~~Confidential~~

Helsinki, 3 November 2022

Addressees
Registrant(s) of AAI_C18_TEPA as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
25/11/2019

Registered substance subject to this decision ("the Substance")
Substance name: Fatty acids C18 unsat, reaction products with tetraethylenepentamine
EC number: 629-725-6

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

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. Growth inhibition study aquatic plants

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

1.1. Information provided

2 You have provided an adaptation under Annex XI, Section 1.5. ('Grouping of substances and read-across'). In support of your adaptation, you provide the following information:

(i) a key study, according to test guideline OECD 201, with source substance tall oil, reaction products with TEPA (EC 271-417-5 / CAS 68555-22-6),

(ii) a supporting study, according to test guideline OECD 201, with 10 different source substances identified as "amidoamines" or "imidazolines" substances.

1.2. Assessment of the information provided

3 We have assessed this information and identified the following issues:

1.2.1. Studies are not adequate and reliable

4 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 corresponding test method referred to in Article 13(3), in this case OECD TG 201, and be adequate for the purpose of classification and labelling and/or risk assessment.

5 For the purpose of classification and labelling, as set out in part 4 of the CLP Regulation and in Section 1.1.3. of the Guidance on the Application of the CLP Criteria, the studies must provide information on hazards, i.e. on the basic properties of the Substance as determined in standard tests or by other means designed to identify hazards under standard conditions. Exposure and risk considerations are not taken into consideration for the purpose of classification and labelling.

6 Consequently, studies performed with modifications to the standard test conditions impacting exposure cannot be considered relevant to derive the hazards of the Substance.

7 Therefore, the following specifications and test conditions of OECD TG 201 must be met:

8 Technical specifications impacting the sensitivity/reliability of the test:

a) one of the two alternative growth media (i.e. the OECD or the AAP medium) is used. These growth media do not contain suspended particulate matter or dissolved organic matter. Any deviations from recommended test media must be described and justified;

9 Characterisation of exposure:

b) analytical monitoring must be conducted. The method used, including the description on how the test samples were prepared for the quantification of the test substance must be provided. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

c) the results can be based on nominal or measured initial concentration only if the

concentration of the test material has been maintained within ±20 % of the nominal or measured initial concentration throughout the test.

10 Your registration dossier provides two studies according to OECD TG 201 showing the following:

11 Technical specifications impacting the sensitivity/reliability of the test:

a) The key study (i) was performed with natural river water with a suspended matter concentration of 16.2 mg/L and a dissolved organic carbon (DOC) concentration of 3.9 mg/L. For the supporting study (ii), 2mg/L of DOC as humic acid was added to the standard OECD algae medium. As a justification for those deviations, you explain that the aquatic toxicity tests were performed using non-standard test media "*to allow a $PEC_{aquatic,bulk}$/$PNEC_{aquatic,bulk}$ approach.* […] *This approach is based on PEC estimations representing 'total aquatic concentrations'. To characterize the risk to the aquatic compartment the $PEC_{aquatic,bulk}$ is compared with the $PNEC_{aquatic,bulk}$ derived from river water ecotoxicity studies.* […] *For a valid bulk approach test the concentration-effect relationship should be based on the sum of adsorbed and dissolved substance in the volume of the medium tested. One of the advantages of the bulk approach tests with these difficult substances is that in the presence of suspended matter, humic acids and/or algae, the residual sorption to glassware will be negligible*".

12 Characterisation of exposure:

a) No analytical monitoring of exposure was conducted for the supporting study (ii) and you do not provide a justification for that deviation. For the key study (i), exposure concentrations were analytically determined. However, you do not provide information on the preparation of the test samples for the quantification analyses performed in the key study (i).

b) For both studies, you have expressed the effect values based on nominal concentrations. You indicate that, for the purpose of the so-called 'bulk-approach' the effect concentrations are defined as the sum of adsorbed as well as dissolved substance in the volume of the medium tested. For the key study (i), you further claim that "*the results of the chemical analyses show that the test organisms were fully exposed to the test substance during the test. Therefore, all effect values given are based on the nominal test item concentrations*".

13 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results.

a) You have not used standard test media and your justification is based on exposure or risk considerations

14 Both the key study (i) and the supporting study (ii) were conducted with non-standard test media, with a higher content of DOC or of suspended particulate matter than recommended by OECD 201.

15 Your justification for using these non-standard test media only considers the relevance of the studies for the risk assessment or a residual sorption to glassware for which you have not explained the relevance for the hazard assessment. However, such conditions impact exposure and thus are not relevant for deriving the hazards of the test substances to the aquatic organisms. As such, they are not adequate for the purpose of classification and labelling. Therefore, for both studies, the modifications of the test media are not acceptable.

b) Information on analytical monitoring is either absent or incomplete

16 No analytical monitoring of exposure was conducted for the supporting study (ii) and there is no justification provided for that deviation.

