~~Confidential~~

Helsinki, 12 January 2022

Addressees
Registrant(s) of JS_10042-59-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
20/08/2019

Registered substance subject to this decision ("the Substance")
Substance name: 2-propylheptan-1-ol
EC number: 233-126-1

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 ***18 July 2025***.

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

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

1. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203)

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

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

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) by oral route, in rats, specified as follows:
   - At least two 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) with extension to mate the Cohort 1B animals to produce the F2 generation which shall be followed to weaning; and
   - Cohorts 2A and 2B (Developmental neurotoxicity).

You must report the study performed according to the above specifications. Any expansion of the study must be scientifically justified.

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 VIII 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 and VIII to REACH, for registration at 10-100 tpa;
- 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". 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.

Authorised[1] under the authority of Mike Rasenberg, 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 in accordance with Annex XI, Section 1.5:

- *Pre-natal developmental toxicity study in a second species (Annex IX, Section 8.7.2., column 2)*
- *Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)*

ECHA has considered the scientific and regulatory validity of your grouping and 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. Firstly, 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. Secondly, 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.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

A. Predictions for toxicological properties

You have provided a read-across justification document [redacted] in section 13 of IUCLID, referred herafter as "*justification document*".

You read-across between the structurally similar substances bis(2-propylheptyl) phthalate (EC: 258-469-4; referred to in the dossier as source substance 2) and the Substance.

You have provided the following reasoning for the prediction of toxicological properties: *"Source substance 2 undergoes metabolic degradation to form the target substance and the respective monoester derivates or phthalic acid",* furthermore*, "Toxicokinetic data indicates that the target substance is systemically available after source substance 2 being absorbed and rapidly hydrolyzed. Therefore, source substance 2 can be used for read-across to the target substance in the assessment of systemic effects".*

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the formation of common (bio)transformation products. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

ECHA has analysed the provided information and identified the following issues:

Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[2]. The set of supporting

[2] ECHA Guidance; Chapter R.6: Section R.6.2.2.1.f

information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include, among others toxicokinetic information on the formation of the common compounds.

As indicated above, your read-across hypothesis is based on the (bio)transformation of the source substance 2 to your Substance. In this context, one important aspect in establishing that substances have similar effects or follow a regular pattern is the comparison of absorption, distribution, metabolism and elimination of your Substance and the source substance. This allows assessing the qualitative and quantitative internal systemic exposure of the test organism and the determination whether the substances, which govern the systemic toxicity profiles are known and considered in the predictions.

Your read-across hypothesis is based on the assumption that the properties of your Substance are predicted to be quantitatively equal to those of the source substance, due to "rapid ester hydrolysis" of the source substance 2 to the Substance.

To support of your hypothesis, you refer to several toxicokinetic studies. performed with the source substance 2 in humans after oral exposure (Leng, G. et al. 2014; Wittassek M and Angerer J. 2008) and in rats after single oral exposure (Klein D. et al,. 2016). For the Substance, you state that no toxicokinetic data is available, however its toxicokinetic profile *"can be deduced from other alcohols".* In addition, you reported 28-day metabolome study in rats, performed with the Substance and source substance 2 ([redacted] 2019). You concluded that for both substances the main target organ is the liver and the main common effect is the peroxisome proliferation, therefore "*the treatment with 2-Propylheptanol will lead to the same effects as Bis-(2-propylheptyl) phthalate and accordingly, the read-across from source substance 2 to the target substance is justified".*

Based on the reported information, ECHA notes that the absorption rates of the Substance and the source substance 2 are not defined. Further, in your justification document you state that "*Toxicokinetic data indicates that the target substance is systemically available after source substance 2 being absorbed and rapidly hydrolyzed",* however, you did not provide any hydrolysis data to substantiate your claim, neither you did specify the actual amount of the Substance formed as a result of biotransformation of the source substance 2. Without such information, as well as the lack of information on the absorption level of the Substance and the source substance, it is not possible to determine if the qualitative and quantitative internal systemic exposure of the test organism is the same or similar to the Substance when administered *per se* and as a result of biotransformation of the source substance. Further, the peroxisomal proliferation reported in the metabolomic study may inform on common effect in the liver, however, it is not relevant to predict the reproductive and developmental toxicity properties of the Substance and the source substance 2.

