Helsinki, 30 July 2020

Addressee
Registrant of [redacted] listed in the last Appendix of this decision

Date of submission for the Opt out dossier subject of this decision
02/10/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Tributylmethylammonium chloride
EC number: 260-135-8
CAS number: 56375-79-2

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

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadlines provided.

A. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. Justification for an adaptation of a Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.) based on the study requested under Section IX; with the Substance;

2. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method OECD 421/422) in rats, oral route with the Substance;

B. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the Substance;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211) with the Substance;

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation.
Therefore you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa.

The Appendix on general considerations addresses issues relevant for several requests while

the other Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in points A.1-2, B.3. above in an updated registration dossier by ***7 May 2021*** and the information requested in points B.1-2. above by ***7 February 2022***.

You must also update the chemical safety report, where relevant, including any changes to classification and labelling based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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, has to 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] 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 general considerations

(i) Assessment of the Grouping of substances and read-across approach, in light of the requirements of Annex XI, Section 1.5.

You seek to adapt the following standard information requirements by applying read-across approaches in accordance with Annex XI, Section 1.5:

- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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

Grouping of substances and read-across approach

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 (addressed under 'Predictions for (eco)toxicological properties').

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 (eco)toxicological properties

You read-across between the following structurally similar substances:

- Benzyltriethylammonium chloride (EC No 200-270-1),
- N,N-dimethyl-N-[3-(trimethoxysilyl)propyl]octadecan-1-aminium chloride (EC No 248-595-8),
- 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride (EC No 230-525-2)
- and carboxylatomethyl)dodecyldimethyl ammonium (EC No 211-669-5) as source substances

and the Substance as target substance.

Absence of read-across documentation

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a

[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

justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).[5]

You have provided studies conducted with other substances than your Substance in order to comply with the REACH information requirements. You have not provided any documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance(s).

In your comments on the initial draft decision you provided further read-across adaptation. We have assessed this information and identified the following issues:

Read-across hypothesis based on QSAR

In addition to the read-across substances listed above, you have included new source substances:

- (1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts (EC No 263-058-8)
- 3-chloropropyl-dimethylammonium chloride (EC No 226-467-2)
- Tributyltin chloride (EC No 215-958-7)
- N,N,N',N'-Tetrabutyl-N,N'-diethyl-1,6-hexanediaminium (CAS No 111960-92-0)
- Tributylamine (EC No 203-058-7)
- Tetrapropylammonium bromide (EC No 217-727-6)

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

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled to apply grouping and read-across. 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 (read-across approach).

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the substances[1]. It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

Your documentation presents a set of physico-chemical properties and alerts obtained from the QSAR Toolbox v3.4 for the Substance and for each of the source substances. On the basis of this information you derived conclusions on the structural similarities, similarities in physico-chemical properties and similarities in the alert profiles between the Substance and each of the above similar substance.

[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.6.1

You conclude that *"There is insufficient toxicity data on target chemical Tributylmethylammonium chloride (CAS No. 56375-79-2). Hence, in silico evaluation is conducted to determine read-across analogues for this material. Based on structural similarity, reactivity, metabolism, physical–chemical properties, organic functional groups and general mechanistic approach" [...] are identified as read-across analogues with sufficient data for toxicological evaluation"*.

While structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar human health or ecotoxicological properties.

You have not provided a well-founded hypothesis to establish a reliable prediction for toxicological or ecotoxicological properties, based on recognition of the structural similarities and differences between the source substance(s) and your Substance.

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"*[6]. The set of supporting 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).

As indicated above, 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(s) is necessary to confirm that both substance cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

You did not provide any study with the Substance. Additionally, the data set reported in the technical dossier and included in your comment does not include relevant, reliable and adequate information for the Substance and of the source substances to support your read-across hypothesis, e.g. bridging studies of comparable design and duration.

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

Absence of adequate supporting information to compare properties of the substance(s)

For the use of QSAR models under Annex XI, Section 1.3., the following cumulative conditions shall be necessarily met: results are derived from a (Q)SAR model whose scientific validity has been established; the substance falls within the applicability domain of the model; results are adequate for the purpose of classification and labelling and/or risk assessment; adequate and reliable documentation of the applied method is provided.

Provided that the applicability domain is appropriate, the results from using QSAR models may be used for read-across where such data are considered alongside other relevant data.

