~~Confidential~~

Helsinki, 23 January 2024

Addressees
Registrants of JS_86-29-3_[redacted] as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
17 February 2022

Registered substance subject to this decision ("the Substance")
Substance name: Diphenylacetonitrile
EC/List number: 201-662-5

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 ***30 January 2026***.

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

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

1. Skin sensitisation (Annex VII, Section 8.3.)
    a) *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E) (Annex VII, Section 8.3.1.); and
    b) only if the *in vitro/in chemico* test methods specified under point a) above are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429).
2. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, OECD TG 471 (2020)).

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

Information required depends on your tonnage band

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

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested

by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report**, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the 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 common to several requests

0.1. Assessment of weight of evidence adaptations

1 You have adapted the following standard information requirements by using Annex XI, Section 1.2. (weight of evidence):

- Skin sensitisation (Annex VII, Section 8.3.)
- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)

2 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.

3 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.

4 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.

0.1.1. Lack of documentation justifying the weight of evidence adaptation

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

6 You have not included a justification for your weight of evidence adaptation for each of the relevant information requirement, which would include an adequate and reliable (concise) documentation as to why the sources of information together provide similar information that is produced by the information requirements under consideration.

7 In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation. Your weight of evidence approach has deficiencies that are common to all information requirements under consideration and also deficiencies that are specific for these information requirements individually.

8 The common deficiencies are set out here, while the specific ones are set out under the information requirement concerned in the Sections below:

0.1.2. Reliability of the information provided from analogue substances

9 For the information on analogue substances to reliably contribute to the weight of evidence approaches, it would have to meet the requirements for Grouping of substances and read-across approaches.

10 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

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

0.1.2.1. Predictions for toxicological properties

12 You have not provided any read-across justification documentation and reasoning for the prediction of toxicological properties.

13 You predict the properties of the Substance from information obtained from the following source substances in a read-across approach as part of your weight of evidence adaptation:

- phenylacetonitrile, EC 205-410-5 (source substance 1);
- benzonitrile, EC 202-855-7 (source substance 2);
- 1,3-Benzenedicarbonitrile, EC 210-933-7 (source substance 3);
- benzene, 1,1'-oxybis-, EC 202-981-2 (source substance 4);
- 1,4-Dicyanobenzene, EC 210-783-2 (source substance 5).

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

15 We have identified the following issues with the predictions of toxicological properties:

0.1.2.2. Absence of read-across documentation

16 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 "an explanation why the properties of the registered 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 (eco)toxicological and environmental fate properties 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.).

17 You have provided robust study summaries for studies conducted with other substances than the Substance in order to comply with the REACH information requirements. 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 substances.

18 In the absence of such documentation, the information on the analogue substances cannot reliably contribute to the weight of evidence apdations intended to identify the properties of the Substance.

19 Beside this critical deficiency common to all information requirements under consideration, your weight of evidence approach has additional deficiencies.

20 Additional deficiencies that are specific for each of the information requirements individually are addressed under request(s) X, Y, and Z.

Reasons related to the information under Annex VII of REACH

1. Skin sensitisation

21 Skin sensitisation is an information requirement under Annex VII, Section 8.3. Under Section 8.3., Column 1, the registrants must submit information allowing (1) a conclusion whether the substance is a skin sensitiser and (2) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

1.1. Information provided

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

(i) a skin sensitisation study in human volunteers on the safety of the test chemical (2000) with the source substance 1 (EC 205-410-5);

(ii) a guinea pig maximisation test (2000) with the source substance 2 (EC 202-855-7).

1.2. Assessment of the information provided

1.2.1. Weight of evidence adaptation rejected

23 In addition to the deficiencies identified in Section 0.1., ECHA identified endpoint-specific issue(s) addressed below.

1.2.1.1. Assessment whether the Substance causes skin sensitisation

24 Information that can be used to support a weight of evidence adaptation for the information requirements of Annex VII, Section 8.3. includes similar information to that investigated by the internationally recognised *in vitro*, in chemico and/or *in vivo* test methods on skin sensitisation. The key parameters of such test methods address each of the 3 key events of skin sensitisation, either individually or in an integrated approach as follows:

(1) investigation of cell proliferation in the draining lymph nodes (local lymph node assay), or

(2) investigation of local responses in animals or humans (guinea pig assays or human studies), or

(3) investigation of molecular interaction with proteins, inflammatory response in keratinocytes and activation of dendritic cells (*in vitro* and in chemico assays).

1.2.1.1.1. Investigation of local responses in animals or humans

25 The sources of information (i) and (ii) may provide relevant information on investigation of local responses in humans and animals, respectively.

26 However, the reliability of these sources of information is significantly affected by the following deficiencies:

1.2.1.1.2. General issue affecting the reliability of the contribution of information from on analogue substances to the weight of evidence adaptation

27 As explained in Section 0.1.2., the grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. Therefore, the information from these analogue substances cannot reliably contribute to your weight of evidence adaptation.