Therefore, you did not demonstrate that the properties of your Substance are quantitatively and qualitatively equal to the properties of the source substance 2.

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 VIII of REACH

1. Short-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

You have provided an OECD TG 203 key study ([redacted], 1995) with the Substance.

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 203 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Technical specifications impacting the sensitivity/reliability of the test

- the test is conducted on juveniles of similar age (or size);

Additional requirements applicable to difficult to test substances

- if the test material is forming dispersion or emulsions (*e.g.* certain surfactants, aliphatic amines), the dispersibility limit or the critical micelle concentration (CMC) of the test material in the specific test solution under the test conditions is determined in a preliminary solubility study;
- surface-active test chemicals are tested at concentrations below their critical micelle concentration (CMC) in the test medium;

Characterisation of exposure

- a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;

The Substance is difficult to test due to its surface active properties (surface tension = 46.1 mN/m at 20 ºC).

Your registration dossier provides an OECD TG 203 study showing the following:

Technical specifications impacting the sensitivity/reliability of the test

- the mean size of fish was 3.2 cm, which does not correspond to the size of juveniles for *Danio rerio* i.e. 1-2 cm according to OECD TG 203;

Additional requirements applicable to difficult to test substances

- no information on preliminary solubility study to determine the critical micelle concentration (CMC) in the test medium is provided;
- the test concentrations ranged from 0.464 to 10.0 mg/L and you do not report in your dossier the CMC of the test material;
- you report that during the test "*undissolved test substance was visible at the water surface increasing with the increase in the concentration.*"

Characterisation of exposure

- no information on the analytical method used to monitor exposure concentrations is provided, including information on sampling method and performance parameters of the analytical method (e.g. LOD, LOQ, recovery etc…);

Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically:

- The test was not conducted with juvenile animals (i.e. size of tested organisms above 2 cm). This may underestimate the toxicity, because the sensitivity of test organisms may be lower than if tested with juveniles organisms (i.e. 1-2 cm according to OECD TG 203).
- As explained above the Substance is difficult to test due to its surface active properties. You provide no information on the critical micelle concentration (CMC) of the Substance in the test medium, therefore it is not possible to verify if test concentrations were below the CMC. However, there are indications that tested concentrations exceeded the CMC since undissolved test material was observed in the study. Undissolved test material can affect test organisms by other means than toxicity of the tested material and might thus bias hazard conclusion. In addition, you have not demonstrated that the test organisms were exposed to the freely dissolved chemical species and not the micelle, which can alter the uptake of the test chemical. Furthermore, you report an LC50 of 1.9 mg/L based on measured concentrations. However, in the absence of information on the analytical method used to monitor exposure concentrations including sampling procedure and performance parameter, you have neither demonstrated that effect concentrations reflect dissolved fraction of the test material only, nor that performance parameters of this method were sufficiently reliable by means of sensitivity and specificity.
  Consequently, reported effect values must be regarded non reliable.

Therefore, the study does not comply with the requirements of OECD TG 203 and OECD GD 23.

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision, you indicate your intention to perform the fish early life stage study (OECD TG 210) requested in Appendix B. Section 1 instead of a new OECD TG 203 study as requested. You consider that the short-term toxicity testing on fish does not need to be conducted.

REACH Annex VIII section 9.1.3 column 2 specifies that the short-term toxicity study does not need to be conducted if a long-term aquatic toxicity study on fish is available. At present no long-term toxicity study on fish is provided in the IUCLID dossier, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline

Study design

As explained above, the Substance is difficult to test. OECD TG 203 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the

effect concentration based on measured values as described in OECD TG 203. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions. Furthermore, exposure concentrations must be below the critical micelle concentration (CMC). This will ensure that test organisms are exposed to the freely dissolved chemical species and not the micelle which can alter the uptake of the test chemical.

