~~Confidential~~

Helsinki, 07 September 2023

Addressees
Registrants of JS_242_016_2 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
16 April 2020

Registered substance subject to this decision ("the Substance")
Substance name: 3-(4-tert-butylphenyl)propionaldehyde
EC/List number: 242-016-2

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 ***12 June 2025.***

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

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

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202).

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

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. C/D/E/F/OECD TG 301B/C/D/F or EU C.29./OECD TG 310).

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

4. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: EU C.1./OECD TG 203).

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)

Contents

Reasons common to several requests

0.1. Read-across adaptation rejected

1 In your dossier, you have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

2 While you have not identified the information provided on short-term daphnia as a read-across approach, the test material used is indicated to be the source substance (cyclamen aldehyde; EC 203-161-7). Therefore, the study on the short-term daphnia will be evaluated as a read-across adaptation under Annex XI, Section 1.5 of REACH.

3 ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following sections.

4 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.

5 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).

0.1.1. Scope of the grouping of substances

6 You provide a read-across justification document in IUCLID Section 13/CSR and as a study record under the growth inhibition study aquatic plants.

7 You predict the properties of the Substance from information obtained from the following source substance(s):

- cyclamen aldehyde: 3-p-cumenyl-2-methylpropionaldehyde, EC 203-161-7.

8 You provide the following reasoning for the prediction of aquatic toxicity:

- The Substance and the source substance cyclamen aldehyde (EC 203-161-7) are structurally similar;
- The OECD QSAR toolbox assigns the same acute aquatic toxicity classification and mode of action to both chemicals;
- Both substances have similar measured log Kow values (3.2 and 3.4 respectively) and as such are expected to have similar of aquatic toxicity;
- Similar strength of aquatic toxicity is supported by experiment on short-term daphnia (The 48h EC50 values are 1.8 and 1.4 mg/L) and on microorganisms;
- Both substances are readily biodegradable.

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

0.1.2. Predictions for ecotoxicological properties

0.1.2.1. Missing supporting information to compare the properties of the substances

10 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 provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

11 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substance causes the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration with the Substance and the source substance.

12 Your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects. In particular, you provided no bridging studies to compare properties of the source substance. Hence, your claim that the Substance and the source substance having similar aquatic toxicity is not substantiated.

13 In the absence of such information, you have not established that the Substance and the source substance are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.2.2. Inadequate or unreliable source studies

14 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:

(1) be adequate for the purpose of classification and labelling and/or risk assessment;

(2) have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement.

15 Specific reasons why the studies on the source substance do not meet these criteria are explained further below under the applicable information requirement sections 1 and 2. Therefore, no reliable predictions can be made for these information requirements.

0.1.3. Conclusion

16 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approach under Annex XI, Section 1.5. is rejected.

Reasons related to the information under Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

17 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

1.1. Information provided

18 In your dossier, you have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on experimental data from the following substances:

(i) a short-term toxicity study on *daphnia magna* (2012), performed according to the OECD TG 202, with the source substance Cyclamen Aldehyde, EC 203-161-7.

1.2. Assessment of the information provided

1.2.1. Read-across adaptation rejected

19 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. provided in your registration dossier is rejected. In addition, ECHA identified endpoint-specific issue addressed below.

1.2.1.1. Inadequate or unreliable study on the source substance

20 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 202, and meet the specifications of OECD GD 23 if the substance is difficult to test. Therefore, the following specifications must be met:

Reporting of the methodology and results

a) the number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;

21 In study (i):

Reporting of the methodology and results

a) tabulated data on the number of immobilised daphnids after 24 and 48 hours for each treatment group and control are not reported;

22 Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, without data on the number of immobilised daphnids, it is not possible to verify whether the validity criterion was fulfilled and the interpretation of the results is appropriate.

23 On this basis, the specifications of OECD TG 202 are not met.

24 Based on the above, the study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameters of the corresponding OECD TG.

