~~Confidential~~

Helsinki, 7 June 2023

Addressees
Registrant(s) of JS_111-29-5_Pentane-1,5-diol as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
18/01/2021

Registered substance subject to this decision ("the Substance")
Substance name: Pentane-1,5-diol
EC number: 203-854-4

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 ***14 September 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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

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

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

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

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

Information required depends on your tonnage band

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

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

How to comply with your information requirements

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

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

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

Appeal

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

Failure to comply

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

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

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

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

An in vitro gene mutation study in bacteria is an information requirement under Annex VII to REACH (Section 8.4.1.).

1.1. Information provided

You have provided the following study:

i. In vitro gene mutation study in bacteria (1992) with the Substance.

1.2. Assessment of the information provided

We have assessed this information and identified the following issue(s):

1.2.1. Study not adequate for the information requirement

To fulfil the information requirement, the study must meet the requirements of OECD TG 471 (2020), which includes:

- The test must be 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).

The study i. is described as In vitro gene mutation study in bacteria. However, the following specifications are not according to the requirements of OECD TG 471 (2020):

- results for the appropriate 5 strains, that includes the required fifth strain, S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).

Therefore the information requirement for in vitro gene mutation study in bacteria is not fulfilled.

1.3. Specification of the study design

To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) should be performed using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

Reasons related to the information under Annex IX of REACH

2. Long-term toxicity testing on aquatic invertebrates

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

2.1. Information provided

You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.:

"*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that chronic tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic invertebrates. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of pentane-1,5-diol reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. Therefore, a chronic test in aquatic invertebrates is not provided*".

2.2. Assessment of the information provided

We have assessed this information and identified the following issue(s):

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

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

2.3. Information provided in your comments

In your comments to the draft decision, you propose to adapt the information requirement by using Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs) according to Annex XI, section 1.3 of REACH.

You have derived a 21-d NOEC for reproduction of Daphnia magna using a trend analysis developed with the OECD QSAR Toolbox v4.5.

In addition, you have used several profilers included in the OECD QSAR Toolbox to conclude that the Substance is not expected to cause critical long-term effects to aquatic organisms.

Annex XI, Section 1.3. specifies that the following conditions must be fulfilled whenever a (Q)SAR approach is used:

i. the predictions need to be derived from scientifically valid models,

ii. the substance must fall within the applicability domain of the models,

iii. results need to be adequate for the purpose of risk assessment or

classification and labelling, and

iv. adequate and reliable documentation of the method must be provided.

With regard to these conditions, we have identified the following issues:

2.3.1. Inadequate documentation of the model (QMRF)

Under Appendix C of the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) and ECHA Guidance R.6.1.6.3., adequate and reliable documentation must include a (Q)SAR Model Reporting Format document (QMRF) which reports, among others, the following information:

- the predicted endpoint, including information on experimental protocol and data quality for the data used to develop the model;
- an unambiguous definition of the algorithm, the descriptor(s) of the model and its applicability domain,
- an estimate of the goodness-of-fit and of the predictivity of the model, including information on training set and validation statistics.

In your comments to the draft decision and the associated documentation you have provided as attached files[2], you indicate that a total of 48 data points from the following chemicals were used to constitute the training set of your model: Ethyl(tert-amyl) ether, Benzene, (vinyloxy)cyclohexane, 1,4-Cyclohexanedimethanol, t-butanol, Anethole, Hexalin, Acetone, 2-phenylpropene.

However, you have not provided the data, the information on the experimental protocol used to generate those data, or the data quality for the dataset used to develop the model. In the absence of such documentation, ECHA cannot trace the source and verify the quality of the individual data points. As such, the information provided is insufficient for ECHA to assess the quality and reliability of those data and how they could support the prediction.

2.3.2. The prediction is not adequate due to low reliability

Under ECHA Guidance R.6.1.3.4 a prediction is adequate for the purpose of classification and labelling and/or risk assessment when the model is applicable to the chemical of interest with the necessary level of reliability. ECHA Guidance R.6.1.5.3. specifies that, among others, the following cumulative conditions must be met:

- the model predicts well substances that are similar to the substance of interest,
- reliable input parameters are used,
- the prediction must be reliable based on the representativeness (and homogeneity) of the elements in the training set.

You use the following chemicals as a training set for your model: Ethyl(tert-amyl) ether, Benzene, (vinyloxy)cyclohexane, 1,4-Cyclohexanedimethanol, t-butanol, Anethole, Hexalin, Acetone, 2-phenylpropene.

Your Substance (1,5-Pentanediol) is a linear diol. However, none of the chemicals in the training set are linear diols. They have different functional groups or different meaningful fragments, different physico-chemical, (eco)toxicity or mechanistic profiles (as it can be

[2] "A-1_Daphnia_chronic_Prediction report.pdf"; "A-4_111-29-5_IUCLID_AquaticToxicity_2022-01-20.pdf"

demonstrated using e.g. the profilers from the OECD QSAR Toolbox), and you have not demonstrated that they can be regarded as structurally similar to the Substance (e.g. the Tanimoto similarity indices are <<80%, irrespective of the fingerprint method used to encode the structures).