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

1. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision, you agree to perform the requested study.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.1.

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 provided a Pre-natal developmental toxicity studies (according to or equivalent to OECD TG 414) in rat on the Substance.

For the information on a PNDT in a second species, you have sought to adapt the standard information requirement according to Annex XI, section 1.5.

You have provided the following information, relevant for this endpoint:

i. Prenatal developmental toxicity study in rabbit (according to OECD TG 414, GLP), performed with the source substance 2

As explained in the Appendix on Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

Therefore, the information requirement is not fulfilled.

In the comments to the draft decision, you agree to perform the requested study.

Study design:

A PNDT study according to the OECD TG 414 should be performed in the rabbit or rat as the preferred species. The test in the first species was carried out by using a rodent species (rat). Therefore, a PNDT study in a second species must be performed in the rabbit as preferred non-rodent species.

2. Extended one-generation reproductive toxicity study

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 defines the conditions under which the study design needs to be expanded.

You have sought to adapt the standard information requirement according to Annex XI, section 1.5.

You have provided the following information, relevant for this endpoint:

i. Two-generation reproductive toxicity study in rats (OECD TG 416, GLP, 2009), performed with the source substance 2.

As explained in the Appendix on Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

Therefore, the information requirement is not fulfilled.

<u>The specifications for the study design</u>

Premating exposure duration and dose-level setting

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.

A 2-week premating exposure duration for P0 animals is sufficient for your Substance, because the F1 animals of Cohort 1B are mated to produce the F2 generation and, thus, the premating exposure duration will be 10 weeks for these Cohort 1B animals.

Therefore, the requested premating exposure duration is at least two weeks.

In order to be compliant and not to be rejected due to too low dose levels, the highest dose level shall 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.

Cohorts 1A and 1B

Cohorts 1A and 1B belong to the basic study design and must be included.

Extension of Cohort 1B

If the Column 2 conditions of 8.7.3., Annex X are met, Cohort 1B must be extended.

The extension is inter alia required, if the use of the registered substance is leading to significant exposure of consumers and professionals (column 2, first paragraph, lit. (a) of Section 8.7.3., Annex X) and there are indications of one or more relevant modes of action related to endocrine disruption from available *in vivo* studies or non-animal approaches (column 2, first paragraph, lit. (b), third indent of Section 8.7.3., Annex X).

The use of the Substance is leading to significant exposure of professionals and consumers because the Substance is used by professionals as solvent (PROC 5, 8a, 8b, 10, 11) and by consumers in biocidal products (e.g. disinfectants, pest control). Further, there are indications of one or more relevant modes of action related to endocrine disruption: histopathological changes in the thyroid gland (diffuse follicular hypertrophy, observed in 7/10 male rats) and of the pituitary gland (vacuolation basophilic (thyrotropic) cells) are reported in an OECD TG 408 study on the Substance in male rats.

In the comments to the draft decision you disagree with the extension of cohort 1B. You argue that the findings on the thyroid gland and pituitary gland that triggered the extension of the cohort are only occurring in males and are of medium severity. You further state "*We think it is plausible that these findings are the sequel of phase II enzyme induction (with increased glucuronidation and the elimination of T3/T4 and subsequent stimulation of the hypothalamus–pituitary–thyroid gland axis) which has yet not been experimentally confirmed"*. You further state that "*peroxicome proliferation and phase II enzyme induction in rats are effects that lack human relevance*".

Based on this, you propose to perform the study without extension of cohort 1B for animal welfare reasons.

ECHA reiterates that the effect to the thyroid gland, even though observed only in males and of medium severity, cannot be disregarded. Furthermore, your statements that the effects may be secondary to phase II enzyme induction and that these effects are not likely to be human relevant, are not substantiated by experimental data.