25 Therefore, the information requirement is not fulfilled.

26 In your comments to the draft decision, you state that the study (i) was performed on the Substance and not on the analogue substance Cyclamen Aldehyde, EC 203-161-7. You acknowledge that the test material identity was incorrectly assigned to the source substance. In your comments, you also attach the extract of the study report that includes the missing information listed under point a) above. You state that you intend to correct the name of the test material and provide the missing information in an update of your registration dossier.

27 ECHA acknowledges that your comments on the draft decision address the issues identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

1.3. Study design

28 The Substance is difficult to test due to the fact that the Substance is surface active (48.7 mN/m at 20.0 ± 0.5°C). In addition, you report in the OECD TG 209 (2012) that "[t]he test substance (i.e., the Substance) is not soluble enough in water to allow the preparation of an aqueous stock solution in tap water". Thus the solubility of the Substance in the test solution could pose an issue. OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 201. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

2. Growth inhibition study aquatic plants

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

2.1. Information provided

30 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on experimental data from the following substances:

(i) Growth inhibition study on aquatic plants/algae (2012), performed according to the OECD TG 201, with the source substance Cyclamen Aldehyde, EC 203-161-7.

2.2. Assessment of the information provided

2.2.1. Read-across adaptation rejected

31 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. In addition, ECHA identified endpoint-specific issue(s) addressed below.

2.2.1.1. Inadequate or unreliable study on the source substance

32 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 201, and meet the specifications of OECD GD 23 if the substance is difficult to test. Therefore, the following specifications must be met:

Validity criteria

a) exponential growth in the control cultures is observed over the entire duration of the test;

b) at least 16-fold increase in biomass is observed in the control cultures by the end of the test;

Reporting of the methodology and results

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

d) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided (for volatile, unstable or strongly adsorbing test substances, additional samplings for analysis at 24 hour intervals is required).

33 In study (i):

Validity criteria

a) and b): the biomass at the start and end of the test was 1.06E+04 (mean) 1.03E+04 (mean), respectively. Therefore, it indicates that neither the exponential growth in the control cultures is observed nor at least 16-fold increase in biomass is observed in the control cultures by the end of the test.

Reporting of the methodology and results

c) tabulated data on the algal biomass determined daily for each treatment group and control are not reported;

d) The results of the analytically determined exposure concentrations are not provided with 24 hr intervals. In the study records, you state that:

- "*Due to the possible light sensitive nature of the test item all test item preparation was performed under laboratory safety lighting/shielded from the light*",
- "*The test was conducted in 250 mL glass conical flasks each completely filled with test preparation and sealed with ground glass stoppers to reduce evaporation*", and
- "*The concentration and stability of the test item in the test solutions were verified by chemical analysis at 0, 24, 48, 72 and 96 hours*."

These statements indicate that the test material (i.e. source substance cyclamen aldehyde) is unstable (light sensitive and volatile) and you have conducted analytical monitoring with 24 h interval. However, you did not provide the full results (only 0 and 96 hr and measured geometric mean of 72 hr and 96 hr provided).

34 Based on the above,

- the validity criteria of OECD TG 201 are not met.

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically without data on the algal biomass and analytical monitoring, it is not possible to verify whether the validity criteria were fulfilled and/or the interpretation of the results is appropriate.

35 On this basis, the specifications of OECD TG 201 are not met.

36 Based on the above, the study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameter(s) of the corresponding OECD TG.

37 Therefore, the information requirement is not fulfilled.

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

2.1. Study design

39 OECD TG 202 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design" under request 1.

3. Ready biodegradability

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

3.1. Information provided

41 You have provided a ready biodegradability study, performed according to the OECD TG 301F (2011) with the Substance.

3.2. Assessment of the information provided

3.2.1. The provided study does not meet the specifications of the test guidelines

42 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following specifications must be met:

Reporting of the methodology and results

a) the source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;

b) the test temperature is reported;

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

43 In the provided study:

Reporting of the methodology and results

a) You did not specify whether the inoculum was pre-adapted to the test material. In your comments to the draft decision, you provide information on the source of the inoculum that confirm consistency with the guideline requirements;

b) the test temperature is reported to be 22.3 °C — 22.9 °C, as well, as *"at a constant temperature (11 °C)"*. Therefore, the test temperature is unclear. In

your comments to the draft decision, you confirm that the measured test temperature was 22.3 °C — 22.9 °C;

c) the results of measurements at each sampling point in each replicate is not reported in a tabular form. You state that "*Oxygen uptake curves can be found in Appendix 1. Calculated % biodegradation curves and detailed results are reported in Appendixes 2 to 4 (attached)*". However these are not found in the technical dossier. In your comments to the draft decision, you provide the missing information.

