~~Confidential~~

Helsinki, 31 May 2024

Addressees
Registrants of JS_DCA_79-43-6 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
02 February 2021

Registered substance subject to this decision ("the Substance")
Substance name: Dichloroacetic acid
EC/List number: 201-207-0

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 ***6 September 2027***.

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

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

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

2. 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).

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

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

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210).

5. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25/OECD TG 309) at a temperature of 12°C.

6. Identification of degradation products (Annex IX, Section 9.2.3.; test method: EU C.25/OECD TG 309)

The reasons for the requests 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 request(s)
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 request(s)

Reasons related to the information under Annex VII of REACH

1. Growth inhibition study aquatic plants

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

1.1. Information provided

2 You have provided:

(i) a toxicity to aquatic algae and cyanobacteria according to ASTM E1218-04 (2014) with the Substance;

(ii) a non guideline toxicity to aquatic algae and cyanobacteria (1982) with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided studies do not meet the specifications of the test guideline

3 To fulfil the information requirement, a study must comply with OECD TG 201 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Key parameter measured

a) the concentrations of the test material leading to a 50 % and 0% (or 10%) inhibition of growth at the end of the test are estimated. Growth must be expressed as the logarithmic increase in biomass (average specific growth rate) during the exposure period;

In studies (i) and (ii), growth is expressed based on cell number and based on biomass, respectively.

Characterisation of exposure

b) the test media prepared specifically for analysis of exposure concentrations during the test is treated identically to those used for testing (i.e. inoculated with algae and incubated under identical conditions);

For study (ii), you state that the analytical verification of exposure concentrations was not conducted. However, you also claim that "[i]*n a separate experiment, it was demonstrated by DOC anylsis that that the recovery was 93%.*" but you have not specified whether the above condition was met.

Reporting of the methodology and results

c) adequate information on the identity of the test material is provided;

For study (ii), you have not specified the purity of the test material.

d) the test conditions are reported (*e.g.*, composition of the test medium, test temperature, test species, biomass density at the beginning of the test);

For study (ii), you have not described the composition of the test medium and the biomass density at the beginning of the test

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

This information is not provided for studies (i) and (ii).

4 Based on the above:

- for studies (i) and (ii), the key parameter of OECD TG 201 is not covered as no information on growth as expressed as the logarithmic increase in biomass is provided
- for study (ii), there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, you have not provided adequate information to demonstrate that the test organisms were satisfactorily exposed to the test material during the exposure phase;
- for studies (i) and (ii), the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of adequate reporting of biomass data, ECHA cannot conduct an independent assessment as to whether the validity criteria specified in the OECD TG 201 were met for studies (i) and (ii). In addition, for study (ii), you have not demonstrated that the test was conducted under conditions that are consistent with the test guideline requirements.

5 In your comments to the draft decision, you disagree with the request. In your comments you have responded only in relation to the deficiencies noted above with respect to study (i). In particular, you agree that a key parameter of OECD TG 201 is not covered as no information on growth as expressed as the logarithmic increase in biomass is provided and there is no raw data available to recalculate the results obtained based on cell density to ErC50 data. Therefore, the issue under a) is not addressed. You also do not provide any information to address issue explained under e) above.

6 You argue that study (i) is still sufficient for risk assessment purposes. You consider that the EyC50, i.e. effect concentration based on yield, would be more conservative when compared to the ErC50.

7 However, the OECD TG 201 states that the use of average specific growth rate for estimating toxicity is scientifically preferred. The ErC_x value is needed for classification and labelling purposes. For example, the Guidance on the Application of the CLP Criteria, section 1.2.3.1 specifies that "*Classification shall be based on both, the algal growth rate reduction endpoint, ErC50 [= EC50 (growth rate)] and NOErC [= NOEC (growth rate)]*" (…). "*This endpoint is preferred because it is not dependent on the test design, whereas the endpoint biomass (growth) inhibition (EbC50) depends on both, growth rate of the test species as well as test duration and other elements of test design".*

8 Taken together, the information you provided with your comments to the draft decision do not address the issues identified with study (i).On this basis, the specifications of the OECD TG 201 are not met by any of the provided studies.

