~~Confidential~~

Helsinki, 08 June 2023

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

Date of submission for the jointly submitted dossier subject to this decision
30/06/2020

Registered substance subject to this decision ("the Substance")
Substance name: Bis(dibutyldithiocarbamato-S,S')copper
EC number: 237-695-7

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 42(1) OF THE REACH REGULATION

Under Article 42(1) of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***16 September 2024***.

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

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

1. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: OECD TG 305, dietary exposure)

Reasons for the request(s) are explained in the Appendix entitled "Reasons to request information required under Annexes IX of REACH".

Information required depends on your tonnage band

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

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

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 A: Reasons to request information required under Annex IX of REACH

1 Bioaccumulation in aquatic species

Bioaccumulation in aquatic species is an information requirement under Annex IX to REACH (Section 9.3.2.).

1.1 Information provided

You have adapted this information requirement by using Column 2 of Annex IX, Section 9.3.2. To support the adaptation, you have provided following information: *"According to ECHA's guidance on information requirements and chemical safety assessment chapter R.11 "PBT/vPvB assessment" (v3.0 ; June 2017 ; p. 66), "The option of waiving the bioaccumulation test according to Column 2 of REACH Annex IX can only be taken if the information from the experimental test is not required for the conclusion on the PBT/vPvB-properties". As a matter of fact, the registered substance and its relevant degradation products are not persistent according to the criteria laid down under annex XIII of REACh regulation. Thus, none of them is PBT/vPvB. Bioaccumulation studies are therefore not needed. The bioaccumulation study on the registered substance is also waived in accordance with column 2 of annex IX of REACh and the ITS advocated in ECHA's guidance R.11. This waiver is also in accordance with article 25 of REACh which aims to minimize the use of vertebrates in regulatory testing."*

1.2 Assessment of information provided

We have assessed this information and identified the following issues:

1.2.1 Reference to the PBT/vPvB assessment

A registrant may only adapt this information requirement based on the rules listed in the Column 2 of Section 9.3.2 of Annex IX or on the general rules set out in Annex XI.

It is noted that neither the rules listed in the Column 2 of Section 9.3.2 of Annex IX nor the general rules set out in Annex XI allow omitting the need to submit information on bioaccumulation if this is not necessary for the PBT/vPvB assessment of the Substance.

Therefore, your adaptation referring to the needs of the PBT/vPvB assessment is rejected.

For the sake of completeness, ECHA disagrees with your conclusion of the PBT/vPvB assessment.

The substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.) if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it meets the criteria P/vP as set out in Annex XIII, *i.e.* degradation half-life >40 days in fresh or estuarine water and/or >60 days in marine water and/or >120 days in fresh or estuarine sediment or in soil and/or >180 in marine sediment / >60 days in marine, fresh or estuarine water and/or >180 days in marine, fresh or estuarine sediment or in soil;
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a high potential to partition to lipid storage (*e.g.* log K_{ow} > 4.5);
  - for some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid.

Your registration dossier provides the following:

- the Substance is not readily biodegradable (0% degradation after 28 days in OECD TG 301F);

- the Substance meets the P/vP criteria:

  According to ECHA guidance R.11 (Section R.11.4.1.1.3), Non-Extractable Residues (NER) have to be considered as non-degraded substance unless demonstrated that a certain part of the residues can be considered to be irreversibly bound.

  Based on the sediment simulation study (OECD TG 308) provided in the dossier, you estimated that the half-life of the Substance in the total system is 13.6 days for the Goose river sediment and 22.1 days for the Golden lake sediment both at 12°C. The results from the sediment simulation study show that a substantial amount of NER are formed: by the end of the test in the Goose river system 35.8% of applied radiocarbon (AR) and 34.3% AR in the Golden Lake system.