1.2.1.1.3. Adequacy of the provided source study (i) for hazard identification

28 A study must be adequate for the corresponding information requirement. According to the Guidance on IRs and CSA, Section R.4. (page 1), "The evaluation of data quality includes assessment of adequacy of the information for hazard/risk assessment and C&L purposes". The Guidance on IRs and CSA, Section R.4. (page 1) defines adequacy as "the usefulness of data for hazard/risk assessment purposes". As a consequence, a study must be relevant for hazard assessment and for classification and labelling purposes

29 Despite the limited information provided in the study record, ECHA understands that you have provided study (i) according to the Human Repeat Insult Patch Test (HRIPT) and you consider that the test material is not a skin sensitiser. ECHA understands also that the study has been performed for a safety assessment by testing a 2% solution of the source substance 1 in healthy human volunteers.

30 However, the source study (i) appears to have been designed to establish safe levels for specific intended uses, rather than to investigate the intrinsic properties of the source substance 1 as required for the purpose of hazard identification. In particular, the dose level used in this study is far lower (i.e. 2% concentration) than the doses expected to be used for hazard assessment purposes, as the method (HRIPT) is only intended to confirm the absence of irritation and sensitisation potential under specific uses.

1.2.1.1.4. Methodological deficiencies of study (ii)

31 The evaluation of the reliability of the contribution of each relevant line of information to the weight of evidence approach includes an assessment of each source of information against the specifications of the test guideline followed.

32 The study (ii) is described as a guinea pig maximisation test. The OECD TG 406 describes the specifications applicable to a guinea pig maximisation tests. This test guideline requires:

a) a dose level selection rationale is provided;

b) the induction concentration is the highest causing mild-to-moderate irritation to the skin;

c) the challenge dose is the highest non-irritation concentration;

d) positive and negative controls are included to establish the sensitivity and reliability of the experimental technique.

33 In source study (ii):

a) no dose level selection rationale was provided;

b) no information is provided on the concentration used for induction and whether it caused mild-to-moderate irritation;

c) not reported whether the challenge concentration was the highest non-irritating concentration;

d) no information on positive and negative control groups was provided.

34 As a result of the methodological deficiencies listed above, the provided study (ii) cannot be considered a reliable source of information that could contribute to the conclusion on the key parameters investigated by the required study.

1.2.1.2. Conclusion on the weight of evidence adaptation

35 While you have provided information on key parameters, i.e. investigation of local responses in animals and humans, the provided studies (i) and (ii) cannot be considered a reliable source of information that could contribute to the conclusion on the key parameters investigated by the required study.

1.2.1.3. No assessment of potency

36 To be considered compliant and enable a conclusion in cases where the substance is considered to cause skin sensitisation, the information provided must also allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

37 As the currently available data do not allow to conclude whether the Substance causes skin sensitisation (see section 1.2.1.1. above), this condition cannot be assessed.

1.2.2. Conclusion

38 Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for skin sensitisation.

39 Based on the above, your weight of evidence adaptation under Annex XI, Section 1.2. is rejected.

40 Therefore, the information requirement is not fulfilled.

1.3. Study design

41 To fulfil the information requirement for the Substance, information on molecular interaction with skin proteins and inflammatory response in keratinocytes and activation of dendritic cells (OECD TG 442C and OECD TG 442D and OECD TG 442E) must be provided. Furthermore an appropriate risk assessment is required if a classification of the Substance as a skin sensitiser (Cat 1A or 1B) is warranted.

42 In case no conclusion on the skin sensitisation potency can be made for the Substance based on newly generated in vitro/in chemico data, in vivo skin sensitisation study must be performed and the murine local lymph node assay (EU Method B.42/OECD TG 429) is considered as the appropriate study for the potency estimation.

43 In your comments on the draft decision, you indicate your intentions to apply the Defined Approach (DA) described in the OECD TG 497. You indicate that you will perform 2 in vitro studies and if these studies indicate that the Substance should be classified, you will perform a third study to determine the applicable hazard class. ECHA considers that the DA is an appropriate alternative to the tests listed above.

2. *In vitro* gene mutation study in bacteria

44 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

2.1. Information provided

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

(i) an *in vitro* gene mutation study in bacteria (1972) with the Substance;

(ii) an *in vitro* gene mutation study in bacteria (2019) with the source substance 3 (EC 210-933-7);

(iii) an *in vitro* gene mutation study in bacteria (1983) with the source substance 4 (EC 202-981-2);

(iv) an *in vitro* gene mutation study in bacteria (2019) with the source substance 5 (EC 210-783-2).

2.2. Assessment of the information provided

2.2.1. Weight of evidence adaptation rejected

46 In addition to the deficiencies identified in Section 0.1., ECHA identified endpoint-specific issue(s) addressed below.