9 Therefore, the information requirement is not fulfilled.

2. Ready biodegradability

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

2.1. Information provided

11 You have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following experimental data:

(i) biodegradation in water: screening test according to "*modified OECD confirmatory test*" (1985) with the Substance;

(ii) biodegradation in water: screening test with an unspecified method (1992) with the Substance;

(iii) biodegradation in water: ready biodegradability test claimed similar to OECD TG 301F (1979) with the Substance;

(iv) biodegradation in water: inherent biodegradability test according to OECD TG 302B (2008) with the Substance;

(v) biodegradation in water: ready biodegradability test according to OECD TG 301E (1982) with the Substance.

2.2. Assessment of the information provided

2.2.1. Weight of evidence adaptation rejected

12 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.

13 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.

14 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.

2.2.1.1. Lack of documentation justifying the weight of evidence adaptation

15 Annex XI, Section 1.2. requires that adequate and reliable documentation is provided to describe a weight of evidence approach.

16 You have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

17 Beside this critical deficiency, ECHA has also assessed the other aspects of your adaptation.

18 Information that can be used to support weight of evidence adaptation for the information requirement of Annex VII, Section 9.2.1.1. includes similar information that is produced by the OECD TG 301 or OECD TG 310. The OECD TG 301 and OECD TG 310 require the study to investigate the following key parameter:

- the ultimate aerobic biodegradation (as measured by parameters such as DOC removal, CO2 production and oxygen uptake) of the test material under low inoculum concentration measured at sufficiently frequent intervals to allow the identification of the beginning and end of biodegradation.

19 The study (i) was conducted under anaerobic conditions and therefore does not inform on aerobic biodegradation. Study (iii) was conducted at inoculum concentrations ranging from

100 to 1000 mg/L which is well above the acceptable range specified in the OECD TG 301 and OECD TG 310. Studies (iv) was conducted according to the OECD TG 302B at an inoculum concentration of 1 g activated sludge/L. Therefore, studies (iii) and (iv) are not regarded as being conducted "under low inoculum concentration".

20 As a result, the sources of information (i), (iii) and (iv) do not provide relevant information on the key parameter normally investigated by the OECD TG 301 or OECD TG 310.

21 For studies (ii) and (v), you have provided no information on the inoculum concentration at the beginning of the test. Therefore, the relevance of this information cannot be ascertained. For the sake of completeness the reliability of these sources of information is further assessed below.

2.2.2. The sources of information have low reliability dues to major deviations from the test guidelines specifications

22 To inform on ready biodegradability, a study must normally comply with the OECD TG 301 or 310 (Article 13(3) of REACH). The OECD 301 and 310 require the following specifications to be met the following specifications must be met:

Reporting of the methodology and results

a) adequate information on the identity of the test material is provided;

   For study (ii) and (v), you have not specified the purity of the test material.

b) the test temperature is reported;

   This information is not provided for studies (ii) and (v).

c) the concentration of the inoculum in the test;

   As already explained above, for studies (ii) and (v), you have provided no information on the initial inoculum concentration.

d) the test material concentration is reported;

   For study (v), you have not provided this information.

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

   This information is not provided for studies (ii) and (v).

23 Based on the above, there are severe reporting deficiencies which prevent to conduct an independent assessment of the reliability of the sources of information (ii) and (v). ECHA notes that these sources of information provide contradicting information on whether or not the Substance should be regarded as readily biodegradable. In the absence of an adequate reporting of these studies, it is not possible to assess whether these studies were conducted under conditions that are consistent with the test guideline requirements, whether these studies could be regarded as fulfilling the validity criteria of the corresponding test method and to confirm the adequacy of the results interpretation. Consequently, these sources of information cannot be considered as contributing to the overall weight of evidence for the information requirement under consideration.

24 Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for Ready biodegradability.

25 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

2.3. Study design

26 To fulfil the information requirement, the test methods according to OECD TG 301A/B/C/D/E/F or OECD TG 310 are in general appropriate. You can choose any of these methods, but you must ensure that the Substance is within the applicability domain of the test method chosen.

27 In your comments to the draft decision, you agree to perform the requested study.

Reasons related to the information under Annex IX of REACH

3. Long-term toxicity testing on aquatic invertebrates

28 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

3.1. Information provided

29 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided no justification.

30 You have also adapted this information requirement by using Annex XI, Section 3. (substance-tailored exposure-driven testing). To support the adaptation, you have provided the following information:

(i) a statement claiming that "*Based on the outcome of the risk assessment, this test is not needed*";

(ii) a quantitative risk assessment reported in your CSR and a supporting document describing the risk assessment based on easyTRA.