Structural similarity indices (e.g. the Tanimoto similarity index) and profilers (e.g. those included in the OECD QSAR Toolbox) show that the substances in the training set are not only very different from the Substance but also generally very different from each other. Therefore, you have not demonstrated that the training set of your model can be regarded as homogeneous. This significantly affects its representativeness for the) Substance you aim to predict. The heterogeneity of the training set increases the uncertainty on the prediction which is partly reflected by the large 95% prediction interval reported by the OECD QSAR Toolbox: i.e. 4.28 to 1410 mg/L.

The information provided in your comments does not establish that the training set used for your model is representative and homogeneous. You have not established that your model predicts well substances that are similar to the Substance, and you have not established that it is applicable to your Substance with the necessary level of reliability. Therefore, you have not demonstrated that your model is scientifically valid and that the prediction from this model is adequate for the purpose of classification and labelling and/or risk assessment.

2.3.3. Profilers are as such not adequate to predict the absence of concern

Under ECHA Guidance R.6.1.3., a (Q)SAR model must fulfil the principles described in the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) to be considered scientifically valid. For that purpose, the fourth OECD principle requires that appropriate measures of the internal performance (i.e. goodness-of-fit and robustness using the learning data set) and predictivity (using a test data set) of the model are available.

You have used several profilers included in the OECD QSAR Toolbox to conclude that the mode of action of the Substance is narcotic and that critical long-term effects on aquatic organisms are not to be expected.

Profilers included in the OECD QSAR Toolbox were developed for the purpose of identifying analogues but not to make predictions. Measures of internal performance and predictivity are not available for those profilers. Therefore, profilers as such are not considered a scientifically valid approach to meet the information requirement.

2.4. Conclusion

Therefore, the information requirement is not fulfilled.

3. Long-term toxicity testing on fish

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

3.1. Information provided

You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.:

"*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that chronic tests shall be proposed by the registrant if the chemical safety assessment indicates the need to*

investigate further the effects on fish. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of pentane-1,5-diol reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. Therefore, and for reasons of animal welfare a chronic test in fish is not provided".

3.2. Assessment of the information provided

We have assessed this information and identified the following issue(s):

3.2.1. Your interpretation of the legal basis used in your justification is incorrect

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

3.2.2. Animal welfare is not a legal basis to omit the required information

Animal welfare does not constitute as such a valid justification to omit the standard information requirements of Annexes VII – X or a valid adaptation to these information requirements.

Therefore, your adaptation is rejected.

3.3. Information provided in your comments

In your comments to the draft decision, you propose to adapt the information requirement by using Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs) according to Annex XI, section 1.3 of REACH.

You have derived a 28-d NOEC for growth of fish and a 28-d NOEC for mortality of fish using two distinct trend analyses developed with the OECD QSAR Toolbox v4.5.

In addition, you have used several profilers included in the OECD QSAR Toolbox to conclude that the Substance is not expected to cause critical long-term effects to aquatic organisms.

Annex XI, Section 1.3. specifies that the following conditions must be fulfilled whenever a (Q)SAR approach is used:

i. the predictions need to be derived from scientifically valid models,

ii. the substance must fall within the applicability domain of the models,

iii. results need to be adequate for the purpose of risk assessment or classification and labelling, and

iv. adequate and reliable documentation of the method must be provided.

With regard to these conditions, we have identified the following issues:

3.3.1. Inadequate documentation of the models (QMRF)

Under Appendix C of the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) and ECHA Guidance R.6.1.6.3., adequate and reliable

documentation must include a (Q)SAR Model Reporting Format document (QMRF) which reports, among others, the following information:

- the predicted endpoint, including information on experimental protocol and data quality for the data used to develop the model;
- an unambiguous definition of the algorithm, the descriptor(s) of the model and its applicability domain,
- an estimate of the goodness-of-fit and of the predictivity of the model, including information on training set and validation statistics.

In your comments to the draft decision and the associated documentation you have provided as attached files[3], you indicate that:

- A total of 10 data points from the following chemicals were used to constitute the training set for the model to predict 28-d NOEC for growth of fish: Acetone, Dibromomethane, Carbamazepine, Bromoform, 1-Chloronaphthalene, Acenaphtene, 1,2,4,5-Tetrachlorobenzene, 1,2,3-trichlorbenzene, Toluene;
- A total of 22 data points from the following chemicals were used to constitute the training set for the model to predict 28-d NOEC for mortality of fish: 1,1,2 Trichloroethane, Anethole, Dichloromethane, 3,4-Dichlorotoluene, 4-Butoxy-2,3-difluor-4'-methyl-1,1'-biphenyl, Dibromomethane, 4-Ethoxy-2,3-difluor-4'-propyl-1,1'-biphenyl, 1,1,2,2-Tetrachloroethane, Diuron.