17 As for the key study (i), the information on the preparation of the test samples for the analyses is insufficient. In particular, there is no information on whether the measured concentrations reported for that study relate to the "total concentration" of the test substance in the test medium (i.e. freely available substance in the water phase + substance bound to the dissolved organic matter + substance adsorbed onto the suspended particulate matter), or to its "dissolved concentration" (i.e. freely available substance in the water phase + substance bound to the dissolved organic matter). The results of the chemical analyses suggest that the adsorption to the glassware is negligible, but they do not provide information on the quantity of the test substance adsorbed to the suspended particulate matter or bound to the dissolved organic matter.

c) You have reported results based on nominal concentrations but you have not demonstrated that the test concentrations remained within ±20 % of the nominal or measured initial concentration throughout the test

18 For both studies, you have expressed the effect values based on nominal concentrations.

19 As a justification, for the key study (i), you claim that "the results of the chemical analyses show that the test organisms were fully exposed to the test substance during the test". However, you provide no adequate information to justify your claim.

20 Standard aquatic toxicity tests are designed so that the test organisms are exposed to a test substance via the water phase and potential adsorption of the test substance is minimised. Only substance freely available in the water phase, i.e. not adsorbed to suspended particulate matter or to dissolved organic matter, is deemed to cause aquatic toxicity. A test substance adsorbed to suspended particulate matter or to dissolved organic matter may be inaccessible to the test organisms and may not cause toxicity to aquatic organisms.

21 All the substances in this category have a high potential for adsorption. For example, you report Kd values of 47000, 150000 and 19000 respectively for loamy sand, silt and clay soils for tall oil DETA imidazoline (EC 270-500-3 / CAS 68442-97-7), and Kd values of 44324, 165856 and 42721 respectively for loamy sand, silt and clay soils for tall-oil, reaction products with polyethylenepolyamines (EC 272-756-1 / CAS 68910-93-0). You estimate that 59% of the substance will be adsorbed if the concentration of suspended matter is 15 mg/L. Therefore, the test substance used in study (i), as well as the Substance or other source substances, are highly adsorptive and may tend to bind to any suspended particulate matter and/or dissolved organic matter present in the test medium. For the key study (i), and based on your calculations, the fraction of the test substance adsorbed can be expected to be above 59% of the nominal concentrations, i.e. well above the threshold of 20% mentioned in the test guideline.

22 As explained above, an unambiguous interpretation of the concentrations measured by the chemical analyses performed for the key study (i) is not possible. There is no indication that those measurements quantified the freely available substance in the water phase and they do not provide information on the quantity of the test substance adsorbed to the suspended particulate matter or bound to the dissolved organic matter. Therefore, your claim that "the results of the chemical analyses show that the test organisms were fully exposed to the test substance during the test" is not demonstrated.

d) Conclusion

23 The use of non-standard test media may have substantially lowered the actual exposure of the test organisms to the test substances. The information on analytical monitoring is either absent or insufficient to demonstrate that the test concentrations remained within ±20 %

of the nominal concentrations. However, considering the high adsorption potential of the substances in this category, the fraction of the test substances adsorbed can be predicted to be well above 20%. Therefore, effect values based on nominal concentrations may underestimate the hazards of the test substances.

24 In your comments to the draft decision, you claim that the 'bulk-approach' could be appropriate for the risk assessment of the Substance. However, you also acknowledge that results from the aquatic toxicity studies performed according to the 'bulk-approach' are less suitable for Classification and Labelling as they use a non-standard test medium and do not allow the quantification of the intrinsic toxicity of the Substance. You agree to perform the requested test.

1.2.2. Conclusion on the assessment of the information provided

25 Therefore, the studies submitted in your adaptation, as currently reported in your dossier, do not provide an adequate and reliable coverage of the key parameters of OECD TG 201 and are not adequate for the purpose of classification and labelling.

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

1.3. Study design and test specifications

27 As explained above, all the substances in this category have a high potential for adsorption. Furthermore, they are ionisable surface-active substances with surface tension values lower than 45 mN/m. Therefore, the Substance is difficult to test. 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.

28 For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

29 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

Reasons related to the information under Annex IX of REACH

2. Long-term toxicity testing on aquatic invertebrates

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

2.1. Information provided

31 You have provided an adaptation under Annex XI, Section 1.5. ('Grouping of substances and read-across').

32 In support of your adaptation, you provide a key study according to OECD TG 211, with source substance tall oil, reaction products with TEPA (EC 271-417-5 / CAS 68555-22-6).

2.2. Assessment of the information provided

33 We have assessed this information and identified the following issues:

2.2.1. Studies are not adequate and reliable

34 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 corresponding test method referred to in Article 13(3), in this case OECD TG 211, and be adequate for the purpose of classification and labelling and/or risk assessment.

35 For the purpose of classification and labelling, as set out in part 4 of the CLP Regulation and in Section 1.1.3. of the Guidance on the Application of the CLP Criteria, the studies must provide information on hazards, i.e. on the basic properties of the Substance as determined in standard tests or by other means designed to identify hazards under standard conditions. Exposure and risk considerations are not taken into consideration for the purpose of classification and labelling.

36 Consequently, studies performed with modifications to the standard test conditions impacting exposure cannot be considered relevant to derive the hazards of the Substance.