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

No information on the applicability domain of the expert systems used to generate the alert profiles of the substances has been provided.

Therefore the reliability of these predictions cannot be assessed.

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 for the requests to comply with Annex VIII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. Justification for an adaptation of the Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)

A Short-term repeated dose toxicity study (28 days) is a standard information requirement in Annex VIII to REACH. This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Column 2 of Annex VIII or a general adaptation rule under Annex XI.

You have provided one OECD 422 study performed with Benzyltriethylammonium chloride (EC No 200-270-1).

We have assessed this information and identified the following issue(s):

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. In your comments on the initial draft decision you explain that "*Justification for read across analogue used will be provided to fulfil this requirement by using grouping of substances and read-across approach under Annex XI, Section 1.5*".

As explained in the Appendix on general considerations your adaptation is rejected.

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

Column 2 of Annex VIII, Section 8.6.1. provides that an experimental study for this endpoint is not needed if a reliable sub-chronic (90 days) or chronic toxicity study is available.

The present decision requests the registrants concerned to generate and submit a reliable sub-chronic toxicity study (90 days) (see Section B.1.). According to Column 2 of Annex VIII, Section 8.6.1., and to prevent unnecessary animal testing, a short term toxicity study (28 days) does not therefore need to be conducted.

Because you still must comply with the information requirement in Annex VIII, Section 8.6.1., you are requested to submit a justification for the adaptation provided in Column 2 of that provision.

2. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

Screening for reproductive/developmental toxicity is a standard information requirement in Annex VIII to REACH.

You have provided two studies performed with analogue substances:

- OECD TG 422 study with Benzyltriethylammonium chloride (EC No 200-270-1)
- Developmental toxicity study with N,N-dimethyl-N-[3-(trimethoxysilyl)propyl]-octadecan-1-aminium chloride (EC No 248-595-8)

We have assessed this information and identified the following issue(s):

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. In your comments on the initial draft decision you explain that "*Justification for read across analogues used will be provided to fulfil this requirement by using grouping of substances and read-across approach under Annex XI, Section 1.5*".

As explained in the Appendix on general considerations your adaptation is rejected and the information requirement is not fulfilled.

Information on study design
A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats with oral[7] administration of the Substance.

The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you must request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs[8].

ECHA considers nine months a sufficiently reasonable time for the registrant to seek permission to refer to the other registrant's full study report.

[7] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[8] https://echa.europa.eu/regulations/reach/registration/data-sharing

Appendix B: Reasons for the requests to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

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

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

Assessment of data in the dossier

You have provided one OECD TG 422 study performed with Benzyltriethylammonium chloride (EC No 200-270-1).

We have assessed this information and identified the following issue(s):

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

As explained in the Appendix on general considerations your adaptation is rejected. In addition, the following endpoint-specific deficiencies have been identified in your read-across adaptation:
To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of OECD TG 408. The following key parameter(s) of this test guideline include, among others

- Dosing of the Substance daily for a period of 90 days until the scheduled termination of the study
- At least 10 female and 10 male animals should be used at each dose level (including control group.

The Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) you have submitted does not have the exposure duration of 90 days as required in OECD TG 408, because the exposure duration of the screening test is approximately 64 days. Furthermore the organ weight and histopathological investigations in OECD TG 422 are only conducted using 5 animals per sex per group and not 10 per sex per group as required in OECD TG 408.

ECHA acknowledges your willingness to perform the requested study, if necessary.

In your comments on the initial draft decision you present two subchronic studies which are not included in your dossier. The studies were performed with analogue substances (1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts [CAS number: 61789-40-0; EC number: 263-058-8] and 3-chloropropyl-dimethylammonium chloride [CAS number: 5407-04-5; EC number: 226-467-2]. As explained in the Appendix on general considerations your read-across adaptation is rejected.

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

Information on study design
Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the

substance is a liquid of very low vapour pressure and no uses with spray applications are reported that could potentially lead to aerosols of inhalable size.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

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

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

Assessment of data in the dossier

You have provided two studies performed with analogue substances:
- OECD TG 422 study with Benzyltriethylammonium chloride (EC No 200-270-1)
- Developmental toxicity study with N,N-dimethyl-N-[3-(trimethoxysilyl)propyl]-octadecan-1-aminium chloride (EC No 248-595-8)

We have assessed this information and identified the following issue(s):

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

As explained in the Appendix on general considerations your adaptation is rejected and the information requirement is not fulfilled.

