~~Confidential~~

Helsinki, 22 August 2022

Addressees
Registrant(s) of DBO_JS_1 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
07/10/2020

Registered substance subject to this decision ("the Substance")
Substance name: Dibenzyl ether
EC number: 203-118-2

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

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***29 August 2024***.

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

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

1. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. A/B/C/D/E/F/OECD TG 301A/B/C/D/E/F or EU C.29./OECD TG 310)

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

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

3. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requirements for testing and reporting new tests under REACH, see Appendix 4.

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

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

1. Ready biodegradability

1 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

1.1. Information provided

2 You have provided a study similar to OECD TG 301C.

1.2. Assessment of information provided

3 We have assessed this information and identified the following issues:

4 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following requirements must be met:

a) The test duration is normally 28 days. The duration of the test may only be shortened if the biodegradation curve has reached a plateau for at least three consecutive determinations;

b) The results of measurements at each sampling point in each replicate is reported in a tabular form;

c) The test material is the sole source of added organic carbon (validity criterion).

5 Your registration dossier provides a study similar to OECD TG 301C showing the following:

a) The test duration was 14 days and you have not demonstrated that a plateau was reached for at least three consecutive determinations;

b) The results of measurements at each sampling point in each replicate is not reported;

c) The test material contains benzaldehyde at concentration of 8 %, which may constitute an additional source of carbon beyond the test substance.

6 Based on the above, the duration parameter of OECD TG 301 is not covered, the validity criterion of OECD TG 301 in respect of the sole carbon source is not met and the reporting of the study is not sufficient to conduct an independent assessment of its reliability including fulfilment of validity criteria of OECD TG 301, beyond the sole source of carbon.

7 Therefore, the requirements of OECD TG 301 are not met. On this basis, the information requirement is not fulfilled.

2. Growth inhibition study aquatic plants

8 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

2.1. Information provided

9 You have provided a study according to OECD TG 201.

2.2. Assessment of information provided

10 We have assessed this information and identified the following issues:

11 To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

12 Your registration dossier provides an OECD TG 201 showing the following:

a) the results of algal biomass determined in each flask at least daily during the test period are not reported;

13 Based on the above, ECHA is not able to conduct an independent assessment of its reliability including fulfilment of validity criteria of OECD TG 201.

14 Therefore, the requirements of OECD TG 201 are not met. On this basis, the information requirement is not fulfilled.

15 In the comments to the draft decision, you have attached a copy of a Robust Study Summary (RSS). The RSS includes the information listed above as missing in the dossier. You have proposed to update your dossier with the modified RSS.

16 The information provided as part of your comments addresses the incompliances identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

Reasons related to the information under Annex VIII of REACH

3. Screening for reproductive/developmental toxicity

17 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII to REACH (Section 8.7.1.), if there is no evidence from analogue substances, QSAR or in vitro methods that the substance may be a developmental toxicant.

3.1. Information provided

18 You have adapted the standard information requirement(s) mentioned above according to Annex XI, Section 1.2. of REACH (weight of evidence).

19 In support of your adaptation, you have provided the following sources of information:

(i) an experimental study, multi-generation reproductive toxicity (4 gen), by Kieckebusch W & Lang K, no guideline provided, 1960, with the analogue substance benzoic acid , EC No. 200-618-2;

(ii) an experimental study, screening for reproductive / developmental toxicity according to OECD TG422, 1999, with the analogue substance 4-hydroxybenzoic acid, EC no. 202-804-9;

(iii) a study waiver: *"Dibenzyl ether (CAS 103-50-4) No studies on reproduction are available for dibenzyl ether (CAS 103-50-4)…[…]*

1) Waiving according to Annex XI, 1.5 [2] based on read-across with the 4-generation study of benzoic acid and the reproductive/developmental screening test of 4-hydroxybenzoic acid …[…]

2) Waiving based on read-across with ditolyl ether (Annex XI 1.5 [1]) and use of a pre-natal developmental toxicity study (Annex VIII, 8.7.1 column 2).

3) Waiving based on Weight-of-evidence with available reproductive data on dibenzyl ether (Annex XI, 1.2))…[…]

20 You have also submitted a Column 2 adaptation using source of information (iii)(2).

3.2. Assessment of the information provided

21 We have assessed this information and identified the following issues:

3.2.1. Weight of evidence

22 Based on the presented sources of information, you argue that the available data gives sufficient information to conclude on reproductive toxicity because you claim that no particular concern was identified within the supporting information from two potential metabolites (study (i and ii), from the analogue substance ditolyl ether [3] and data on reproductive organs from a repeated dose toxicity study with the substance.

23 Annex XI, Section 1.2 states that there may be sufficient 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.

24 According to ECHA Guidance R.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 and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, 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.

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

26 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 investigated by the required study.

27 Irrespective of the above mentioned deficiencies on the documentation, which in itself could lead to the rejection of the adaptation, ECHA has assessed the provided sources of information.

28 Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 7.8.1 at Annex VIII includes similar information that is produced by the OECD TG 421/422.

