Helsinki, 21 October 2020

Addressees
Registrants of JS_benzyltoluene as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
11/04/2019

Registered substance subject to this decision ("the Substance")
Substance name: Benzyltoluene
EC number: 248-654-8
CAS number: 27776-01-8

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***27 July 2023***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from all the Registrants subject to Annex VII of REACH

1. Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105/OECD GD 29)

2. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. / OECD TG 471) with the Substance using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

B. Information required from all the Registrants subject to Annex IX of REACH

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat)

2. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12 °C

3. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)

C. Information required from all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit)

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) in rats, oral route, specified as follows:
   - Ten weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting shall aim to induce systemic 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.

Reasons for the request(s) are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to X of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Approved[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[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 on Reasons common to several requests

1. Assessment of your read-across approach under Annex XI, Section 1.5.

You seek to adapt the following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.)
- Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

ECHA has considered the scientific and regulatory validity of your read-across approach in general before assessing the specific standard information requirements in the following appendices.

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used:

- there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category;
- it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[2] and related documents[3, 4].

A. Predictions for toxicological properties

You have provided a read-across justification document in IUCLID Section 7.8., to support the read-across between the structurally similar substances, dibenzyltoluene, EC number 248-654-8 (CAS RN 53585-53-8) as source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties: *"Dibenzyl toluene (DBT) has been identified as a suitable analogue based on structural similarities, identical functional groups and availability of the (eco)toxicological data"*. Both the source and the target substances *"have similar chemical structures, physico-chemical properties, metabolic pathways, toxicity profilers, toxicological properties and modes of action"*.

ECHA understands that you predict the reproductive and developmental properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects and that the properties of the Substance are predicted to be quantitatively equal to those of the source substance.

ECHA notes the following shortcomings with regards to your predictions of toxicological properties.

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[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals. 2008 (May) ECHA, Helsinki. 134. pp. Available online: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

[3] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[4] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

i. Read-across hypothesis

To fulfil the first condition of Annex XI, Section 1.5., a read-across hypothesis needs to be provided, establishing why a prediction for a toxicological property (reproductive and developmental toxicity) is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the source substance(s) and your Substance[5]. It should explain why the differences in the chemical structures should not influence the toxicological properties or should do so in a regular pattern.

Your read-across hypothesis is that the similarity in chemical structures and in some of the physicochemical and toxicological properties between the source substance and your Substance is a sufficient basis for predicting the reproductive and developmental properties of your Substance.

Similarity in chemical structure and similarity of some of the physicochemical and toxicological properties does not necessarily lead to predictable or similar human health properties in other endpoints.

While you have information on the similarity between the two substances, you have not explained specifically why the difference in structure does not impact or influence the prediction of reproductive and developmental properties of the Substance from source information. Furthermore you have not explained how you can predict with confidence these properties from information on acute toxicity, local irritation, mutagenicity or repeated dose toxicity studies, none which covering any mating or reproductive and developmental stages.

As described above, a well-founded hypothesis is needed to establish a reliable prediction for a toxicological property, based on recognition of the structural similarities and differences between the source substances and your Substance.

ii. Absence of the supporting information

To fulfil the second condition of Annex XI, Section 1.5., and as stated in the ECHA Guidance[6] "*it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/ endpoint being read across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals*".

In order to support your claim that the Substance and the source substance have similar reproductive and developmental properties in the read-across approach, you referred to their acute toxicity, skin irritation, eye irritation, skin sensitisation, subchronic toxicity and genotoxicity properties. You have not submitted any studies relevant to the two information requirements, such as a reproductive and developmental toxicity study on both substances.

While the data set you provided (including acute toxicity, local irritation, mutagenicity or repeated dose toxicity studies) suggests that the substances may have similar properties for these endpoints, you have not submitted supporting information on both the source substance and the Substance, relevant to the information requirements under consideration. These information requirements relate to the behaviour of the tested materials regarding reproductive / developmental toxicity properties, while you provided data on acute toxicity, local irritation, mutagenicity or repeated dose toxicity studies.

[5] Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals.
[6] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

Therefore the supporting studies you submitted do not inform on the developmental and reproductive toxicity properties of the target and source substances, and accordingly, are not considered as relevant to support prediction of the endpoints you wish to address under your read-across approach.

iii. Missing toxicokinetics and water solubility data

To substantiate the similar effects, you need to submit information on both the target and source substance, as your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance must confirm that both substances cause the same type of effects. This includes information on toxicokinetics and water solubility.

However, your registration dossier does not contain:

1. experimental data on absorption, distribution, metabolism and excretion of the source and target substances; and
2. water solubility data with the Substance (see Section A.1.).