31 ECHA understands that you have adapted this information requirement under Annex XI, Section 3.2 (a).

3.2. Assessment of the information provided

3.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

32 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to aquatic invertebrates referred to under Column 1, Section 9.1.5.

33 Your adaptation is therefore rejected.

3.2.1. Substance-tailored exposure-driven testing adaptation rejected

3.2.1.1. Lack of appropriate PNEC

34 Under Annex XI, Section 3.2(a)(ii), a relevant and appropriate predicted no effect concentration (PNEC) must be derived.

35 For the reasons explained under request 1, your dossier does not include reliable information on the hazardous properties of the substance on at least three trophic levels (Guidance on IRs and CSA, Section 7.8.5.3).

36 Therefore, you have not demonstrated that an appropriate PNEC can be derived.

37 Your adaptation is therefore rejected.

38 On this basis, the information requirement is not fulfilled.

39 In your comments to the draft decision, you agree to perform the requested study.

4. Long-term toxicity testing on fish

40 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

4.1. Information provided

41 You have provided a non guideline long-term toxicity study on fish similar to OECD TG 204 (1998) with the Substance.

4.2. Assessment of the information provided

4.2.1. The OECD TG 204 is not a valid test guideline to meet this information requirement

42 To fulfil the information requirement, a study must be a long-term fish test. Guidance on IRs and CSA, Section R.7.8.4.1. specifies that only studies in which sensitive life-stages (juveniles, eggs and larvae) are exposed can be regarded as long-term fish tests.

43 Your registration dossier provides an OECD TG 204 study in which only juveniles were exposed to the test material.

44 This study does not provide information on the toxicity of the test material to all relevant sensitive life-stages (i.e. juveniles, eggs and larvae). OECD TG 204 only provides information on prolonged acute toxicity and, based on the above, it does not qualify as a long-term fish test. Therefore, this information is rejected.

4.3. Therefore, the information requirement is not fulfilled.Study design

45 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

46 In your comments to the draft decision, you agree to perform the requested study.

5. Simulation testing on ultimate degradation in surface water

47 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

5.1. Information provided

48 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2.1.2. To support the adaptation, you have provided the following justification: "*the study does not need to be conducted because the substance is readily biodegradable*".

5.2. Assessment of the information provided

5.2.1. Ready biodegradability not demonstrated

49 Under Annex IX, Section 9.2.1.2., Column 2, the study may be omitted if the substance is readily biodegradable.

50 You claim that the Substance is readily biodegradable based on a weight of evidence adaptation.

51 For the reasons explained under request 2, the information on ready biodegradability is rejected.

52 Based on the above, you have not demonstrated that the Substance is readily biodegradable and your adaptation is rejected.

53 Therefore, the information requirement is not fulfilled.

5.3. Study design

54 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.

55 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.).

56 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.

57 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. Paragraph 52 of the OECD TG 309 provides that the "total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

58 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, 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 (NER - summary 2019 (europa.eu) [1]).

[1] https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342

59 Relevant transformation/degradation products are at least those detected at ≥ 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.).

60 In your comments to the draft decision, you agree to perform the requested study if results of request 2 show that the Substance is not readily biodegradable.

6. Identification of degradation products

61 Identification of abiotic and biotic degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

62 You have not submitted any information for this requirement.

63 Therefore, the information requirement is not fulfilled.

6.1. Study design

64 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.

65 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

66 You must obtain this information from the degradation study requested in request 5.

67 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 5) 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).

68 In your comments to the draft decision, you agree to perform the requested study if results of request 2 show that the Substance is not readily biodegradable.

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).
Guidance for monomers and polymers; ECHA (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are 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 05 June 2023.

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

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

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

In your comments to the draft decision, you requested an extension of the deadline to provide information from 30 to 36 months from the date of adoption of the decision.

You justify your request based on documented limited capacities in contract research organisation.

On this basis, ECHA has extended the deadline to 36 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: Addressee(s) 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]
[redacted]	[redacted]	[redacted]
[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 summaries (https://echa.europa.eu/practical-guides).
(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

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.

With that detailed information, ECHA can confirm 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 (https://echa.europa.eu/manuals).