44 Based on the above, the reporting of the study as currently provided in your dossier is not sufficient to conduct an independent assessment of its reliability. In particular, it is not possible to verify whether:

- the validity criteria were fulfilled,
- the technical specifications of the OECD TG 301 F were met, and
- the interpretation of the results is appropriate.

45 On this basis, the specifications of OECD TG 301F are not met.

46 Therefore, the information requirement is not fulfilled.

47 However, ECHA acknowledges that, based on the additional information provided in your comments to the draft decision, the study meets the information requirement. Nevertheless, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

3.3. Study design

48 To fulfil the information requirement, the test method(s) according to OECD TG 301B/C/D/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.

Reasons related to the information under Annex VIII of REACH

4. Short-term toxicity testing on fish

49 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

4.1. Information provided

50 You have adapted this information requirement by using Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs). To support the adaptation, you have provided the following information:

(i) a prediction from QSAR ECOSAR v1.11. (2012).

4.2. Assessment of the information provided

4.2.1. The prediction is not adequate due to low reliability

51 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, and
- reliable input parameters are used, and
- the prediction is consistent with other information available (e.g. for related endpoint(s)).

52 Your registration dossier provides the following information:

(i) Predicted LC_{50} (96h) =0.1045 mg/L based on aldehyde (mono) model;

(ii) Predicted LC_{50} (96h) =2.815 mg/L based on neutral organic model.

53 The following information is also available for the Substance used as input for the prediction:

- Predicted log Kow value for Bourgeonal of 3.943
- Internal performance for Aldehydes (mono) n=59 and R^2=0.5513

54 The aldehyde (mono) model (i) prediction for the Substance used as input is not reliable because the correlation with logKow is poor as indicated by a low R^2 of 0.55.

55 Furthermore, the neutral organics model (ii) does not apply, as the substance has a reactive group and the aldehyde (mono) model clearly indicates higher short term fish toxicity for aldehydes compared to the baseline toxicity.

56 Therefore, you have not demonstrated that the prediction for the Substance is adequate for the purpose of classification and labelling and/or risk assessment.

57 Based on the above, your QSAR adaptation under Annex XI, Section 1.3. is rejected.

58 Therefore, the information requirement is not fulfilled.

59 In the comments to the draft decision, you agree with the request. However, you indicate your intention to adapt this information requirement by means of weight of evidence

according to Annex XI, Section 1.2, of the REACH Regulation. You propose to "*apply a number of non-animal alternative methods in a weight-of evidence approach*". You state that the "*approaches explored will include, but are not necessarily limited to, appropriate valid and reliable LC50 predictions using the OECD QSAR toolbox and the RT gill-WI cell line assay (OECD 249)*".

60 ECHA acknowledges your intention. As indicated in your comments, this strategy relies essentially on data, which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

4.3. Study design

61 OECD TG 203 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design" under request 1.

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 (2012).
***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 August 2022.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 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 requests.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 12 to 24 months from the date of adoption of the decision. You justify the request by the additional time required to update the CSR and due to anticipated schedules provided by Contract Research Organisations (CROs). With regard your claim of limited CRO capacity, you have provided documentary evidence from two CROs. You also claim that according to the 'Guidance on registration', Section 7.2., 12 months should additionally be granted to update the CSR. ECHA points out that the section of the Guidance you are referring to relates to a dossier update in the registrant's own initiative. In the present case, Section 7.3 of that Guidance is applicable (*i.e.*, 'Update as a consequence of an ECHA or a Commission decision'). In such case, the registration dossier, including the CSR, must be updated with the additional information requested by the deadline set in the decision. However, considering the documentary evidence provided from two CROs, ECHA has partially agreed with your request and has extended the deadline to 18 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;

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]

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).