

Helsinki, 28 November 2022

Addressees

Registrant(s) of JS_201-029-3 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision

08/09/2017

Registered substance subject to this decision ("the Substance")

Substance name: Hexachlorocyclopentadiene

EC number: 201-029-3

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 **7 June 2027**.

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

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

1. Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.
2. Soil simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.23./OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.
3. Sediment simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.
4. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: EU C.25./OECD TG 309, EU C.23./OECD TG 307 or EU C.24./OECD TG 308).
5. Bioaccumulation in aquatic species (triggered by Annex I, sections 0.6.1. and 4.; Annex XIII, Section 2.1.; test method: EU C.13./OECD TG 305, aqueous exposure)

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. In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

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.

Authorised¹ 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**

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Reasons related to the information under Annex VIII of REACH**1. Simulation testing on ultimate degradation in surface water**

- 1 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).
- 2 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.). This is the case if the Substance itself or any of its constituent or impurity present in concentration $\geq 0.1\%$ (w/w) or relevant transformation/degradation product meets the following criteria:
 - It is potentially persistent or very persistent (P/vP) as:
 - it is not readily biodegradable (*i.e.* 'months and longer' according to Biowin 3 or Biowin 6 and 'does not biodegrade fast' according to Biowin 5 models prediction), and
 - It is potentially bioaccumulative or very bioaccumulative (B/vB) as:
 - it has a high potential to partition to lipid storage (*e.g.* $\log K_{ow} > 4.5$);
 - It meets the T criteria set in Annex XIII: NOEC or $EC_{10} < 0.01$ mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.
- 3 *1.1. Information provided*
 - 3 Your registration dossier provides the following:
 - The Substance is not readily biodegradable ("months and longer" based on Biowin 3 and Biowin 6 and "does not biodegrade fast" based on Biowin 5 model predictions);
 - The Substance has a high potential to partition to lipid storage ($\log K_{ow}$ of 5.04);
 - The Substance is classified as STOT RE 1.
 - 4 Under Section 5.3.1 of your IUCLID dossier, you have further provided a bioaccumulation study conducted according to the OECD 305 (Bioconcentration: Flow-through Fish Test). Based on the results of this study (*i.e.* BCF = 11), you conclude that the Substance is not B/vB ($BCF < 2000/5000$).
 - 5 However, the information on this study is not considered reliable for the following reasons:
 - 6 To fulfil the information requirement, a study must comply with the OECD TG 305 (Article 13(3) of REACH). Therefore, the following specifications must be met:
 - a) the analytical method used for the quantification of the test material in the test solutions and in fish tissues is described. The recovery efficiency, precision, limits of determination (*i.e.* detection and quantification) and working range are reported;
 - b) the BCF is based on the total concentration in the fish (*i.e.* per total wet weight of the fish). Tissue and/or organ-specific BCFs are only regarded as additional (optional) parameters;

- c) the lipid content measured at least before the beginning and at the end of the uptake phase and the method used for its determination are reported;
- d) individual fish wet weights and total lengths for all sampling intervals are provided, and be linked to the analysed chemical concentration for that individual. The data are used to correct the BCF for growth dilution;
- e) tabulated test material concentration data in individual fish and water (including mean values for test group and control, standard deviation and range, if appropriate) for all sampling times are provided;

- 7 From a) to e) none of the information listed above is reported. Therefore, ECHA cannot verify whether the requirements of the OECD TG 305 are met. Consequently, the information on the bioaccumulation study which you provided is not adequate to conclude on the bioaccumulation potential.
- 8 Nevertheless, based on the other available information presented above (i.e. log Kow of 5.04) on the Substance indicates that it is a potential PBT/vPvB substance.
- 9 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.
- 10 In your comments to the draft decision you have indicated that there are sufficient information on bioaccumulation provided in your comments supporting that the Substance is not bioaccumulative. On this basis you indicate that further degradation testing should be avoided.
- 11 ECHA acknowledges your comments and assessed the information provided on bioaccumulation under Request 5. However, as explained under Request 5 the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

1.2. Study design and test specifications

- 12 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):
- 1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
 - 2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.
- 13 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).
- 14 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.
- 15 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded

Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

- 16 Relevant transformation/degradation products are at least those detected at $\geq 10\%$ of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