  For the estimation of the half-lives you considered NER as irreversibly bound or degraded substance based on the fact that "*The data generated during the study demonstrates that the bound material is not generally remobilizable. Only a small fraction (approximately 10%) of the bound material at the end of the study was mobilized upon addition of the methanol extraction, and having performed extractions with several solvents of differing polarity and dielectric constants, any further extractions would be expected to mobilize an even smaller fraction of the bound material. Additionally, the extractability increased to a maximum at 7-34 days, then decreased at the end of the study. This, in combination with increasing formation of 14CO2 during the study, would indicate that the bound material is generated primarily by binding of metabolites rather than by binding of the test substance.*"

  However, you have not provided sufficient substantiation. For example, no exhaustive extraction methods such as Soxhlet extraction as a last extraction step was used which could demonstrate irreversible bounding. Therefore, you have not sufficiently demonstrated that the NER are irreversibly bound or degraded substance. Accordingly, the total non-extractable residues must be considered as non-degraded Substance.

  If the NER is considered as non-degraded Substance, the Substance half-life at 12 °C would exceed the vP criterion (for instance, half-life of app. 333.5 days is estimated by CAKE version 3.4 model for the Goose river sediment at 12 °C).

- the Substance has a high potential to partition to lipid storage (Log K_{ow} of 4.7 based on shake-flask method);
- furthermore, due to the presence of copper the Substance is metallo-organic and "*the bioaccumulation potential cannot unequivocally be established by the n-octanol/water partitioning*"[2].

In the comments to the draft decision you explain that previously little information on extraction of residues was available and that NERs were considered by you as irreversibly bound for the interpretation of the simulation study results. Then you explain that "*additional work were performed by the lead Registrant on bioNER determination which lead to a half-life of 196 days*" on the basis of results of sediment simulation study. Therefore, you note that "*from the Registrant point of view the value of 333.5 days is not accurate*".

However, you did not provide the actual information (for instance, on "*bioNER estimation*") with your comments. In the absence of such information ECHA cannot evaluate the data and consequently draw conclusions for the compliance with the information requirement. Further, "*a half-life of 196 days*" also indicates that the vP criterion is met for the Substance.

[2] REVISED INTRODUCTION TO THE OECD GUIDELINES FOR TESTING OF CHEMICALS, SECTION 3, PART 2: BIOACCUMULATION AND BEHAVIOR IN SOILS AND SEDIMENTS, 23 March 2006.

Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance.

1.2.2 The provided adaptation does not meet the criteria of Annex IX, Section 9.3.2., Column 2, first indent

Under Annex IX, Section 9.3.2., Column 2, first indent, the study may be omitted if the substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes. A low log Kow (*i.e.* log Kow < 3) on its own may be used to show low potential for bioaccumulation if bioaccumulation of the substance is solely driven by lipophilicity. Furthermore, Guidance on IRs and CSA, Section R.7.8.5. explains that there is no scientific basis to define molecular characteristics that would render a substance unlikely to cross biological membranes. In this context, the indicators used for low likelihood of a high bioaccumulation potential (Guidance on IRs and CSA, Section R.11, Figure R.11-4) must be considered, including:

- physico-chemical indicators of hindered uptake due to large molecular size (*e.g.* D_{max} > 17.4 Å and MW > 1100 or MML > 4.3 nm) or high octanol-water partition coefficient (log K_{ow} > 10) or low potential for mass storage (octanol solubility (mg/L) < 0.002 x MW), and
- supporting experimental evidence of hindered uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

First, log Kow of the substance reported in the dossier is 4.7 and MW is ca. 472.

Taking this into account, you have not demonstrated that the Substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes.

Second, copper is present in the Substance as well as an organic moiety. So, the Substance is a metallo-organic and as noted above, "*the bioaccumulation potential cannot unequivocally be established by the n-octanol/water partitioning*".

In your comments to the draft decision you first, acknowledge that "*the adaptation of the bioaccumulation study is no more compliant […] the information need to be updated*". Then you provide and note the following regarding low potential to cross biological membranes:

- physico-chemical indicators which you consider supportive of hindered uptake: solubility in water below 1 mg/l;
- that there is no experimental toxicokinetic study available, but:
  - "*According to the QSAR pkCSM the registered substance is expected to be well absorbed by oral route and inhalation (100%), but lesser by dermal route (10%)*"
  - high value of log Kow (>4) and the low solubility in water are generally favourable for a low oral absorption;
  - "*According to the IH skin perm (QSAR), the dermal absorption of the substance is 0.1%*"
- 90-days repeated-dose toxicity study with rats, a long-term toxicity studies in aquatic invertebrates/fish/algae and that no toxic effects were observed in either of those studies;
- that the Substance "*is likely to dissociate into copper and dithiocarbamate*" and "*since no toxicity were visible during*" testing of the Substance, the dissociation of the Substance in fish is not verified; you conclude that "*This can be seen as another line of evidence indicating that CDBC* (the Substance) *passage through biological barriers is unlikely*";
- data on bioaccumulation for similar substances collected by using QSAR toolbox.