In the absence of such information, you cannot establish that the Substance and the source substance are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

B. Conclusions on the read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

Appendix A: Reasons to request information required under Annex VII of REACH

1. Water solubility

Water solubility is a standard information requirement in Annex VII to REACH.

You have provided a key study ([redacted], 1995) using EU method A.6 and column elution, conducted with the substance "[redacted]" (mixture of benzyltoluene and dibenzyltoluene).

You also provided the following statement to justify your derivation of the water solubility value: *"The key study has been carried out on a mixture of benzyltoluene (3/4) and dibenzyltoluene (1/4). The measured solubility was 56 µg/L. As it is known from another experiment carried out in same conditions that solubility of pure dibenzyltoluene was 18 µg/L, it can be concluded that 38 µg/L on the present study can be attributed to benzyltoluene."*

ECHA has assessed the above information and identified the following issue:

Inadequate method
To fulfil the information requirement, a study must comply with OECD TG 105/EU method A.6 (Article 13(3) of REACH). Therefore, the following requirement must be met:

- coverage of the key parameter which is the saturation mass concentration of the Substance in water at 20°C.

As regards the applicability domain of the method the following must be adhered to:
- the column elution method is not applicable to mobile oils or liquids (ECHA Guidance Chapter R.7a, Table R.7.1-5.). This is due to likely issues with loading of the support material when the test substance is deposited as an oil. Any such issues should be examined and reported as required by OECD TG 105.

However, you have provided a study performed with the column elution method and have tested "[redacted]". You explain that the measured solubility value in the study is not for the Substance but rather for *"a mixture of benzyltoluene (3/4) and dibenzyltoluene (1/4)"*. You derive the saturation mass concentration of the Substance in water based on this result and the results of another study on "dibenzyltoluene" which is not included in the dossier.

Your Substance and the tested substance "[redacted]" are mobile liquid hydrocarbons and therefore fall outside of the applicability domain of the colum elution method. You have not justified in your dossier why you condider this method applicable.

Additionally, you have not provided the saturation mass concentration of the Substance in water at 20°C as derived from an OECD TG 105. Mixtures of organic compounds can behave differently from their single constituent compounds when brought into contact with water, therefore the water solubility value you derive is not considered reliable.

The requirements of OECD TG 105/EU method A.6 are not met.

Therefore, the provided information does not fulfil the information requirement.

2. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is a standard information requirement in Annex VII to REACH.

You have provided a key study and two supporting studies in your dossier:

i. [redacted] (1994) as a key study on the Substance; with the following *S. typhimurium* strains, TA 98, TA 100, TA 1535, TA 1537, and TA 1538;
ii. [redacted] (1981) as a supporting study on the Substance; with the following *S. typhimurium* strains, TA 98, TA 100, TA 1535, TA 1537, and TA 1538; and
iii. [redacted] (1990) as a supporting study on the Substance; with the following *S. typhimurium* strains, TA 98, TA 100, TA 1535, TA 1537, and TA 1538.

We have assessed this information and identified the following issue:

To fulfil the information requirement, the data submitted has to meet the requirements of OECD TG 471 (1997). One of the key parameters of this test guideline requires the test to be performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101)

The reported data did not include results for the appropriate 5 strains, that is the required fifth strain, *S. typhimurium* TA 102 or *E. coli* WP2 uvrA or *E. coli* WP2 ivrA (pKM101) was not provided. The information provided does not cover one of the key parameters required by OECD TG 471.

Therefore, the information requirement is not fulfilled.

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) should be performed using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

Appendix B: Reasons to request information required under Annex IX of REACH

1. Pre-natal developmental toxicity study in one species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5., between benzyl toluene and dibenzyl toluene.

You have also provided a study from Kurosaki *et al.* (1988, Rel. 1, non GLP): developmental toxicity study on rats with the analogue substance dibenzyltoluene (EC number 258-649-2) according to the OECD TG 414.
However, as explained in the Appendix on "Reasons common to several requests" your adaptation is rejected. Therefore, the information requirement is not fulfilled.

Based on the above, the information you provided does not fulfil the information requirement.

How to fulfil the request

In a previous decision "TPE-D-2114321175-60-01/F" of 11 March 2016, ECHA has requested the registrant concerned to generate and submit a reliable "*Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route, on benzyltoluene*". The requested study was submitted to ECHA and deemed as fulfilling the information requirement.

Under Article 25 of the REACH Regulation, in order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort.

