~~Confidential~~

Helsinki, 01 June 2023

Addressees
Registrant(s) of Ethylparaben as listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject to this decision
21/01/2021

Registered substance subject to this decision ("the Substance")
Substance name: Ethyl 4-hydroxybenzoate
EC number: 204-399-4

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

DECISION TAKEN UNDER ARTICLE 41 OF THE REACH REGULATION

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***7 September 2026***.

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. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method: OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487) with the registered substance;

2. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the registered substance if the test listed in section 1 gives a negative result;

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

B. Information required from 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: EU B.26./OECD TG 408) in rats with the registered substance;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance.

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 IX 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;

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.

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.

i. Assessment of the Grouping of substances and 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:

- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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. Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

A. Predictions for toxicological properties

You have provided a read-across justification document in IUCLID Section 13.

You read-across between the structurally similar substances methyl 4-hydroxybenzoate (EC 202-785-7) and propyl 4-hydroxybenzoate (EC 202-307-7), and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties:

"All parabens are readily metabolized to p-hydroxybenzoic acid by esterases in different tissues, thereafter conjugated with sulphate, glucuronide or glycine, and then rapidly excreted in the urine that leads to an negligible systemic exposure to parabens"

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.

[2] 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)

[3] 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

The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

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

Read-across hypothesis contradicted by existing data

Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances. The ECHA Guidance[1] indicates that "*it is important to provide supporting information to strengthen the rationale for the read-across*".

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 of formation of a common (bio)transformation product, i.e. p-hydroxybenzoic acid, from the Substance and the source substances. You further argue that the metabolism of parabenes leads to an negligible systemic exposure to the parabens.

Regarding hydrolysis, in your updated dossier you have provided a study record for the study "Single Oral Dose Toxicity Study in Rats with Methyl 4-hydroxybenzoate, Ethyl 4-hydroxybenzoate, Propyl 4-hydroxybenzoate and Butyl 4-hydroxybenzoate" (2020) and the publication "Application of grouping and read-across for the evaluation of parabens of different chain lengths with a particular focus on endocrine properties" (2021).

To support your read-across hypothesis based on (bio)transformation, you have demonstrated for the Substance that mean plasma concentrations had decreased to between 2.0 and 5.9% of the mean maximum concentrations one hour after dosing, and exposure within the first hour after dosing represents between 50.0 and 70.2% of mean AUC0-t.

This new information demonstrates that systemic exposure to the parent compound takes place, and it contradicts your read-across hypothesis that systemic exposure to parabens is negligible.

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*"[4]. 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, exposure to the parent compound cannot be excluded. For that reason supporting information must include toxicological information to allow comparison of the hazard profiles of your Substance and the source substances (RAAF scenario 2).

[1] Guidance on information requirements and chemical safety assessment (version 6.0, July 2017), Chapter R.6, Section R.6.2.2.1.f

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

In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substances 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 provided with your current dossier update relevant and reliable studies with the source substances. You did not provide any relevant and reliable and studies with the Substance for repeated dose toxicity, in vitro genotoxicity or reproduction toxicity.

Taken together, the data set reported in the technical dossier does not include relevant, reliable and adequate information for the Substance to support your read-across hypothesis.

In the absence of such information the impact of exposure to the parent compound cannot be assessed, and you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Comments on the draft decision

In your comments to the draft decision you argue that due to the demonstrated very close similarities regarding chemical structure, bioavailability, metabolism, toxicokinetics and toxicological profile of methyl, ethyl and propyl 4- hydroxybenzoate, which all point to biological equivalence of all three parabens, the "read-across" approach to fill data gaps on repeated dose toxicity, genotoxicity and reproductive / developmental toxicity on ethyl 4-hydroxybenzoate is scientifically justified and any additional animal testing clearly would be not in line with animal welfare principles.

You agree, however, that a certain exposure to the parent compound might occur, although this exposure would not invalidate your read-across approach as, in your opinion, it has been demonstrated that the three parabenes have similar toxicological profiles.

If exposure to the parent compound cannot be excluded supporting information must include toxicological information to allow comparison of the hazard profiles of your Substance and the source substances (RAAF scenario 2).

ECHA has assessed the availability of toxicological information to allow comparison of the hazard profiles of your Substance and the source substances (bridging data) in its response to your comments. As a starting point Table 4 in your comments (Mammalian toxicity – data matrix) has been examined.