Taking this into account, ECHA nevertheless considers the available information on the

Substance do not support that the Substance is unlikely to cross biological membranes.

- As already explained above, log Kow and MW of the Substance do not indicate that the substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes. Furthermore, low solubility in water also does not indicate unlikelihood to cross biological membranes and low bioaccumulation potential. For instance, OECD TG 305 indicates that bioaccumulation testing via aqueous exposure may become increasingly difficult for a substances with a water solubility below 0.1-0.01 mg/l but then recommends testing via dietary route of exposure.
- Information on QSAR predicted good absorption of the Substance via oral route and inhalation, which does not support the conclusion that the Substance is unlikely to cross biological membranes.
- While lack of toxicity observed in the above listed studies with the Substance may indicate that copper was not released from the Substance, you have not explained how the absence of release of copper should indicate that the passage of the Substance "through biological barriers is unlikely".
- There is also no supporting evidence provided to substantiate your claim that the Substance "*is likely to dissociate into Copper and dithiocarbamate*".
- As explained in the Section 1.3.1 below, the properties of the Substance cannot be reliably predicted from the data on the similar substances (source substances) collected by using QSAR toolbox.

On that basis the information provided with your comments to the draft decision does not allow to conclude that the Substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes.

Therefore, your adaptation is rejected.

1.2.3 The provided adaptation does not meet the criteria of Annex IX, Section 9.3.2., Column 2, second indent

Under Annex IX, Section 9.3.2., Column 2, second indent, the study may be omitted if direct and indirect exposure of the aquatic compartment is unlikely. Therefore, it must be demonstrated that there is no release to the environment at any stage in the life cycle of the substance (Guidance on IRs and CSA, Section R.7.10.4.5.).

In your chemical safety report (version from 23rd January 2020) you report releases to the environment (e.g. 0.041 kg/day release to water and 64.25 kg/day to air for the exposure scenario 1).

This indicates that direct and/or indirect exposure of the aquatic environment is not unlikely.

Therefore, your adaptation is rejected.

1.2.4 The provided adaptation does not meet the criteria of Annex IX, Section 9.3.2., Column 2 or Annex XI

Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under Column 2 of Section 9.3.2 of Annex IX or the general rules of Annex XI.

Therefore your adaptation is rejected.

1.2.5 Assessment of further information provided with your comments to the draft decision

1.2.5.1 Assessment of adaptation based on weight of evidence approach according to Annex XI, section 1.2

In the comments to the draft decision you have provided arguments "*to support its conviction that a bioaccumulation study is not required for the registered substance*". You propose to adapt this information requirement by using weight of evidence (WoE) approach according to Annex XI, Section 1.2 of the REACH Regulation on the basis of low bioaccumulation potential of the Substance. Your conclusion is based on the following arguments:

i. Hydrophobicity of the Substance.
ii. Other descriptors of low potential of bioaccumulation based on:
    1. the unlikelihood to cross biological membranes;
    2. low water solubility and absence of toxicity of the Substance;
    3. considerations based on trans-epithelial electrical resistance (TEER) supported by QSAR predictions for absorption of the Substance;
    4. copper toxicity and bioaccumulation potential;
    5. data on bioaccumulation for similar substances by using QSAR toolbox.

Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

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 on the corresponding information requirement.

ECHA has assessed your adaptation and identified issue(s) addressed below.

Information that can be used to support weight of evidence adaptation for the information requirement of Annex IX, Section 9.3.2. includes similar information that is produced by the OECD TG 305. OECD TG 305 requires the study to investigate the following key parameters:

- the uptake rate constant (k_1) and loss rate constants including the depuration rate constant (k_2), and/or
- the steady-state bioconcentration factor (BCF_{SS}), and/or
- the kinetic bioconcentration factor (BCF_K), and/or
- the biomagnification factor (BMF).