In accordance with Title III of the REACH Regulation, you must request the "*Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route, on benzyltoluene*" from the other registrant identified in the notification letter of the present decision. Article 27(2) to (5) should apply adapted as necessary.

2. Simulation testing on ultimate degradation in surface water

Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

In your dossier you have provided an adaptation under Annex IX, Section 9.2., Column 2, with the following justification: "*the substance is not considered PBT/vPvB and that there is no identified risk for the water compartment.*"

We have assessed this information and identified the following issue:

The information requirement may be adapted under column 2 if the Chemical Safety Assessment (CSA) demonstrates and documents that risks arising from the Substance are controlled (Annex I, Section 0.1; Annex IX, Section 9.2, Column 2). To this end, you need to provide a justification as to why there is no need to provide any further information for simulation testing on ultimate degradation in water taking into account the PBT/vPvB properties of the Substance itself and of any of its constituent, impurity or transformation/degradation product present in concentration ≥ 0.1% (w/w).

Furthermore, if there are indications for potential PBT/vPvB properties (Annex I Section 4; Annex XIII, Section 2.1) further testing on degradation is required. Screening information demonstrating potential PBT/vPvB properties include (ECHA Guidance R.11.4):

- the Substance is potentially persistent or very persistent (P/vP) if:
  - it is not readily biodegradable (*i.e.* <60% degradation in an OECD 301B), and
- the Substance is potentially bioaccumulative or very bioaccumulative (B/vB) if:
  - it has a high potential to partition to lipid storage (*e.g.* log K_{ow} > 4.5).

The information provided in your dossier indicates that:

- the Substance is potentially P/vP since it is not readily biodegradable (46% degradation after 28 days in an OECD TG 301B);
- the Substance is potentially B/vB since the Log K_{ow} is close to the threshold of 4.5 depending on the regression method used to calculate. More specifically, when using the regression method from the OECD Guidelines for HPLC determination of log Pow (December 1988), you obtained log Kow values of 4.45 and 4.57 for the isomers of the substance. When using other regression methods you also derived values slightly lower than 4.5 but you have not indicated the standard deviation or error associated with your regressions. Taking all of this information together ECHA concludes that you cannot demonstrate a lack of bioaccumulation potential.

Based on the above the Substance may have PBT/vPvB properties and your CSA does not rule out the need to investigate further the degradation of the substance and its degradation products for the purpose of the PBT/vPvB assessment.

Therefore, the provided information does not fulfil the information requirement.

3. Identification of degradation products

Identification of the degradation products is an information requirement under Annex IX of REACH (Section 9.2.3.).

In your dossier you have provided an adaptation under Annex IX, Section 9.2., Column 2, with the following justification: "*the substance is not considered PBT/vPvB and that there is no identified risk for the water compartment.*"

Under Annex IX, Section 9.2, Column 2 , this information may be omitted if the chemical safety assessment (CSA) does not indicate the need for further biotic degradation testing. In the context of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance, the CSA must address relevant transformation/degradation products (Annex XIII, 5th paragraph; ECHA Guidance R.11.4.1.).

Your justification is solely based on the properties of the parent substance and does not address the identity and PBT/vPvB properties of its relevant transformation/degradation products.

Without this information, your CSA does not demonstrate that there is no need for further biotic degradation testing.

Therefore, your adaptation is rejected.

Appendix C: Reasons to request information required under Annex X of REACH

1. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5., between benzyl toluene and dibenzyl toluene.

You have also provided a statement informing that "*This information will be submitted later based on ECHA communication/decision number CCH-D-2114432929-37-01/F. According to ECHA final decision CCH-D-2114432929-37-01/F of 9 july 2018, an OECD 414 study* [second species]*, on the analogue substance, dibenzylbenzene, ar-methyl derivative (EC number: 258-649-2, CAS number: 53585-53-8, Registration number:* [redacted]*) will be submitted in an updated registration dossier by 17 January 2022.".*

We have assessed this information and identified the following issues:

As a result of various provisions of REACH, to fulfil an information requirement registrants must provide either one of the following pieces of information:

- A compliant study, performed according to the relevant test method (EU test method or OECD test guideline) and fulfilling its validity criteria; or
- A valid adaption foreseen either in column 2 of the relevant Annex and section of REACH or in Annex XI, including a well-documented justification and relevant supporting information; or
- A proposal for further testing, where you identified data gaps which are relevant to information required from Annex IX and/or X.