47 Information that can be used to support weight of evidence adaptation for the information requirement of Annex VII, Section 8.4.1. includes similar information that is produced by the OECD TG 471. The OECD TG 471 requires the study to investigate the following key parameters:

(1) Detection and quantification of gene mutations in cultured bacteria including data on the number of revertant colonies

48 The sources of information (i) to (iv) may provide relevant information on detection and quantification of gene mutations in cultured bacteria including data on the number of revertant colonies.

49 However, the reliability of these sources of information is affected by the following deficiencies:

2.2.1.1. Methodological deficiencies of study (i)

50 The evaluation of the reliability of the contribution of each relevant line of information to the weight of evidence approach includes an assessment of each source of information against the specifications of the test guideline followed.

51 The study (i) is described as an *in vitro* gene mutation study in bacteria. The OECD TG 471 describes the specifications applicable to an *in vitro* gene mutation study in bacteria. This test guideline requires:

a) two separate test conditions are assessed: in absence of metabolic activation and in presence of metabolic activation;

b) the test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101);

c) at least 5 doses are evaluated, in each test condition;

d) triplicate plating is used at each dose level;

e) concurrent strain-specific positive controls, both with and without metabolic activation, are included in each assay and the number of revertant colonies per plate induced by the positive controls demonstrates the effective performance of the assay;

f) a concurrent negative control is included in each assay and the number of revertant colonies per plate for the concurrent negative control is inside the historical control range of the laboratory;

g) the mean number of revertant colonies per plate is reported for the treated doses and the controls;

h) negative results are confirmed in a repeat experiment with modification of study parameters to extend the range of conditions assessed, or a justification why confirmation of negative results is not considered necessary is provided.

52 In study(i):

a) only one test condition (in the absence of metabolic activation) was assessed;

b) no information on the strains is provided as it is only reported that the test was performed in *S. typhmimurium*;

c) no information on doses and how many doses were evaluated in absence and in presence of metabolic activation (i.e., 5 or less doses evaluated);

d) not reported whether triplicate plating was used at each dose level;

e) the effective performance of the assay is not demonstrated as the positive control results are not specified;

f) not reported whether a concurrent negative control was not included in the study;

g) the mean number of revertant colonies per plate for the treated doses and the controls was not reported;

h) no repeat experiment was performed to confirm the negative results and no justification was provided.

53 The methodological deficiencies listed above limit the reliability of the contribution of the provided study (i) to the conclusion on the key parameters investigated by the required study.

2.2.1.2. General issue affecting the reliability of the contribution of information from the analogue substances (studies (ii) to (iv)) to the weight of evidence adaptation

54 As explained in Section 0.1.2., the information from the source substances cannot reliably contribute to your weight of evidence adaptation.

2.2.1.2.1. Methodological deficiencies of studies (ii) to (iv)

55 The evaluation of the reliability of the contribution of each relevant line of information to the weight of evidence approach includes an assessment of each source of information against the specifications of the test guideline followed.

56 The studies (ii) to (iv) are *in vitro* gene mutation studies in bacteria. The OECD TG 471 describes the specifications applicable to an *in vitro* gene mutation study in bacteria. This test guideline requires:

a) the test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101);

b) triplicate plating is used at each dose level;

c) a concurrent negative control is included in each assay and the number of revertant colonies per plate for the concurrent negative control is inside the historical control range of the laboratory;

d) the mean number of revertant colonies per plate is reported for the treated doses and the controls;

e) negative results are confirmed in a repeat experiment with modification of study parameters to extend the range of conditions assessed, or a justification why confirmation of negative results is not considered necessary is provided.

57 In the source studies (ii) to (iv):

a) the test was performed with S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 strains (i.e., the strain *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) is missing) in study (iii);

b) triplicate plating was not used in studies (ii) and (iv);

c) not reported whether the number of revertant colonies per plate for the concurrent negative control was inside the historical control range of the laboratory in studies (ii) to (iv);

d) the mean number of revertant colonies per plate for the treated doses and the controls was not reported in studies (ii) to (iv);

e) no repeat experiment was performed to confirm the negative results and no justification was provided in studies (ii) to (iv).

58 The methodological deficiencies listed above limit the reliability of the contribution of the studies (ii) to (iv) to the conclusion on the key parameters investigated by the required study.

2.2.1.3. Conclusion on the weight of evidence adaptation

59 While you have provided information on key parameters, i.e. detection and quantification of gene mutations in cultured bacteria including data on the number of revertant colonies, the corresponding sources of information (i) to (iv) have deficiencies affecting their reliability. On this basis, you have not provided any reliable information on key parameters.

60 Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for in vitro gene mutation study in bacteria.

61 On this basis, your weight of evidence adaptation under Annex XI, Section 1.2. is rejected and the information requirement is not fulfilled.

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

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 24 January 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 amended the request(s).

As a result of one or more changes of registration tonnage band or registration type, the requests for *in vitro* micronucleus study, *in vitro* gene mutation study in mammalian cells, short-term repeated dose toxicity (28 days) and screening study for reproductive/developmental toxicity were removed from the decision.

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]

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).