1. Genotoxicity

Only data on mutagenicity in bacteria is available for your Substance. You do not indicate that data from an OECD TG 471 can be used as bridging data for cytogenicity or mutagenicity in mammalian cells. ECHA agrees that data from an OECD TG 471 study cannot be used as bridging information for cytogenicity or mutagenicity in mammalian cells as all three genotoxicity in vitro tests requested address different information requirements. Therefore, there is no bridging information for cytogenicity or mutagenicity in mammalian cells.

2. Repeated dose toxicity

For this information requirement you refer to two studies, Sado (1973) and Matthews (1956). These studies were evaluated in the ECHA decision CCH-D-2114412040-75-01/F and among other things the following issues were raised on their quality:

a. The study by Sado covers only a part of the parameters investigated in an OECD TG 408 study. In addition, the reliability of the parts that are covered is questioned by the low number of animals used, by the lack of information on test materials, and by the lack of verification of doses.
b. The study by Matthews covers only a part of the parameters investigated in an OECD TG 408 study. In addition, the reliability of the parts that are covered is questioned by the lack of information on test materials and by the lack of verification of doses.
c. In your IUCLID dossier you have included two additional studies with reliability 4 from 1929. As there is almost no reporting of these studies they cannot be assessed and therefore not used for bridging purposes.

ECHA concludes that even if the information included in the respective studies by Sado and Matthews were combined, there is still a lack of information for several important parameters, and there are reliability issues in relation to the coverage of the parameters investigated under an OECD TG 408 study. For those reasons there is no acceptable bridging information for repeated dose toxicity.

3. Screening for reproductive/developmental toxicity

For this information requirement you refer to Oishi (2004) as a source of bridging information. However, the study by Oishi exposes only male animals. As there is no information on reproductive parameters in female animals, and no information on functional evaluation of male reproductive capacity and offspring parameters, the study is not an adequate bridging study for parameters investigated in an OECD TG 421 or 422 study.

4. Pre-natal developmental toxicity

For this endpoint you refer to Oishi (2004) as a source of bridging information. However, the study by Oishi exposes only male animals. As there was no mating of animals and no exposure of pregnant females, there is no information on pre-natal developmental toxicity. Therefore the study is not an adequate bridging study for parameters investigated in an OECD TG 414.

In conclusion ECHA disagrees with your claim that bridging information that could justify your read-across approach is available. Therefore you have not provided sufficient supporting information to scientifically justify 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 VIII of REACH

1. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is an information requirement under Annex VIII to REACH (Section 8.4.2.).

You have provided:
- An in vivo mammalian germ cell study: cytogenicity / chromosome aberration (1974) with the analogue substance methyl 4-hydroxybenzoate (EC 202-785-7) as already evaluated by ECHA in the ECHA decision CCH-D-2114412040-75-01/F;
- An in vitro cytogenicity / chromosome aberration study in mammalian cells (1978) with the analogue substance methyl 4-hydroxybenzoate, and
- An in vitro cytogenicity / micronucleus study (2018) with the analogue substance propyl 4-hydroxybenzoate (EC 202-307-7).

As explained in the Appendix entitled "Reasons common to several requests" your adaptation according to Annex XI Section 1.5. is still rejected. Therefore, the information requirement is not fulfilled.

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

Comments to the draft decision
In your comments to the draft decision you disagree to perform this study as you find that your read-across approach should be acceptable.

As explained in the Appendix on Reasons common to several requests the information you provided in your comments is not adequate and therefore your adaptation still does not comply with the general rules of adaptation as set out in Annex XI Section 1.5. on grouping and read-across approach.

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

2. In vitro gene mutation study in mammalian cells

You were requested to submit information derived with the registered substance for In vitro gene mutation study in mammalian cells.

You have provided:
- An in vitro gene mutation study in mammalian cells (2012) with the analogue substance propyl 4-hydroxybenzoate (EC 202-307-7) as already evaluated by ECHA in the ECHA decision CCH-D-2114412040-75-01/F, and
- An in vitro gene mutation study in mammalian cells (2018) with the analogue substance methyl 4-hydroxybenzoate (EC 202-785-7).

As explained in the Appendix entitled "Reasons common to several requests" your adaptation according to Annex XI Section 1.5. is still rejected. Therefore, the information requirement is not fulfilled.

ECHA considers that the in vitro mammalian cell gene mutation tests using the Hprt and Xprt genes (OECD TG 476) and the in vitro mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

Comments to the draft decision
In your comments to the draft decision you disagree to perform this study as you find that your read-across approach should be acceptable.