The source of information ii.5 provides information on BCF or BMF of two substances similar to the Substance.

None of other sources provide information on the above key parameters investigated in OECD TG 305.

ECHA acknowledges that in case of very low (no) uptake a substance can be considered to have (very) low uptake rate constant (k_1) and can be considered as not B and not vB.

Therefore, ECHA understands that you consider that due to a low potential to cross biological membranes sources of information ii.1-to ii.4 indicate low (no uptake) of the substance. However, as explained under section 1.2.2 above, the information provided with your comments to the draft decision does not allow to conclude that the Substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes.

While the source of information ii.5 provides relevant information, you did not demonstrate that the information on the similar substance can reliably contribute to an adaptation based on weight of evidence, for the following reasons:

Absence of read-across documentation for the source of information ii.5.

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 include a an explanation why the properties of the Substance may be predicted from information on the source substance(s).

You have provided "matrix created with the QSAR Toolbox" with the Substance and source substances:

1. Dibutylcarbamodithioic acid, CAS 150-11-8;
2. 4,4'-methylene bis(dibutyldithiocarbamate, CAS 10254-57-6;
3. Zinc bis diethyldithiocarbamate, CAS 14324-55-1; and
4. Zinc bis dimethyldithiocarbamate CAS 137-30-4.

However, you have not provided documentation to explain why this information is relevant for the Substance and why the properties of the Substance may be predicted from information on the source substance(s).

For instance, adequate and reliable documentation must include an explanation why the properties of the Substance may be predicted from other substances in the group, i.e. a read-across hypothesis. This hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.). It should explain why the differences in the chemical structures should not influence the bioaccumulation property or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3.).

You have not provided a well-founded hypothesis to establish a reliable prediction for a bioaccumulation property, explaining why the structural differences do not influence toxicokinetics and toxicodynamics of the substances, and thus why the properties (and bioaccumulation property specifically) of the Substance may be predicted from information on the source substances.

Furthermore, adequate and reliable documentation must include robust study summary for each source study used in the adaptation. Robust study summary must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study (Article 3(28)).

You refer to BCF and BMFkgl values for source substances 3 and 2, respectively. You note that those values can be found via the ECHA website. Furthermore, you refer to BCF for the source substance 4 published in the scientific literature.

However, you have not provided detailed information on the methods, results and conclusions, allowing for an independent assessment of the studies. Therefore, you have failed to provide a robust study summary for each source study used in the adaptation as required by Annex XI, Section 1.5.

In the absence of such documentation, the property of the Substance cannot be reliably predicted from the data on the source substances.

Therefore, while source of information ii.5 provides information on BCF or BMF of two substances similar to the Substance, this information cannot be considered a reliable source of information that could contribute to the conclusion on key parameters investigated by the required study.

1.2.5.2 Conclusion on adaptation based on weight of evidence approach according to Annex XI, section 1.2

Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for bioaccumulation in aquatic species.

Furthermore, as concluded under Section 1.2.2 above, the information provided by you does not allow to conclude that the Substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes.

Based on the above, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

1.3 Study design and test specifications

Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (Guidance on IRs and CSA, Section R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted whenever technically feasible. The low water solubility (<1 µg/L) and the high adsorption potential (log K_{ow} of 4.7 / log K_{oc} of app. 6.2 of the Substance indicate significant uncertainty on the feasibility of a study using aqueous exposure. Therefore, in this case, the test is requested to be performed using dietary exposure. You must also attempt to estimate the corresponding BCF value from the dietary test (OECD 305-III) data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO (2017)16).

Appendix B: 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[3].

B. Test material

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 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[4].

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

Appendix C: Procedure

The Substance is listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2020.

In the decision of 28 November 2016 ("the original decision"), ECHA requested you to submit information by 4 June 2019 in an update of your registration dossier.

In accordance with Article 42(1) of the REACH Regulation, the Agency examined the information submitted by you in consequence of that decision. The Agency considered that this information triggered the request for further information. Therefore, 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 request.

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 D: List of references - ECHA Guidance[5] 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)[6]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[7]

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[8]

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

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.