29 To fulfil this information requirement, normally a study performed according to EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be provided. OECD TGs 421/422 require to investigate the following key elements: 1) sexual function and fertility, 2) toxicity to offspring, and 3) systemic toxicity.

3.2.1.1. Sexual function and fertility and Toxicity to offspring

30 Sexual function and fertility on both sexes must include information on mating, fertility, gestation (length), maintenance of pregnancy (abortions, total resorptions), parturition, lactation, organ weights and histopathology of reproductive organs and tissues, litter sizes, nursing performance and other potential aspects of sexual function and fertility.

31 Information on pre- and perinatal developmental toxicity is reflected by litter sizes, postimplantation loss (resorptions and dead foetuses), stillborns, and external malformations, postnatal developmental toxicity reflected by survival, clinical signs and body weights of the pups (or litters), and other potential aspects related to pre-, peri- and postnatal developmental toxicity observed up to postnatal day 13.

32 Studies (i), (ii), and the PNDT study with ditolylether (iii.2) provided under the waiver, provide information on sexual function and fertility as well as toxicity to offspring. However the repeated dose toxicity study included in the waiver (iii.3) with the substance does not contain the information on the above.

33 While the sources of information (i), (ii) and (iii.2) provide relevant information, these sources of information have the following deficiencies affecting their reliability.

3.2.1.1.1. Reliability of the Read-across approach

34 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.

35 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

Predictions for toxicological properties

36 You provide a read-across justification document in IUCLID Section 7.8.1.

37 You predict the properties of the Substance from information obtained from the following source substance(s):

[1] benzoic acid, EC No. 200-618-2
[2] 4-hydroxybenzoic acid, EC No. 202-804-9

38 You provide the following reasoning for the prediction of toxicological properties: ”Dibenzyl ether is predicted to metabolize into benzylalkohol, benzaldehyde, benzoic acid and hydroxylated compounds e.g. 4-hydroxybenzoic acid. Taking into account all available data on reproductive toxicity/fertility and on repeated dose toxicity (examinations of reproductive organs) for dibenzyl ether, the benzoates group and 4-hydroxybenzoic acid there is sufficient and reliable data, including a reliable 4-generation reproduction study with benzoic acid and an OECD combined repeat dose and reproductive/developmental toxicity study with 4-hydroxybenzoic acid to conclude that the predicted metabolites are not toxic to fertility”.

Hypothesis A:

39 ECHA understands that your read-across hypothesis is based on the formation of common (bio)transformation products. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

40 Furthermore, you predict the properties of the Substance from information obtained from the following source substance:

[3] ditolyl ether EC No. 248-948-6

41 You provide the following reasoning for the prediction of toxicological properties: ”Dibenzyl ether is chemically similar to ditolyl ether based on structural similarity and a common functional ether group. A read-across between dibenzyl ether and ditolyl ether is justified based on chemical and toxicological similarities. Although no screening test for reproductive/developmental toxicity is available for both compounds a comprehensive developmental toxicity study according to OECD Guideline 414 is available for ditolyl ether. Since no screening test for reproductive/developmental toxicity (OECD 421 or 422) is required according REACH Annex VIII when a pre-natal developmental toxicity study is available, the developmental toxicity data of ditolyl ether are very relevant to waive the screening test for reproductive/developmental toxicity.”

Hypothesis B:

42 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

43 We have identified the following issue(s) with the prediction(s) of toxicological properties in regard to the hypothesis on the formation of common (bio)transformation products [hypothesis A].

Missing supporting information on the formation of common compound regarding source substances [1] and [2]

44 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" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.). 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).

45 Supporting information must include toxicokinetic information on the formation of the common compound.

46 As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance to common compounds, the source substances. In this context, information characterising the rate and extent of the (bio)transformation of the Substance is necessary to confirm the formation of the proposed (bio)transformation product and to assess the impact of the exposure to the parent compounds.

47 In support of your hypothesis you have provided in IUCLID section 7.1.1

- A QSAR toolbox report for Dibenzyl ether CAS103-50-4

48 At the end of the QSAR report it is concluded that the "Based on the data generated a read-across will not be performed. Short explanation why/why not: The analogous substances identified and proposed by the toolbox for a read-across are structurally not quite similar to the target compound".

49 In the QSAR report, the hydrolysis simulator within the toolbox indicates benzyl alcohol (CAS No 100-51-6), benzyl aldehyde (CAS 100-52-7) and benzoic acid (CAS 65-85-0) as potential metabolites.

50 However, no QPRF nor QPRF is provided although this is necessary to assess the adequacy and reliability of the QSAR information (ECHA Guidance R.6.1.6.3).

51 Further, there is no evidence on metabolites and their fate to support your hypothesis.

52 Therefore, the data set reported in the technical dossier does not include relevant, reliable and adequate information for the Substance and of the source substance(s) to support your read-across hypothesis A.

53 In the absence of reliable information, 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.

54 In order to further support the hypothesis on metabolism to the above mentioned source substances [1] and [2] (hypothesis A) you provide a Toxicokinetic report explaining the fate of a similar substance, namely 3,5-di-tert-Butyl-4-hydroxybenzyl ether [4]. However we have identified the following issue.