As explained in the Appendix on Reasons common to several requests the information you provided in your comments is not adequate and therefore your adaptation still does not comply with the general rules of adaptation as set out in Annex XI Section 1.5. on grouping and read-across approach.

Therefore, pursuant to Article 41 of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: In vitro mammalian cell gene mutation test (test method: OECD TG 476 or OECD TG 490), if the test listed in section 1 gives a negative result.

3. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant.

You have provided:
- The study "Lack of spermatotoxic effects of methyl and ethyl esters of p-hydroxybenzoic acid in rats" (2004) and
- A screening for reproductive / developmental toxicity study (2012) with propyl 4-hydroxybenzoate (EC 202-307-7).

These studies were already evaluated by ECHA in the ECHA decision CCH-D-2114412040-75-01/F.

In addition you have provided a screening for reproductive / developmental toxicity (2019) with methyl 4-hydroxybenzoate (EC 202-785-7), and extended one-generation reproductive toxicity studies with propyl 4-hydroxybenzoate (2019) and methyl 4-hydroxybenzoate (2021).

As explained in the Appendix entitled "Reasons common to several requests" your adaptation according to Annex XI Section 1.5. is still rejected. Therefore, the information requirement is not fulfilled.

Comments to the draft decision
In your comments to the draft decision you disagree to perform this study as you find that your read-across approach should be acceptable.

As explained in the Appendix on Reasons common to several requests the information you provided in your comments is not adequate and therefore your adaptation still does not comply with the general rules of adaptation as set out in Annex XI Section 1.5. on grouping and read-across approach.

Therefore, pursuant to Article 41 of the REACH Regulation, you are requested to provide Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: OECD 421/422) in rats, oral route with the registered substance.

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

1. Sub-chronic toxicity study (90-day)

You were requested to submit information derived with the registered substance for sub-chronic toxicity study (90-day).

In response, you provided: the same four repeated dose toxicity studies (rabbit 1929, RL4; dog 1929, RL4; rat 1956; and rat 1973) with the registered substances as already evaluated by ECHA in the ECHA decision CCH-D-2114412040-75-01/F.

In addition you submitted sub-chronic toxicity studies with the analogue substances propyl 4-hydroxybenzoate (2018) and methyl 4-hydroxybenzoate (2019).

As explained in the Appendix entitled "Reasons common to several requests" your adaptation according to Annex XI Section 1.5. is still rejected. Therefore, the information requirement is not fulfilled.

Comments to the draft decision
In your comments to the draft decision you disagree to perform this study as you find that your read-across approach should be acceptable.

As explained in the Appendix on Reasons common to several requests the information you provided in your comments is not adequate and therefore your adaptation still does not comply with the general rules of adaptation as set out in Annex XI Section 1.5. on grouping and read-across approach.

Therefore, pursuant to Article 41 of the REACH Regulation, you are required to provide Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats with the registered substance.

2. 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 provided:

- Developmental toxicity studies (1972, 1973) in rat, mouse, hamster and rabbit with the analogue substance methyl 4-hydroxybenzoate (EC 202-785-7) as already evaluated by ECHA in the ECHA decision CCH-D-2114412040-75-01/F.

In addition you submitted a developmental toxicity in rat (2018) with the analogue substance propyl 4-hydroxybenzoate (EC 202-307-7).

As explained in the Appendix entitled "Reasons common to several requests" your adaptation according to Annex XI Section 1.5. is still rejected. Therefore, the information requirement is not fulfilled.

Comments to the draft decision
In your comments to the draft decision you disagree to perform this study as you find that your read-across approach should be acceptable.

As explained in the Appendix on Reasons common to several requests the information you

provided in your comments is not adequate and therefore your adaptation still does not comply with the general rules of adaptation as set out in Annex XI Section 1.5. on grouping and read-across approach.

Therefore, pursuant to Article 41 of the REACH Regulation, you are required to provide Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.

Appendix C: 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[5].

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[6].

[5] https://echa.europa.eu/practical-guides
[6] https://echa.europa.eu/manuals

Appendix D: Procedure

In accordance with Article 42(1) of the REACH Regulation, the Agency examined the information submitted by you in consequence of decision of 16 July 2018 ("the original decision"). The Agency considered that this information did not meet one or more of the requests contained in that decision. A new decision-making process was initiated under Article 41 of the REACH Regulation.

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.

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.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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 E: List of references - ECHA Guidance[7] 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)[8]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[9]

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[10]

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

Appendix F: 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.