37 Therefore, the following specifications and test conditions of OECD TG 211 must be met:

38 Technical specifications impacting the sensitivity/reliability of the test:

a) the test is conducted with a fully defined test medium, with a concentration of total organic carbon (TOC) ≤ 2 mg/L. Any deviation must be specified and clearly described;

39 Characterisation of exposure:

b) analytical monitoring must be conducted. The method used, including the description on how the test samples were prepared for the quantification of the test substance must be provided;

c) the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within ±20 % of the nominal or measured initial concentration throughout the test.

40 Your registration dossier provides a study according to OECD TG 211 showing the following:

41 Technical specifications impacting the sensitivity/reliability of the test:

a) The study was performed with natural river water with a suspended matter concentration of 16.2 mg/L and a total organic carbon (TOC) concentration of 3.9 mg/L. As a justification for those deviations, you explain that the aquatic toxicity tests were performed using non-standard test media "*to allow a $PEC_{aquatic,bulk}/PNEC_{aquatic,bulk}$ approach.* […] *This approach is based on PEC estimations representing 'total aquatic concentrations'. To characterize the risk to the aquatic compartment the $PEC_{aquatic,bulk}$ is compared with the $PNEC_{aquatic,bulk}$ derived from river water ecotoxicity studies.* […] *For a valid bulk approach test the concentration-effect relationship should be based on the sum of adsorbed and dissolved substance in the volume of the medium tested. One of the advantages of the bulk approach tests with these difficult substances is that in the presence of suspended matter, humic acids and/or algae, the residual sorption to glassware will be negligible*".

42 Characterisation of exposure:

b) Exposure concentrations were analytically determined in this study. However, you do not provide information on the preparation of the test samples for the quantification analyses.

c) You have expressed the effect values based on nominal concentrations. You indicate that, for the purpose of the so-called 'bulk-approach' the effect concentrations are defined as the sum of adsorbed as well as dissolved substance in the volume of the medium tested. You further claim that "*the results of the chemical analyses show that the test organisms were fully exposed to the test substance during the test. Therefore, all effect values given are based on the nominal test item concentrations*".

43 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. Those deficiencies are similar to those already addressed above in Section 1 for 'Growth inhibition study aquatic plants' in 'Reasons related to the information under Annex VII of REACH':

44 The study was conducted with a non-standard test medium containing suspended particulate matter and with a content of TOC exceeding the one recommended by OECD 211. Furthermore, you have expressed the effect values based on nominal concentrations. However, as already explained in Section 1 for 'Growth inhibition study aquatic plants', those deviations and your justifications for those deviations are not acceptable.

45 Therefore, 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 OECD TG 211 and is not adequate for the purpose of classification and labelling.

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

47 In your comments to the draft decision, you claim that the 'bulk-approach' could be appropriate for the risk assessment of the Substance. However, you also acknowledge that results from the aquatic toxicity studies performed according to the 'bulk-approach' are less suitable for Classification and Labelling as they use a non-standard test medium and do not allow the quantification of the intrinsic toxicity of the Substance. You agree to perform the requested test.

2.3. Study design and test specifications

48 OECD TG 211 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 and test specifications' under Section 1 for 'Growth inhibition study aquatic plants'.

3. Long-term toxicity testing on fish

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

3.1. Information provided

50 You have provided the following justification to omit the study:

51 "The safety assessment according to Annex 1 does not indicate the need to investigate further the effects on aquatic organisms. Therefore no chronic fish testing is considered to be required".

3.2. Assessment of the information provided

52 We have assessed this information and identified the following issue:

3.2.1. Your justification to omit the study has no legal basis

53 A registrant may only adapt this information requirement based on the general rules set out in Annex XI. It is noted that Column 2 of Annex IX, Section 9.1, does not allow omitting the need to submit information on long-term toxicity to fish under Column 1 (Decision of the Board of Appeal in case A-011-2018).

54 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

55 Therefore, you have not demonstrated that this information can be omitted.

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

57 In your comments to the draft decision, you agree to perform the requested test.

3.3. Study design and test specifications

58 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.).

59 OECD TG 210 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 Section 1 for 'Growth inhibition study aquatic plants'.

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 20 August 2021.

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

ECHA took into account your comments and amended the deadline.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 12 to 30 months from the date of adoption of the decision. You explained that the Substance is difficult to test and supported your request to extend the deadline with a letter from your test laboratory.

On this basis, ECHA has granted the request and extended the deadline to 30 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: 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]
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[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[2].

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:
   a) the variation in compositions reported by all members of the joint submission,
   b) the boundary composition(s) of the Substance,
   c) 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*

   a) 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.
   b) The reported composition must identify all the constituents as far as possible as well as their concentration (OECD GLP (ENV/MC/CHEM(98)16) and EU Tests Methods Regulation (EU) 440/2008 (Note, Annex). Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

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.

[2] https://echa.europa.eu/practical-guides

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

2. General recommendations for conducting and reporting new tests

2.1. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

[3] https://echa.europa.eu/manuals