According to Appendix A of ECHA and EFSA Guidance for the identification of endocrine disruptors[3] to investigate whether liver enzyme induction is responsible for the effects seen on TH levels and/or thyroid histopathology and weight, as well as whether the effect is or not likely to be human relevant, the following three pieces of information are needed:

1. Results of analysis of serum/plasma samples (if available) for TSH, T3 and T4 in the existing repeated dose toxicity studies. If unavailable, a specifically designed *in vivo* toxicity study should be considered. In this study, TSH, T3 and T4 should be measured and, where possible, additional data on liver enzyme induction (e.g. measurement of UDPGT) should be included.
2. Comparative studies of enzyme activity induced by the test substance in liver *in vitro* systems should be measured in both the relevant test species (e.g. rat, mouse and dog) and humans. The metabolism of the specific substance (ADME properties) in both test species and humans, and the activity of possible metabolites must be considered when this comparison is conducted.
3. The presence of other possible thyroid-disrupting modes of action such as interference with TH synthesis should also be excluded, e.g. by evaluating *in vitro* the potential for inhibition of the sodium–iodide symporter (NIS) (Cianchetta et al., 2010; Hallinger et al., 2017; Kogai and Brent, 2012) and thyroid peroxidase (TPO) (Kambe and Seo, 1997; Paul et al., 2014; Paul Friedman et al., 2016; Wu et al., 2016). It must, however, be acknowledged that substances may interfere with the thyroid hormone system through many different mechanisms of action, and that currently validated/standardised *in vitro* assays do not exist to investigate all these different pathways and a reasonable effort is anticipated, based on available tools and current understanding of thyroid physiology.

You did not provide any of the specific investigations, listed above, therefore you did not prove the follicular hyperthrophy of the thyroid gland as secondary effect to live enzyme induction.

Therefore, Cohort 1B must be extended.

The F2 generation shall be followed to weaning allowing assessment of nursing and lactation of the F1 parents and postnatal development of F2 offspring. Investigations for F2 pups must be similar to those requested for F1 pups in OECD TG 443 and described in OECD GD 151[4]. It is recommended to aim at 20 litters per dose group.

Cohorts 2A and 2B

The developmental neurotoxicity Cohorts 2A and 2B need to be conducted in case of a particular concern on (developmental) neurotoxicity.

[3] https://doi.org/10.2903/j.efsa.2018.5311.
[4] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2013)10&doclanguage=en

Existing information on the Substance, derived from an OECD TG 408 study, shows evidence of toxicity on the thyroid. Signs of thyroid toxicity rise a particular concern on developmental neurotoxicity (ECHA Guidance R.7a).

In the comments to the draft decision, you disagree with the extension of cohorts 2A and 2B. for the same reasons as explained for the extension of Cohort 1B.

ECHA reiterates that the observed thyroid toxicity rises a particular concern for developmental neurotoxicity. As explained above, ECHA does not consider the follicular hyperthrophy of the thyroid gland as secondary effect.

Therefore, the developmental neurotoxicity Cohorts 2A and 2B need to be conducted.

Species and route selection

The study must be performed in rats with oral[5] administration.

Further expansion of the study design

No triggers for the inclusion of Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of 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[6].

[5] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[6] 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[7].

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[8].

[7] https://echa.europa.eu/practical-guides
[8] https://echa.europa.eu/manuals

Appendix E: Procedure

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

The compliance check was initiated on 05 January 2021.

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

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

ECHA took into account your comments and did not amend the request(s).

However, in the draft decision communicated to you, the time indicated to provide the requested information was 30 months from the date of adoption of the decision. In your comments on the draft decision you requested ECHA to extend the standard granted time to a total of 39 months. You considered that the extension of 9 months is needed due to the limited capacity of the testing laboratories. You provided a statement from a CRO, indicating that based on the current capacity of the laboratory, 39 months is more relevant timeline.

ECHA took into account the reasoning for extension of deadline provided by the registrants. ECHA believes that a deadline 39 months from the adoption of the decision is sufficient to enable performing and submitting the studies under the current circumstances.

Therefore, ECHA has accepted the request and set the deadline to 39 months.

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 F: List of references - ECHA Guidance[9] 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)[10]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[11]

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.

[9] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[10] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[11] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[12]

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

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.

[12] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix G: Addressees of this decision and their corresponding information requirements

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]
[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.