However, you have not provided the data, the information on the experimental protocol used to generate those data, or the data quality for the dataset used to develop the model. In the absence of such documentation, ECHA cannot trace the source and verify the quality of the individual data points. As such, the information provided is insufficient for ECHA to assess the quality and reliability of those data and how they could support the predictions.

3.3.2. The predictions are not adequate due to low reliability

Under ECHA Guidance R.6.1.3.4 a prediction is adequate for the purpose of classification and labelling and/or risk assessment when the model is applicable to the chemical of interest with the necessary level of reliability. ECHA Guidance R.6.1.5.3. specifies that, among others, the following cumulative conditions must be met:

- the model predicts well substances that are similar to the substance of interest,
- reliable input parameters are used,
- the prediction must be reliable based on the representativeness (and homogeneity) of the elements in the training set.

For the prediction of 28-d NOEC for growth of fish, you use the following chemicals as a training set: Acetone, Dibromomethane, Carbamazepine, Bromoform, 1-Chloronaphthalene, Acenaphtene, 1,2,4,5-Tetrachlorobenzene, 1,2,3-trichlorbenzene, Toluene.

[3] "A-2_Fish_chronic_growth_Prediction report.pdf"; "A-3_Fish_chronic_mortality_Prediction report.pdf"; "A-4_111-29-5_IUCLID_AquaticToxicity_2022-01-20.pdf"

For the prediction of 28-d NOEC for mortality of fish, you use the following chemicals as a training set: 1,1,2 Trichloroethane, Anethole, Dichloromethane, 3,4-Dichlorotoluene, 4-Butoxy-2,3-difluor-4'-methyl-1,1'-biphenyl, Dibromomethane, 4-Ethoxy-2,3-difluor-4'-propyl-1,1'-biphenyl, 1,1,2,2-Tetrachloroethane, Diuron.

Your Substance (1,5-Pentanediol) is a linear diol. However, for both models, none of the chemicals in the training sets are linear diols. They have different functional groups or different meaningful fragments, different physico-chemical, (eco)toxicity or mechanistic profiles (as it can be demonstrated using e.g. the profilers from the OECD QSAR Toolbox), and you have not demonstrated that they can be regarded as structurally similar to the Substance (e.g. the Tanimoto similarity indices are <<80%, irrespective of the fingerprint method used to encode the structures).

For both models, structural similarity indices (e.g. the Tanimoto similarity index) and profilers (e.g. those included in the OECD QSAR Toolbox) show that the substances in the training sets are not only very different from the Substance but also generally very different from each other. Therefore, for both models, you have not demonstrated that the training sets can be regarded as homogeneous. This significantly affects their representativeness for the Substance you aim to predict. The heterogeneity of the training sets increases the uncertainty on the predictions which is partly reflected by the large 95% prediction intervals reported by the OECD QSAR Toolbox: i.e. 1.66 to 791 mg/L for the prediction of 28-d NOEC for growth of fish; 1.29 to 2490 mg/L for the prediction of 28-d NOEC for mortality of fish.

The information provided in your comments does not establish that the training sets used for your models are representative and homogeneous. You have not established that your models predict well substances that are similar to the Substance and you have not established that they are applicable to your Substance with the necessary level of reliability. Therefore, you have not demonstrated that your models are scientifically valid and that the predictions from those models are adequate for the purpose of classification and labelling and/or risk assessment.

3.3.3. Profilers are as such not adequate to predict the absence of concern

Under ECHA Guidance R.6.1.3., a (Q)SAR model must fulfil the principles described in the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) to be considered scientifically valid. For that purpose, the fourth OECD principle requires that appropriate measures of the internal performance (i.e. goodness-of-fit and robustness using the learning data set) and predictivity (using a test data set) of the model are available.

You have used several profilers included in the OECD QSAR Toolbox to conclude that the mode of action of the Substance is narcotic and that critical long-term effects on aquatic organisms are not to be expected.

Profilers included in the OECD QSAR Toolbox were developed for the purpose of identifying analogues but not to make predictions. Measures of internal performance and predictivity are not available for those profilers. Therefore, profilers as such are not considered a scientifically valid approach to meet the information requirement.

3.4. Conclusion

Therefore, the information requirement is not fulfilled.

3.5. Specification of the study design

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.).

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 4 March 2021.

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

You have provided information in your comments and in your updated registration dossier (submission date: 9 March 2023) during the decision-making phase which was found to address some of the incompliances identified in the draft decision. Therefore, the original requests for skin sensitisation, in vitro cytogenicity study in mammalian cells or in vitro micronucleus study, in vitro gene mutation study in mammalian cells, justification for an adaptation for a 28-day study, screening for reproductive/developmental toxicity, sub-chronic toxicity study (90-day), and pre-natal developmental toxicity study, were removed.

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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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[4].

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 dossiers[5].

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