2. Soil simulation testing

- 17 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).
- 18 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).
- 19 As already explained in section 1 above, the Substance is a potential PBT/vPvB substance.
- 20 Further, the Substance has low water solubility (1.3 mg/L), high partition coefficient (Log Kow of 5.04) and high adsorption coefficient (Log Koc of 4.06), indicating high potential to adsorb to soil.
- 21 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil represents a relevant environmental compartment.
- 22 In your comments to the draft decision you have indicated that there are sufficient information on bioaccumulation provided in your comments supporting that the Substance is not bioaccumulative. On this basis you indicate that further degradation testing should be avoided.
- 23 ECHA acknowledges your comments and assessed the information provided on bioaccumulation under Request 5. However, as explained under Request 5 the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

2.1. Study design and test specifications

- 24 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):
- 1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
 - 2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

- 25 In accordance with the specifications of the OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (i.e. varying in their organic content, pH, clay content and microbial biomass).
- 26 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 307.
- 27 In accordance with the specifications of the OECD TG 307, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.
- 28 Relevant transformation/degradation products are at least those detected at $\geq 10\%$ of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 307; Guidance on IRs and CSA, Section R.11.4.1.).

3. Sediment simulation testing

- 29 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).
- 30 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).
- 31 As already explained in section 1 above, the Substance is a potential PBT/vPvB substance.
- 32 Further, the Substance has low water solubility (1.3 mg/L), high partition coefficient ($\log K_{ow}$ of 5.04) and high adsorption coefficient ($\log K_{oc}$ of 4.06), indicating high potential to adsorb to sediment.
- 33 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, sediment represents a relevant environmental compartment.
- 34 In your comments to the draft decision you have indicated that there are sufficient information on bioaccumulation provided in your comments supporting that the Substance is not bioaccumulative. On this basis you indicate that further degradation testing should be avoided.
- 35 ECHA acknowledges your comments and assessed the information provided on bioaccumulation under Request 5. However, as explained under Request 5 the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

3.1. Study design and test specifications

- 36 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):
- 1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
 - 2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.
- 37 In accordance with the specifications of the OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.
- 38 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.
- 39 In accordance with the specifications of the OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.
- 40 Relevant transformation/degradation products are at least those detected at $\geq 10\%$ of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 308; Guidance on IRs and CSA, Section R.11.4.1.).

4. Identification of degradation products

- 41 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).
- 42 As already explained in section 1 above, the Substance is a potential PBT/vPvB substance.
- 43 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.
- 44 In your comments to the draft decision you have indicated that there are sufficient information on bioaccumulation provided in your comments supporting that the Substance is not bioaccumulative. On this basis you indicate that further degradation testing should be avoided.
- 45 ECHA acknowledges your comments and assessed the information provided on bioaccumulation under Request 5. However, as explained under Request 5 the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

4.1. Study design and test specifications

- 46 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You must obtain this information from one of the degradation studies requested in Requests 1, 2 or 3.
- 47 To determine the degradation rate of the Substance, the requested study according to the OECD TG 309 (Request 1) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).
- 48 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308/307 (Requests 2 and 3) must be conducted at 12°C and at test material application rates reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (e.g. 10 times).

5. Bioaccumulation in aquatic species

- 49 Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1 and 4 to REACH).
- 50 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).
- 51 As already explained in section 1 above, the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species.
- 52 Section 1 above also includes the reasons for considering the information on the bioaccumulation study from your registration dossier not adequate and therefore not meeting the information requirement.
- 53 In your comments to the draft decision you have proposed to adapt this information requirement according to Annex XI, Section 1.2. of REACH (weight of evidence) and you refer to the conclusions of the EU RAR on this property of the Substance. In support of your adaptation, you have provided the following sources of information:
- A bioaccumulation study in fish (Veith, 1974, 1984)
 - A bioaccumulation study in fish (Spehar et al., 1979), that is currently in the dossier
 - A bioaccumulation study in fish (Podowski and Khan, 1979)
 - A bioaccumulation study in fish (Podowski and Khan, 1984)
 - A bioaccumulation study in fish (Freitag et al., 1982, 1984, 1985)
 - A bioaccumulation study in fish (Kotzias et al., 1980)
 - A bioaccumulation study in algae (Geyer et al., 1984; Freitag et al., 1982, 1984, 1985)
 - A bioaccumulation study in algae (Kotzias et al., 1980)

54 ECHA has assessed the information against the requirement in OECD TG 305. The information you have provided in your comments addresses the incompliances identified in this decision for this information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

5.1. Study design and test specification

55 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 unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test material in water cannot be maintained within $\pm 20\%$ of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

56 This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH.

57 You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test 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).

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 23 August 2021.

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

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

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.

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.

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]
[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 summaries².

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 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 dossiers³.

² <https://echa.europa.eu/practical-guides>

³ <https://echa.europa.eu/manuals>

2. General recommendations for conducting and reporting new tests

2.1. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.