However:

- the information you provided is not a study;
- the adaptation is not valid under section 1.5 of Annex XI, because (i) as explained in the Appendix on "Reasons common to several requests" your adaptation is rejected and (ii) the PNDT study in a second species relied upon is not yet submitted in the registration dossier ("*available by 17 January 2022*;
- the information you provided is not a proposal for testing, but a statement that a future test will be submitted. Therefore, ECHA cannot examine this information as a testing proposal under Article 40.

Based on the above, the information you provided do not fulfil the information requirement.

Information on study design

A PNDT study according to the OECD TG 414 study should be performed in the rabbit or rat as preferred first species.

As indicated under Section B.1., a test in the first species was carried out using the rodent (rat) species, although it is not available in your dossier. Therefore, the PNDT study in a second species must be performed in the rabbit as preferred non-rodent species.

The study shall be performed with oral[7] administration of the Substance.

2. Extended one-generation reproductive toxicity study

[7] ECHA Guidance R.7a, Section R.7.6.2.3.2.

The basic test design of an Extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is a standard information requirement under Annex X to REACH. Furthermore Column 2 of Section 8.7.3. defines when the study design needs to be expanded.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5., between benzyl toluene and dibenzyl toluene.

You have also provided a statement informing that *"This information will be submitted later based on ECHA communication/ decision number CCH-D-2114432929-37-01/F. According to ECHA final decision CCH-D-2114432929-37-01/F of 9 july 2018, an OECD 443 study on the analogue substance, dibenzylbenzene, ar-methyl derivative (EC number: 258-649-2, CAS number: 53585-53-8, Registration number: [redacted]) will be submitted in an updated registration dossier by 17 January 2022."*

We have assessed this information and identified the following issues:

As a result of various provisions of REACH, to fulfil an information requirement registrants must provide either one of the following pieces of information:

- A compliant study, performed according to the relevant test method (EU test method or OECD test guideline) and fulfilling its validity criteria; or
- A valid adaption foreseen either in column 2 of the relevant Annex and section of REACH or in Annex XI, including a well-documented justification and relevant supporting information; or
- A proposal for further testing, where you identified data gaps which are relevant to information required from Annex IX and/or X.

However:

- the information you provided is not a study;
- the adaptation is not valid because (i) as explained in the Appendix on "Reasons common to several requests" your adaptation is rejected and (ii) the EORGTS study relied upon is not yet submitted in the registration dossier ("*available by 17 January 2022*").
- the information you provided is not a proposal for testing, but a statement that a future test will be submitted. Therefore, ECHA cannot examine this information as a testing proposal under Article 40.

Based on the above, the information you provided does not fulfil the information requirement.

Specifications for the study design

Premating exposure duration

The length of premating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility. It is also required to obtain results adequate for classification and labelling and /or risk assessment. There is no substance specific information in the dossier supporting shorter premating exposure duration.

Therefore, the requested premating exposure duration is ten weeks.

Dose-level setting

In order to be compliant and not to be rejected due to too low dose levels, the highest dose level must aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose level selection should be

based upon the fertility effects. A descending sequence of dose levels should be selected in order to demonstrate any dose-related effect and to establish NOAELs.

If there is no relevant data to be used for dose level setting, it is recommended that range-finding results are reported with the main study.

You have to provide a justification with your study results that demonstrates that the dose level selection meets the conditions described above.

Species and route selection

The study must be performed in rats with oral [8] administration.

Further expansion of the study design

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and/or Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if relevant information becomes available from other studies or during the conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in ECHA Guidance[9].

[8] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[9] ECHA Guidance R.7a, Section R.7.6.

Appendix D: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[10].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

   This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

   Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[11].

[10] https://echa.europa.eu/practical-guides
[11] https://echa.europa.eu/manuals

Appendix E: General recommendations when conducting and reporting new tests for REACH purposes

A. Strategy for the PBT/vPvB assessment

You are advised to consult ECHA Guidance R.7b (Section R.7.9.), R.7c (Section R.7.10) and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

B. Testing strategy for aquatic toxicity testing

You are advised to consult ECHA Guidance R.7b, (Section R.7.8.5) which describes the Integrated Testing Strategy, to determine the sequence of aquatic toxicity tests and testing needed.

C. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituens and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthetize its relevant constituents and/or fractions.

Appendix F: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 06 June 2019.

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the deadline.

The timeline indicated in the draft decision to provide the information requested is 30 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 33 months. You justified your request stating that due to the current situation there might be a possible impact on the limitation of experimental capacities which would lead to a delay in the performance of studies. However, you did not provide documentary evidence to substantiate the claim above.

Therefore, ECHA has not modified the deadline of the decision.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix G: List of references - ECHA Guidance[12] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[13]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[13]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[14]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[12] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[13] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[14] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix H: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.