Assessment of your comments

ECHA acknowledges your willingness to perform the requested study, if necessary.

In your comments on the initial draft decision you present details on the two studies included in your dossier. The studies have been performed with analogue substances. As explained above, your read-across adaptation is rejected and you have not provided any further information in your comments. However, we have assessed the information presented in your comment and identified the following endpoint-specific deficiencies:

In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in one species.

The study with Benzyltriethylammonium chloride you have provided is a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (OECD TG 422). In this study, structural malformations and variations are not investigated as required in the PNDT study (OECD TG 414). Therefore this study does not fulfil the information requirement.

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[9] administration of the Substance.

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to the REACH Regulation.

While an adaptation was not specifically indicated by you, ECHA has evaluated the provided information according to Annex XI, Section 1.2 of REACH (weight of evidence).

In support of your adaptation, you have provided for the Long-term toxicity to aquatic invertebrates endpoint (Annex IX Section 9.1.5.) the following source of information, two experimental studies performed following OECD TG 211 :

1) read-across adaptation based on analogue substance 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride/ 7173-51-5/ 230-525-2 (Tarazako et al., 2002);
2) read-across adaptation based on analogue substance (carboxylatomethyl)dodecyldimethyl ammonium; 1-Dodecanaminium, N-(carboxymethyl)-N,N-dimethyl-, inner salt / 683-10-3 / 211-669-5 Japan Chemical Collaborative Knowledge database, 2018);

Annex XI, Section 1.2 states that there may be sufficient weight of evidence weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory endpoint. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

You have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

Your adaptation is rejected because lack of adequate and reliable (concise) documentation for justification and the information requirement is not fulfilled.

A)
In spite of this deficiency, ECHA has also assessed the sources of information according to the rules of *Grouping of substances and read-across approach* under Annex XI, Section 1.5 and to what extend the sources of information submitted enables a conclusion on long-term toxicity testing on aquatic invertebrates. As explained in the Appendix on general considerations your adaptation is rejected.

In your comments on the initial draft decision you explain that "*Further reliable documentation is also provided to describe the weight of evidence approach which fulfils the requirement of Annex XI, section 1.2*". However, in the comments, only a read-across adaptation was provided. As explained in the Appendix on general considerations your read-across adaptation is rejected.

B)
Aditionally, the OECD TG 211 is preferred to cover this information requirement. The key parameter(s) of this test guideline include, the study needs to be conducted with the species recommended in the test guideline.

You provided an OECD 211 study conducted with "other aquatic crustacea", in your dossier.

The meaning of "other aquatic crustacea" is not clear. Only the use of *Daphnia magna* is recommended by the above mentioned test guideline. Therefore the information provided does not fulfil information requirement.

In your comments on the draft decision you clarify that the test organism used is *Daphnia magna*, instead of "*other aquatic crustacea*". This information needs to be updated in your technical dossier.

Finally, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 211 study because the applied read across and weight of evidence have deficiencies affecting their reliability.

Therefore, your adaptation is rejected and the information requirement is not fulfilled.

Appendix C: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 02 April 2019.

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

ECHA took into account your comments and did not amend the requests.

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

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

Appendix D: Observations and technical guidance

1. The information requirement under Section 8.7.3. of Annex IX to REACH (Extended one-generation reproductive toxicity study, EOGRTS) is not addressed in this decision, because the information from the Sub-chronic toxicity study (90-day), requested in the present this decision, is relevant for the design of the EOGRTS.

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

3. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

4. Test guidelines, GLP requirements and reporting

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

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

   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: 'How to report robust study summaries'[10].

5. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account 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.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

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

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[11].

6. List of references of the ECHA Guidance and other guidance/ reference documents[12]

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 in this decision.

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 in this decision.

ECHA Read-across assessment framework (RAAF, 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.
PNEC derivation
Guidance on information requirements and chemical safety assessment, Chapter R.10 (version 1.0, May 2008), referred to as ECHA Guidance R.10 in this decision

OECD Guidance documents[14]

[11] https://echa.europa.eu/manuals
[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 aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

Appendix E: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	Data requirements to be fufilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.