Read-across hypothesis may be contradicted by existing data

55 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 Guidance on IRs and CSA, Section R.6.2.2.1.f. 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).

56 As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance and of the source substance(s) to a common compound(s).

57 You have provided in IUCLID section 7.1.1:

- Toxikokinetic report "*Information/Assumptions Regarding Toxicokinetics and metabolism for Dibenzyl ether (CAS-No. 103-50-4)*"

58 It contains the experimental outcome that only about one third of the described substance (3,5-di-tert-Butyl-4-hydroxybenzyl ether, [redacted]) is metabolised at all: "[… is absorbed in rats based on results in a 14C labelelled study. 65% of the laellbed substance could be found [undigested] in faeces whereas 30.0% to 3,5-d.i-tert.butyl-4-hydroxy-benzoic acid, 3.5% to unidentified polar constituent(s), 1·4% to 3,5-d.i-tert.-butyl-4- hydroxybenzaldehyde and 0.1% to 3,3',5,5'-tetra-tert.-butyl-4-,4'-stilbene-quinone were detected." There is no information on the time frame by which these results were obtained.

59 You further explain that "the water solubility of dibenzyl ether is much higher and the log Pow much lower. Therefore it is expected, that dibenzyl ether is absorbed to a higher extend from the gastro-intestinal tract and also excreted to a higher extend via the urine compared with di-(3,5-di-tert.-butyl-4-hydroxy-benzyl)ether. The accumulation in body fatty tissues is expected for dibenzyl ether to be lower in comparison with di-(3,5-di-tert.-butyl-4-hydroxy-benzyl)ether due to lower lipophilicity."

60 You have not provided a numerical comparison of the water solubility and log Pow of substance [4] and the Substance, and no quantification of your assumption. You have not provided any further information on the toxicity profile of substance [4]. In your dossier the water solubility of the Substance is reported as 0.042 g/L (20°C) and the partition coefficient as 3.31.

61 Your explanation of differences in water solubility and log Pow does not support the assumption that the Substance would be metabolised entirely different from substance [4]. Instead, the reported physicochemical parameters indicate that the Substance is lipophilic as well and does not exclude that it is as lipophilic, or more, as substance [4]. Therefore, you have not established whether substance [4] and the Substance behave similar or differently regarding the metabolism to common compounds.

62 Furthermore, we have identified the following issue(s) with the prediction(s) of toxicological properties in regard to the hypothesis that different compounds have the same type of effects [hypothesis B].

Missing supporting information to compare properties of the substances

63 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" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.). 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).

64 Supporting information must include bridging studies to compare properties of the Substance and source substances.

65 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 substances 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).

66 For the source substance, you provide the study used in the prediction in the registration dossier. Apart from that study, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects. In addition, you have not explained the impact of the structural differences regarding the CH_2 group (activated aliphatic methylene group between the aromatic ring system and the ether bound) adjacent to the ether link which is not present in the source substance [3] nor provided information that would support such explanation.

67 In the absence of such information, 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.

3.2.1.1.2. Conclusion on the read-across approach

68 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approach under Annex XI, Section 1.5. is rejected.

3.2.1.2. Systemic toxicity

69 Information on systemic toxicity includes clinical signs, survival, body weights, food consumption, haematology, clinical chemistry, organ weights and histopathology of non-reproductive organs and other potential aspects of systemic toxicity in the parental generation up to postnatal day 13.

70 The four studies you submitted provide relevant information on systemic toxicity, but studies included under the data waiver (iii.2 and iii.3) do not cover systemic toxicity up to postnatal day 13. However, the reliability of sources of information i, ii and iii.2 is significantly affected for the reasons explained above.

3.2.1.3. Conclusion on WoE

71 In summary the studies i) and ii) and iii.2) provide relevant information on the three listed key parameters. However, as explained above they are not reliable.

72 The study with the Substance under iii.3 only provides partly relevant information on systemic toxicity and is lacking relevant information on the other key parameters as explained above.

73 Based on the assessment above, your weight of evidence adaptation provide relevant information but it does not include reliable sources of information to conclude on most key investigations of the property reproductive toxicity.

74 Accordingly, 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 421/422 study. Therefore, your adaptation is rejected and the information requirements is not fulfilled.

75 Therefore you adaptation is rejected and information requirement is not fulfilled.

3.2.2. Column 2 adaptation

76 Under Section 8.7., Column 2 of Annex VIII to REACH, the study does not need to be conducted if a pre-natal developmental toxicity study (OECD TG 414) is already available.

77 The study iii.2 is a pre-natal developmental toxicity study study.

78 However, for the reasons explained above the study is not reliable.

79 Therefore, your adaptation is rejected.

3.3. Specification of the study design

80 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.

81 The study must be conducted with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

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

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

The compliance check was initiated on 8 July 2021.

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

ECHA took into account your comments and amended the deadline.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 12 to 24 months from the date of adoption of the decision. You justified the request by providing documentation from a test laboratory.

On this basis, ECHA has extended the deadline to 24 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 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- 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.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[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.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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[2].

1.2. 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 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[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals