section 2.1)**
   - **Manufacturing process;**
2. **Spectral data (Annex VI, Section 2.3.5)**
   - **Ultra-violet spectrum;**
   - **Infra-red spectrum;**
3. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1; test method: Bacterial reverse mutation test, EU B.13/14 /OECD TG 471) with the registered substance;**
4. **In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2, test method: OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487) with the registered substance;**
5. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3; test method: OECD TG 476 or OECD TG 490) with the registered substance; provided that both studies on 3 and 4 above (Annex VII, Section 8.4.1 and Annex VIII, Section 8.4.2) are negative;**
6. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2; test method: EU B.26/OECD TG 408) in rats with the registered substance;**
7. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2; test method: EU B.31/OECD TG 414) in a first species, in rats/rabbits, oral route with the registered substance;**
8. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2; test method: EU B.31/OECD TG 414) in a second species, in rats/rabbits, oral route with the registered substance;**
9. **Extended one-generation reproductive toxicity study (Annex X, Section**

8.7.3; test method: OECD TG 443) in rats, oral route with the registered substance specified as follows:

- **Ten weeks premating exposure duration for the parental (P0) generation;**
- **Dose level setting shall aim to induce some toxicity at the highest dose level;**
- **Cohort 1A (Reproductive toxicity);**
- **Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;**

10. **Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: Adsorption/desorption using an appropriate test method) with the registered substance;**

11. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305) with the registered substance;**

You are required to submit the requested information in an updated registration dossier by **21 December 2020** except for the information requested under point 6 for a sub-chronic toxicity study (90-day) which shall be submitted in an updated registration dossier by **21 June 2018**. You may only commence the extended one-generation reproductive toxicity study as requested under point 9 after **21 September 2018**, unless an indication to the contrary is communicated to you by ECHA before that date. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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.

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 Ofelia Bercaru, Head of Unit, Evaluation E3

[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.

EUROPEAN CHEMICALS AGENCY

Appendix 1: Reasons

IDENTIFICATION OF THE SUBSTANCE

In order to ensure that potential hazardous properties of substance are not underestimated, the substance identification deficiencies must be resolved before identifying the test sample to be used for the testing requested in the present decision.

1. Name or other identifier of the substance (Annex VI, Section 2.1)

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1 of the REACH Regulation.

In the registration dossier you have specified that the registered substance as a multi-constituent substance. According to the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" hereinafter, a multi-constituent substance is defined by its quantitative composition, in which more than one main constituent is present at a concentration ≥ 10 % (w/w) and < 80 % (w/w). However, ECHA considers the registered substance as of unknown or variable composition, complex reaction products or biological materials (UVCB) and not well-defined substance. This conclusion is based on the information included in the IUCLID technical dossier such as the EC and CAS identifiers, the compositional information and the analytical data.

The analytical data included in section 1.4 of the IUCLID dossier demonstrate that the registered substance consists of numerous isomers that cannot individually be identified. This is also confirmed by the statement "[redacted]" included in the remarks field for each constituent listed in section 1.2 of the IUCLID dossier. The reported groups of constituents ([redacted]), refer to groups of constituents with defined alkyl chain lengths but not with defined branching. Since identification of the individual constituents ([redacted]) is not possible and the number of constituents is relatively large, the registered substance cannot be considered a well-defined multi-constituent substance.

The naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance. ECHA observes that you did not provide sufficient information on the manufacturing process to allow for its proper identification, as required under Annex VI Section 2.1 of the REACH Regulation.

The information on the manufacturing process in section 3.1 of the IUCLID dossier states: "[redacted]" This information is not sufficiently detailed because the distillation temperature and pressure are missing from this description. These parameters are important for identification of the registered substance.

In your comment on the draft decision, you agreed to provide additional substance identification information on the high purity of the registered substance as primary alcohol of defined carbon number range, with multiple branched, structurally similar isomers. In addition, you indicated your intention to address the information requirement in an update of the registration. Any such update submitted will be examined by ECHA only after the deadline established in the present decision has passed. Independent of this draft decision and under Article 22 of the REACH Regulation, you can submit updates to the registration dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to:

- Specify UVCB as substance type in section 1.1;
- Include in your description of the manufacturing process the distillation temperature and pressure.

You shall ensure that the information is consistent throughout the dossier.

Further information to describe the manufacturing process shall be included in IUCLID section 3.1.

Additional information on how to report the chemical name and the description of the manufacturing process is available in "Data submission manual Part 18 – How to report the substance identity in IUCLID 5 for registration under REACH" (version: 2.0, July 2012), available on the ECHA website.

2. Spectral data (ultra-violet and infra-red) (Annex VI, Section 2.3.5)

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5 of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this infromation requirement.

ECHA notes that the registration dossier does not contain all the spectral data as specified by section 2.3.5 of the REACH Regulation. In this respect, an ultra-violet (UV) spectrum and infra-red (IR) spectrum are not included in your IUCLID dossier. Moreover, a scientifically based justification for not including this information has also not been included in your IUCLID dossier.

In the absence of a a scientifically based justification, the spectral data requirement specified by section 2.3.5 of the REACH Regulation is not fulfilled.

In your comment on the draft decision, you agreed to provide additional information on spectral data (ultra-violet and infra-red) including the analytical methods on these measurements in the section 1.4 of IUCLID dossier in a dossier update. Any such update submitted will be examined by ECHA only after the deadline established in the present decision has passed. Independent of this draft decision and under Article 22 of the REACH Regulation, you can submit updates to the registration dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit an UV spectrum and an IR spectrum for your substance. You shall ensure that the information is consistent throughout the dossier.

Regarding where to include the spectral data in your IUCLID dossier, it shall be attached in IUCLID section 1.4. You shall ensure that the description of the analytical methods used for recording the spectra is specified in the dossier in such detail to allow the methods to be reproduced, in line with the requirements under Annex VI Section 2.3.7 of the REACH Regulation.

B. INFORMATION RELATING TO INTRINSIC PROPERTIES

Grouping of substances and read-across approach

In the registration dossier, you have proposed to cover the standard information requirements for the registered substance Alcohols, C9-11-branched for the following endpoints:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1);
- In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2);
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3);
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2);
- Pre-natal developmental toxicity study, first species (Annex IX, Section 8.7.2);
- Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3);
- Bioaccumulation test on Fish (Annex IX, 9.3.2);

by adapting the information requirements according to Annex XI, Section 1.5. i.e. using an approach of grouping of substances and read-across by providing study results with the analogue substances: Alcohols, C9-11 branched and linear, C10-rich also called isodecanol (CAS 93821-11-5), Isoheptan-1-ol (CAS 51774-11-9), Alcohols, C7-9-iso, C8-rich (CAS 68526-83-0), Alcohols, C9-11-iso, C10 rich (CAS 68526-85-2), Alcohols, C11-14-iso, C13-rich, (CAS 68526-86-3), and CAS number 91994-92-2 or Isononanol without further references (referred thereafter to as source substances).

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and 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. The following analysis presents your justification for the proposed grouping approach and read-across hypothesis, together with ECHA's analysis concerning the justification in both a generic and an enpoint specific context.

Description of the grouping and read-across approach proposed by the Registrant

ECHA observes, that you have not described in your dossier a hypothesis of the proposed read-across approach for any of the above listed endpoints.

On ground of the presented information in the technical dossier, ECHA understands that the grouping approach is based on the similarity in the chemical structure of the above mentioned substances i.e. all substances contain a hydroxyl moiety, as a functional group i.e. are alcohols.

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

You have provided study records conducted with different source substances on the endpoints as listed above to support the grouping and read-across approach. However, you have provided no read-across justification in your technical dossier or in your chemical safety report (CSR) for any of the endpoints.

ECHA notes that the provided information solely identifies the source substances on which studies are available and are proposed to be used to predict toxicological properties of the registered substance subject to the present decision (the target substance).

ECHA analysis of the grouping and read-across approach in light of the requirements of Annex XI, 1.5.

ECHA understands that the grouping approach is based on the similarity in the chemical structure of the above mentioned substances i.e. all substances contain a hydroxyl moiety as a functional group.

Substance characterisation of the source substances

ECHA notes that you have proposed to use a number of different analogue substances as source substances for your read-across approach. The description of the analogue substances in the dossier is limited to providing the chemical name and EC/CAS numbers (numerical identifiers) of the substances. In some instances, even this information is incomplete. For example, in the [redacted]) for the pre-natal developmental toxicity studies, the analogue substance is identified only by the CAS number 91994-92-2, and no chemical name has been provided, instead the dossier gives the name of the test material as "MRD-94-825" and the name of the substance as Exxal 8N. In the study of Hellwig and Jackh (1997) or last provided pre-natal developmental toxicity study, the name of the test material is described as "isononanol type 1 and type 2, and isodecanol" without providing any additional information.

ECHA concludes that given the lack of information on the identity, the composition and impurities of the proposed source substances, the suitability of the source substances for read-across purposes cannot be verified and there is not an adequate basis for predicting the properties of the registered substance from the data of the source substances.

Structural similarity and dissimilarity

You have provided the statement that the studies proposed to be read across are generated on *"supporting substance (structural analogue or surrogate)"*.

ECHA notes that structural similarity/analogy alone is not sufficient for predicting toxicological properties.

Furthermore, you have not provided the structure of any of the source substances and/or not explained the structural similarities and dissimilarities of the substances (e.g. chain length, branching, saturation of the chain, position and number of the hydroxyl functional group, existence of other functional groups etc.).
Based on the limited information provided in the registration dossier, ECHA observes that:

a) The names of the analogue substances indicate that they have different chain lengths compared to the registered substance;
b) The names of the analogue substances indicate that they may have different branching compared to the registered substance.

Other differences, such as presence of different functional groups, may become apparent if the information on the identity, composition and impurities on the analogue substances were available.

ECHA notes that all the analogue substances, as well as the registered substance, are unknown or variable composition, complex reaction products or biological materials (UVCB) substances. Such substances, by their nature, may have significant variation in the composition, including the identity and concentration of individual constituents as well as impurities.

ECHA concludes that you have not addressed the structural similarities and dissimilarities between the source substances and the target substance and did not explain why the probable differences would not indicate differences in the toxicity profile of target and sources.

Given the lack of information on the structural similarities and dissimilarities between target and sources, ECHA considers that there is not an adequate basis for predicting the properties of the registered substance from the data of the source substances.

Once you may have addressed the structural differences between the source substances and the target substance you will need to explain why those differences would not lead to differences in the toxicity profile of target and source substances in case you still consider a read across approach valid in order to establish a scientific credible link between the structural similarity and the prediction.

Reliability and adequacy of the source studies - proposal

ECHA observes that in the technical dossier of the target substance you have not submitted robust study summaries of any of the available experimental data on the source substances. ECHA notes that currently the source studies which investigate the properties to be read-across to the registered substance cannot be assessed and therefore it cannot be verified in this dossier whether the study design (i.e. coverage of the key parameters and exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3)) is adequate and reliable for the purpose of the prediction, whether the test material used represents the source substance-and whether the results are adequate for the purpose of classification and labelling and/or risk assessment.

In the absence of this information an independent assessment on whether the source studies meet the REACH requirements in terms of reliability and adequacy as requested for any key study is not possible.
On this basis alone (lack of robust study summaries of the experimental data on the source substances) the dossier is non-compliant for all endpoints to which you apply a read-across

approach and there is not an adequate basis for predicting the properties of Alcohols, C9-11-branched from the data of the source substances.

Conclusion on the read-across approach

Due to the general deficiencies listed above, and additionally the endpoint specific deficiencies addressed for the respective endpoints below there is not an adequate basis for predicting the properties of Alcohols, C9-11-branched from the source substances. The adaptation of the standard information requirements for the endpoints:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1)
- In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2)
- Pre-natal developmental toxicity study, first species (Annex IX, Section 8.7.2)
- Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3)
- Bioaccumulation test on Fish (Annex IX, 9.3.2)

in the technical dossier is based on the proposed read-across approach examined above. ECHA does not consider the read-across justification to be a reliable basis to predict the properties of the registered substance for the reasons set out above. Thus, the adaptation does not comply with the general rules of adaptation as set out in Annex XI, 1.5. Therefore, ECHA rejects all adaptations in the technical dossier that are based on Annex XI, 1.5.

In your comment to the draft decision you agreed that the current information on the read across justification and hypothesis for grouping needs to be improved and that you will apply the read-across assessment framework (RAAF) scheme of ECHA, asking for the decision to allow for a response

- on the substance identification requests ,
- on the read-across justification and the appropriateness of the use of source substances for read across following an update containing the approach for the substance to be read-across on other members data of a family called Exxal alcohol family.

You further specified that the substance is used primarily as an intermediate to make derivatives and that this should be considered in the context of an integrated testing strategy (ITS) and to avoid unnecessary animal testing as these substances are also subjected to REACH testing requirements, and that the data on the derivatives should be considered.
Regarding the tonnage of the substance manufactured and used under strictly controlled conditions (SCC), ECHA welcomes this clarification. Nevertheless, based on information provided by you in an informal interaction with ECHA as well as your comments to the draft decision, you indicated that the total tonnage of the substance that is not used under SCC, or that you are unsure of whether it is used under SCC as it is supplied to other actors, is greater 1000 tonnes per annum, and therefore the information requirements of Annex X need to be fulfilled. Furthermore you indicated that the dossier will be updated with new information identifying clearly the respective tonnage as TII and as a substance on its own.

Any such update submitted will be examined by ECHA only after the deadline established in the present decision has passed. Independent of this draft decision and under Article 22 of the REACH Regulation, you can submit updates to the registration dossier.
Therefore, the draft decision was not amended.

Furthermore, in your comment for all the toxicological and mutagenicity endpoint requests based on the rejection of the read-across approach, you proposed the following strategy to fulfill the requests in the draft decision:

1. Submission of full documentation of the read across approach based on the RAAF of the of the Exxal family.
2. Phased approach to testing to ensure optimum design of studies and to ensure animal welfare concerns are addressed.
3. Use of toxicokinetics to provide information on the biological basis for read across and support the setting of appropriate dose levels.
4. Conduction of appropriate repeat dose sub-chronic toxicological studies.
5. Decisions on any further testing based on the results of the toxicokinetic and sub-chronic toxicology testing
6. Proposed testing to be conducted on selected members of Exxal family covering the range of alcohols in this case: Exxal 8 and Exxal 13.

The read across justification and specific testing proposals will be submitted in the near future to ECHA and dossiers will be updated endpoint by endpoint for Exxal 11.

ECHA notes that at that time of the referral of this decision to the competent authorities of the Member States (MSCAs) there were no testing proposals for the substances indicated by you. Therefore, it is not possible for ECHA and the MSCAs to determine if such a testing proposal on analogue substances would be adequate to address the concern for the registered substance subject to the present decision. ECHA notes further that the stepwise approach proposed by you, while logical, provides no certainty that the requests in the current decision can be fulfilled. It is possible that the outcome of such a stepwise approach may be a conclusion that the Registered substance needs to be tested. ECHA is unable to therefore modify the current request based on a hypothetical scenario.

Accordingly, there is a data gap for all endpoints mentioned above and therefore it is necessary to perform testing on the registered substance.

REQUEST FOR IN VITRO GENETIC TOXICITY

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

For each of the following three endpoints information requirements, you have sought to adapt the request as per Annex XI 1.5 by providing study records for analogue substances which are listed below. However, as explained above in the section *'Grouping of substances and read-across approach'* of this decision, your adaptations of the information requirement cannot be accepted for any of these endpoints.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision as explained in sections 3., 4. and 5. underneath.

3. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5 of the REACH Regulation by providing a study record for an *in vitro* mutation study on bacteria, (OECD TG 471) with the analogue substance alcohols, C9-11 branched and linear, C10-rich (EC no 298-696-6), CAS number 93821-11-5.
As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the bacterial reverse mutation test (test method EU B.13/14. / OECD TG 471) is appropriate to address the standard information requirement of Annex VII, Section 8.4.1. of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14. /OECD TG 471).

4. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2)

An "*In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5 of the REACH Regulation by providing the following study records:

1) I*n vitro* mammalian chromosome aberration test (OECD TG 473) with the analogue substance isodecanol (EC no 298-696-6, CAS number 93821-11-5).
2) I*n vitro* mammalian chromosome aberration test (OECD TG 473) with the analogue substance isoheptanol (EC no 257-413-6, CAS number 51774-11-9).

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the *in vitro* mammalian chromosome aberration test (test method OECD TG 473) and the *in vitro* micronucleus test (OECD TG 487) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.2 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* cytogenicity study in mammalian cells (test method: OECD TG 473) or *in vitro* mammalian cell micronucleus study (test method: OECD TG 487).

5. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3)

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3 of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1 and Annex VIII, Section 8.4.2" is obtained. Therefore, adequate information *on in vitro* gene mutation in mammalian cells needs to be present in the technical dossier for the registered substance to meet this information requirement provided that both studies requested under points 3 and 4 show negative results.

You have sought to adapt this information requirement according to Annex XI, Section 1.5 of the REACH Regulation by providing a study record for an *in vitro* mammalian cell gene mutation test (OECD TG 476) with the analogue substance isodecanol (EC no 298-696-6, CAS number 93821-11-5).

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the *in vitro* mammalian cell gene mutation tests using the *hprt* and xprt genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation test using the Thymidine Kinase Gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490) provided that both studies requested under 3. and 4. show negative results.

6. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation

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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a sub-chronic toxicity study (90 day) in the dossier that would meet the information requirement of Annex IX, Section 8.6.2.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for a the following studies:

a) A subacute repeated dose toxicity study (14 days), via the oral route, done according to (OECD TG 407) with the analogue substances iso-octanol, iso-nonanol, iso-decanol, and tridecanol. No further information has been provided on the identity of the test material (e.g. composition, EC or CAS number). The study was not performed according to GLP (Rhodes et al, 1984).
b) A subacute repeated dose toxicity study, with no indication of the guideline followed, via the dermal route, with the analogue substance alcohols, C7-9-iso, C8-rich, (EC number 271-231-4, CAS number 68526-83-0). This study was not performed according to GLP ([redacted]).

However, as explained above the section *'Grouping of substances and read-across approach'* of this decision, your adaptation of the information requirement cannot be accepted. In addition to those general observations, ECHA has the following specific observations regarding the proposed read-across.

With regard to the requirements of Annex XI, 1.5 and 1.2 of the REACH Regulation as indicated in the section *'Grouping of substances and read-across approach'* ECHA has the following observations regarding the reliability and adequacy of these two source studies that appear to be presented in a dual way covering both a weight of evidence approach and the read-across adaptations criteria:

- Rhodes et al study (1984) was reported to be performed according to OECD guideline 407. However, the duration of this study was 14 days, whereas a sub-chronic toxicity has a duration of 90 days. Therefore, the study cannot be considered to have exposure duration comparable or longer to that of a sub-chronic toxicity study. In addition, this study was carried out using a single dose, whereas a sub-chronic toxicity study is done using at least three dose levels and a concurrent control group, except where a limit test is conducted. ECHA notes that the doses used for the different substances ranged from 130 mg/kg to 186 mg/kg/day, whereas a limit dose according to OECD TG 408 should be at least 1000 mg/kg/bw/day. Furthermore, this study does not provide adequate coverage of the key parameters, addressed in a sub-chronic toxicity study, as it does not include adequate pathology, histopathology, or clinical chemistry parameters normally examined in a sub-chronic toxicity study. Finally, only five male rats were used in this study, whereas a sub-chronic toxicity study requires the use of at least 20 animals (10 per sex) at each dose level.

- For [redacted] the dossier does not state what guideline was followed. Similarly to Rhodes et al study, this study does not provide adequate coverage of the key parameters, including pathology, histopathology, and clinical chemistry, it has a shorter duration than a sub-chronic toxicity study, and only a limited number of animals (2 males and 2 females per dose) was used compared to the sub-chronic toxicity study.

The results of the studies do not allow to conclude on the endpoint of Annex IX, 8.6.2 because of the deficiencies of the indiviudal sources on basis of which ECHA cannot come to an assumption/conclusion that the substance subject to the present decision has no toxic properties in repeated exposure (Annex XI, 1.2). In addition to the shortcomings pointed out in the section *'Grouping of substances and read-across approach'* these source studies do not provide the information required by Annex IX, Section 8.6.2 in a read across approach.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, July 2015) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely, there is no concern for severe local effects following inhalation exposure. Furthermore, ECHA points out that no repeated dose toxicity study by the oral route is available. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

According to the test method EU B.26./OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day), oral route (test method: EU B.26./OECD TG 408) in rats.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5 of the REACH Regulation by providing study records for the following studies:

a) A pre-natal developmental toxicity study, done according to OECD TG 414, performed in rats, with the analogue substance with the CAS number 91994-92-2. No further information has been provided on the identity of the test material (e.g. name of the substance, composition) ([redacted]).
b) A pre-natal developmental toxicity study, done according to OECD TG 414, performed in rats, with the analogue substance alcohols, C7-9-iso-, C8 rich, EC number 271-231-4, CAS number 68526-83-0. No further information has been provided on the identity of the test material (e.g. composition) ([redacted]).
c) A pre-natal developmental toxicity study, done according to OECD TG 414, performed in rats, with the analogue substances isononanol type 1 (medium degree of branching), isononanol type 2 (low degree of branching), and isodecanol. No further information has been provided on the identity of the test material (e.g. EC or CAS number, composition) (Hellwig and Jackh, 1997).

However, as explained above in the section *'Grouping of substances and read-across approach'* of this decision, your adaptation of the information requirement cannot be accepted. In addition to those general observations, ECHA has the following specific observations regarding the proposed read-across.

ECHA has the following observations regarding the reliability and adequacy of these source studies:

- [redacted]) was done according to OECD TG 414. However, only 7 animals per sex per dose were used. OECD TG 414 requires that "Each test and control group should contain a sufficient number of females to result in approximately 20 female animals with implantation sites at necropsy. Groups with fewer than 16 animals with implantation sites may be inappropriate."

- Hellwig and Jackh study (1997) was done according to OECD TG 414. However, only 10 animals per sex per dose were used. OECD TG 414 requires that "Each test and control group should contain a sufficient number of females to result in approximately 20 female animals with implantation sites at necropsy. Groups with fewer than 16 animals with implantation sites may be inappropriate."

ECHA concludes that in addition to the issues pointed out in the section *'Grouping of substances and read-across approach'* source studies [redacted]) and Hellwig and Jackh (1997), do not provide the information required by Annex IX, Section 8.7.2, because they does not meet the requirements of Annex XI, 1.5.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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 species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is 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 4.0, July 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a first species (rats or rabbits) by the oral route.

8. Pre-natal developmental toxicity study (Annex X, Section 8.7.2) in a second species

Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2, column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier does not contain information on a pre-natal developmental toxicity study with the registered substance.

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route using the analogue substances as described in Appendix 1, Section 7 above. However, there is no information provided for a pre-natal developmental toxicity study in a second species.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex X, Section 8.7.2 or with the general rules of Annex XI for this standard information requirement.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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 species. On the basis of this default consideration, ECHA considers testing should be performed with rabbits or rats as a second species, depending on the species tested in the first pre-natal developmental toxicity study. ECHA considers that the oral route is 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 4.0, July 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species (rabbits or rats) by the oral route.

Notes for your consideration

You are reminded that before performing a pre-natal developmental toxicity study in a second species you must consider the specific adaptation possibilities of Annex X, Section 8.7.2, column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

9. Extended one-generation reproductive toxicity study (Annex X 8.7.3)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

The basic test design of an extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

a) The information requirement

You have not provided any study record of an extended one-generation reproductive toxicity study in the dossier that would meet the information requirement of Annex X, Section 8.7.3.

You have sought to adapt this information requirement according to Annex XI, Section 1.2. You provided the following justification for the adaptation:

"In accordance with section 1 of REACH Annex XI, testing is not scientifically necessary based on sufficient weight of evidence. There are no studies that have examined the toxic effects of isoundecanol or structurally similar compounds on endpoints associated with reproduction. However, it is expected that isoundecanol will not be a reproductive toxin. First, the information on toxicokinetics demonstrates that isodecanol and similar substances are highly and efficiently metabolized and do not present a bioaccumulation risk. Second, isoundecanol has an inherently low acute toxicity potential. Finally, a repeated dose toxicity study published by Rhodes et al determined there was no effect on testicular weight in male rats exposed to 144 mg/kg/day of isononanol for 14 days."

However, ECHA notes that your adaptation does not meet the general rules for adaptation of Annex XI, Section 1.2, because it is not possible to assume/conclude based on the information if the registered substance has not a hazardous property on sexual function and fertility (weight of evidence from several independent sources of information) for the following reasons:

- ECHA notes first, that the absence of any relevant studies on the registered substance or structurally similar compounds is not evidence of the lack of effects on reproduction.
- While the potential of a substance to bioaccumulate may have an impact on the design of an extended one-generation reproductive toxicity study, the absence of potential for bioaccumulation is in itself not evidence that the substance does not

have hazardous properties with regard to this endpoint. No information has been provided on the hazardous properties of either the parent substance prior to its metabolism, or its possible metabolites.

- The 14 day study referred to in your dossier has been performed on an analogue substance. ECHA has highlighted a number of issues regarding the proposed read-across, as can be seen in the section *'Grouping of substances and read-across approach'*. For these reasons, the proposal to use read-across does not meet the requirements of Annex XI 1.5, and this evidence cannot be used as a part of a weight of evidence approach.
- The 14 day study referred to does not address a number of critical parameters relevant for this endpoint. Especially information on the following relevant aspects in relation to sexual function and fertility have not been covered: the statistical power of 14 day study referred to above is low and the study generates no information on male and female reproductive performance such as gonadal function, mating behaviour, conception, development of the conceptus and parturition. Furthermore, this study does not provide information on hazardous properties to the postnatal development including sexual maturation and histopathological integrity of the reproductive organs at adulthood.
- Acute toxicity studies by their nature do not provide any information on the effects of a substance on reproductive toxicity following repeated administration. Therefore, the low acute toxicity potential of a substance does not provide evidence of the absence of a hazardous property on this endpoint.

Therefore, your adaptation of the information requirement cannot be accepted.

In addition to the adaptation based on weight of evidence above, you have sought to adapt this information requirement according to Annex XI, Section 1.5 of the REACH Regulation by providing a study record for a combined repeated dose and reproductive/developmental toxicity screening study (no guideline cited) with the analogue substance 1-dodecanol (CAS number 112-53-8).

However, as explained above in the section *'Grouping of substances and read-across approach'* of this decision, your adaptation of the information requirement cannot be accepted. In addition to those general observations, ECHA has the following specific observations regarding the proposed read-across.

In any case, the study design of a combined repeated dose/reproductive and developmental toxicity screening study (for example according to OECD TG 422) does not provide the information required by Annex X, Section 8.7.3. More specifically, such a study does not cover key parameters, exposure duration, life stages and statistical power of an extended one-generation reproductive toxicity study. The main missing key aspects/elements are: 10 weeks pre-mating exposure duration, at least 20 pregnant females pre group, and an extensive postnatal evaluation of the F1 generation.

Hence, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint. Thus, an extended one-generation reproductive toxicity study according Annex X, Section 8.7.3 is required. The following refers to the specifications of this required study.

b) *The specifications for the study design*

Premating exposure duration and dose-level setting

To ensure that the study design adequately addresses the fertility endpoint, the duration of the premating exposure period and the selection of the highest dose level are key aspects to be considered. According to ECHA Guidance, the starting point for deciding on the length of premating exposure period should be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required if there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6 (version 4.0, July 2015). In this specific case ten weeks exposure duration is supported by the lipophilicity of the substance to ensure that the steady state in parental animals has been reached before mating.

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

It is recommended that results from a range-finding study (or range finding studies) for the extended one-generation reproductive toxicity study are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

Species and route selection

According to the test method EU B.56/ OECD TG 443, the rat is the preferred species. On the basis of this default assumption, ECHA considers that testing should be performed in rats.

ECHA considers that the oral route is 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 4.0, July 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

c) Outcome

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);

- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;

Currently, no triggers for the extension of Cohort 1B and the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) have been identified based on the available information. However, the sub-chronic toxicity study (90-day) requested in this decision (request 6) and/ or any other relevant formation, including information which has become available since the point in time when the sub-chronic toxicity study (90-day) was requested, may provide information that could trigger such changes in the study design.

Therefore, the sub-chronic toxicity study (90-day) is to be conducted first and the study results submitted to ECHA in a dossier update by **21 June 2018**. In such update you may also include your considerations whether in light of these results and/ or other available information if changes in the study design are needed. If, on the basis of this update, a need for changes to the study design is identified, ECHA will inform you by **21 September 2018** (i.e. within three months after expiry of the 20-month deadline to provide the sub-chronic toxicity study (90-day)) of its intention to initiate a new decision making procedure under Articles 41, 50 and 51 of the REACH Regulation to address the design of the extended one-generation reproductive toxicity study. If you do not receive a communication from ECHA by **21 September 2018**, the request of the present decision for the extended one-generation reproductive toxicity study remains effective and you may commence the conduct of the study which results will need to be submitted **21 December 2020**.

Notes for your consideration

When submitting the study results of the sub-chronic toxicity study (90-day) you may also include in the registration update your considerations whether changes in the study design are needed because new information shows that the triggers for expanding the study as described in column 2 of Section 8.7.3. are met (see also ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6 (version 4.1, October 2015)). Furthermore, in cases where you have already commenced the study in accordance with this decision, you may also expand the study to address a concern identified during the conduct of the extended one-generation reproduction toxicity study and also due to other scientific reasons in order to avoid a conduct of a new study.

The justification for the changes in the study design must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/ triggers must be documented.

10. Adsorption/desorption screening (Annex VIII, Section 9.3.1)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Adsorption/desorption screening" is a standard information requirement as laid down in Annex VIII, Section 9.3.1 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.3 of the REACH Regulation, by providing information based on Qualitative or Quantitative

structure-activity relationship ((Q)SAR) models, such as EPI Suite. You provided a logKoc of 2.4 based on the LOGKOCWIN estimation for one of the component of your registered substance.

This QSAR prediction based on the structures you used does not fulfill REACH requirements for Annex XI 1.3 adaptations and should be rejected based on the following conditions that according to REACH Annex XI, 1.3:

- The substance does not fall within the applicability domain of the (Q)SAR model as indeed the substance is registered as a multi-constituent substance and you provided only one QSAR estimation for only one constituent and, in addition, there are no close analogues in the training sets for all representative structures of your substance;
- the results are not adequate for the purpose of classification and labelling and/or risk assessment as specified above, the substance being a multi-constituent, either several representative structures should have been predicted and used as results or an explanation why you think you used a worst-case representative structure;
- and also adequate and reliable documentation is not provided as neither (Q)SAR Model Reporting Format (QMRF) nor (Q)SAR Prediction Reporting Format (QPRF) were provided.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In your comment on the draft decision, you explained that QSAR were re-evaluated and refined utilizing new test data to derive updated coefficient values. The updated training set includes now an alcohol specific contribution correction factor.
You also stipulated further arguments to use column 2 adaptation justification and indicated that you will provide this information in a dossier update.
All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation. Independent of this draft decision and under Article 22 of the REACH Regulation, you can submit updates to the registration dossier

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Adsorption/desorption screening. Guidance for determining appropriate test methods for the adsorption/desorption screening is available in the ECHA Guidance on information requirements and chemical safety assessment (version 4.1., October 2015), Chapter R.7a, Section R.7.1.15.3.

11. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The following analogue key studies for the bioaccumulation endpoint were provided in the IUCLID technical dossier:

1) A non GLP OECD TG 305 E ([redacted]) with an analogous substance as test material: Alcohols, C9-11-iso, C10 rich. No justification for the analogue approach or no identification (i.e. CAS or EC number) for the test substance was provided. In addition, the exposure duration reported was shorter (uptake 16 days) than the OECD TG 305 guideline recommendation (uptake 28 days) and the test guideline used was already cancelled at the time of the testing.
2) A non GLP, 22 day, fish, dietary Bioaccumulation study, without corresponding guideline ([redacted]) with an analogue test substance: C9-11-iso, C10-rich and Alcohols (CAS 68526-85-2). No details (i.e. purity) of test substance or any justification for the analogue approach taken was provided.
3) A non GLP OECD TG 305 flow through test ([redacted]) with the analogous substance: Alcohols, C11-14-iso, C13-rich. No justification for the analogue approach or CAS or EC number provided. The exposure duration was reported to be 14 days instead of 28 days recommended by the OECD TG 305.
4) A non-GLP, fish, dietary Bioaccumulation study without corresponding guideline ([redacted]) with analogue substance: Alcohols, C11-14-iso, C13-rich, (CAS 68526-86-3). The exposure duration reported was shorter (22 days total) than the OECD TG 305 guideline recommendation (42 days total). No details (i.e. purity) of test substance or any justification for the analogue approach taken was provided.

However, as explained above the section *'Grouping of substances and read-across approach'* of this decision, your adaptation of the information requirement cannot be accepted.
As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Furthermore, the substance has a LogKow =4.7 which raises concern with regard to its potential bioaccumulation in aquatic organisms.

In your comment on the draft decision, you informed ECHA that the information based on the read across substances findings for bioaccumulation testing will be amended with information such as EC and CAS number, purities together with hypothesis on the grouping and applicability of the grouping hypothesis and results obtained with the analogues used to prove the low potential for bioaccumulation of the substance and its members. This will be done in a dossier update.

All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation. Independent of this draft decision and under Article 22 of the REACH Regulation, you can submit updates to the registration dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Bioaccumulation in fish: aqueous or dietary bioaccumulation fish test (test method: OECD TG 305).

Deadline to submit the requested information in this decision

In the draft decision communicated to you the time indicated to provide the requested information was 42 months from the date of adoption of the decision. In your comments on

the draft decision, you indicated that you plan to use an integrated testing strategy, including the performance of toxicokinetic studies, and that this testing strategy could allow you to strengthen your read-across justification. Based on your commitment to use an integrated testing strategy to avoid unnecessary animal testing following Annex XI section 1.5 on grouping and read-across approach, ECHA has granted you an 8 month extension of the timeline. In your comments to the proposals for amendments, you requested an extension of the deadline to submit the sub-chronic toxicity study to 30 months. As ECHA has already granted an extension of the deadline to 20 months, ECHA does not consider further extension (beyond 20 months) to be justified in this case.

Therefore the deadline for submitting an updated dossier including the results of the sub-chronic toxicity studies (90-day) is extended from usual 12 months to 20 months, and the overall deadline of the decision has been extended from a total of 42 to 50 months.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 25 September 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

On 10 December 2015, ECHA sent the draft decision to you and invited you to provide comments within 30 days of the receipt of the draft decision.
On 01 February 2016, ECHA received comments from you on the draft decision.

The ECHA Secretariat considered your comments.
The information is reflected in the Statement of Reasons (Appendix 1) and an extension to the deadline (Section II) were made.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

ECHA received proposal(s) for amendment and did not modify the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision during its MSC-48 meeting and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present 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 your Member State.

3. In relation to the information required by the present decision, the sample of substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance composition manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material 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 test(s) 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally 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.