~~Confidential~~

Helsinki, 04 June 2024

Addressee
Registrant of JS_173832467_FEUC as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
22 December 2014

Registered substance subject to this decision ("the Substance")
Substance name: Fatty acids, C18-unsatd., trimers, 2-ethylhexyl esters
EC/List number: 605-694-4

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 ***11 June 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. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., Column 2; test method: EU C.20./OECD TG 211).

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

2. Short-term repeated dose toxicity (28 days; Annex VIII, Section 8.6.1.) to be combined with the Screening for reproductive/developmental toxicity below.

3. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.64/OECD TG 422) by oral route, in rats.

4. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., Column 2; test method: EU C.47./OECD TG 210).

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

Information required depends on your tonnage band

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

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

How to comply with your information requirements

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

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

Appeal

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

Failure to comply

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

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

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

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

Appendix 1: Reasons for the request(s)

Reasons common to several requests

0.1. Read-across adaptation rejected

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5.:

- Short-term repeated dose toxicity (28 day) (Annex VIII, Section 8.6.1.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

2 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.

3 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.

4 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. Predictions for toxicological properties

5 You provide a read-across justification document in IUCLID Section 13.

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

- Fatty acids, C18-unsatd., dimers, EC 500-148-0 (source substance 1);
- 2-ethylhexanol, EC 203-234-3 (source substance 2).

7 You provide the following reasoning for the prediction of toxicological properties: "*The target and the source substance 1 are esters with the ester group(s) between an alcohol (2-ethylhexanol) and C18unsatd. dimerised or trimerised fatty acids being the common functional groups. Source substance 2 (C18unsatd. dimerised fatty acid) is a substance showing a strong structural relationship to the predicted hydrolysis product (C18unsatd. Trimerized fatty acids) of the target substance. Source substance 3 (2-ethylhexanol), is the second predicted hydrolysis product of the target substance*".

8 ECHA understands that your read-across hypothesis hypothesis is based on the formation of common (bio)transformation products. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

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

9 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(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

10 Supporting information must include studies to compare properties of the target and source substances, if the impact of exposure to the (parent) Substance on the prediction cannot be excluded (see section 0.1.1.1).

11 Your read-across hypothesis is based on the assumption that the structurally similar source substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance(s) 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(s).

12 In the registration dossier, you provide repeated dose toxicity studies for both source substances as well as a developmental toxicity study for the source substance 2 used in the prediction. Apart from these studies, 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 the source substances cause the same type of effects. In particular, you provided no study on the target substance relevant to the adapted information requirements for these endpoints (bridging study), and also no source study for the second of two proposed hydrolysis products (source substance 1) for the information requirement "toxicity to reproduction".

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

0.1.1.2. Missing supporting information on the formation of hydrolysis products

14 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(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

15 As indicated above, your read-across hypothesis is based on the use of data from the primary metabolites of the target substance. In this context, information characterising the rate and extent of the (bio)transformation of the Substance is necessary to confirm the formation of the proposed hydrolysis products and to assess the impact of the exposure to the parent compound.

16 To demonstrate the absence of exposure to the parent compound, supporting information must include toxicokinetic information on the formation of the common compound(s).

17 However, you have not provided any experimental information about the (bio)transformation of the Substance to support your claims regarding the rate and extent of formation of the proposed hydrolysis products.

18 In the absence of this information, you have not provided supporting evidence establishing that the proposed hydrolysis products are formed as assumed in your read-across hypothesis, and allowing the assessmemt of the (lack of) impact of exposure to the parent compound. Therefore, you have not provided sufficient supporting information to scientifically justify your read-across hypothesis.

0.1.1.3. Missing supporting information on the impact of non-common compound(s)

19 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(s) (Guidance on IRs and CSA R.6., Section R.6.2.2.1.f.).

20 Supporting information must include information on the impact of exposure to common and non common compounds.

21 As indicated above, your read-across hypothesis is based on the the use of data from the proposed hydrolysis products of the target substance. In this context, exposure to the Substance and of the source substance(s) may also lead to exposure to other compounds than the common compound of interest. The impact of exposure to these non-common compounds on the prediction of properties of the target needs to be assessed to ensure that a reliable prediction can be made.

22 In your read-across justification document, the composition information indicates that the Substance contains a majority of trimers (60-80% of tris 2-ethylhexy trimerate and 10-20% of di 2-ethylhexyl trimerate) whereas the UVCB source substances contain a majority of dimers (>70%). Dimers have a smaller molecular weight than trimers, which can lead to differences in bioavailability between the source and target substances. You have provided no justification or experimental data on the impact of these differences of composition and chemical structure on toxicological properties and thus, for the Substance, trimer-specific effects cannot be excluded.

23 In the absence of such information, you have not established that a reliable prediction of the property under consideration of the Substance can be derived on the basis of your read-across hypothesis. Therefore, you have not provided sufficient supporting information to scientifically justify for the read-across.

0.1.1.4. Inadequate or unreliable source study

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

25 Specific reasons why the studies on the source substance(s) do not meet these criteria are explained further below under the applicable information requirement section 3. Therefore, no reliable predictions can be made for this information requirement.

0.1.2. Conclusion

26 Based on the 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. Long-term toxicity testing on aquatic invertebrates

27 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1. However, under Column 2, long-term toxicity testing on aquatic invertebrates may be required by the Agency if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

1.1. Triggering of the information requirement

28 In the provided OECD TG 105 (2013), the saturation concentration of the Substance in water was determined to be below the limit of detection of the analytical method (i.e. < 1 mg/L).

29 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

1.2. Information provided

30 You have adapted this information requirement and provided the following justification:

(i) *"Testing proposal removed. Registration only required for up to 100 tonnes per year therefore testing proposal removed since Long term toxicity to aquatic invertebrates is not a standard requirement according to Regulation (EC) No. 1907/2006, Annex VII - VIII Request to reduce tonnage of registration being progressed via INC000000117676."*

1.3. Assessment of the information provided

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

31 A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

32 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 aquatic invertebrates under Column 1 (Decision of the Board of Appeal in case A-011-2018).

33 Long term testing is an information requirement at Annex VII. Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH and the legal basis you are relying on for your intended adaptation is not apparent to ECHA.

34 Based on the above, you have not demonstrated that this information can be omitted.

35 Therefore, the information requirement is not fulfilled.

1.4. Study design

36 The Substance is difficult to test due to the low water solubility (<1 mg/L) and adsorptive properties (Log K_{ow} > 10). OECD TG 211 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 211. 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.

37 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).

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

- 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 VIII of REACH

2. Short-term repeated dose toxicity (28 days)

39 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1.

2.1. Information provided

40 You have adapted this information requirement by using Annex VIII, Section 8.6.1, column 2 based on the following experimental data from the source substances according to Annex XI, Section 1.5. (Grouping of substances and read-across approach):

(i) a subchronic repeated-dose toxicity study (OECD TG 408, 1996) with the source substance Fatty acids, C18-unsatd., dimers, List 500-148-0;
(ii) a subchronic repeated-dose toxicity study (OECD TG 408, 1996) with the source substance 2-ethylhexanol, EC 203-234-3.

41 Given that your column 2 adaptation relies on a read-across approach, it will be assessed under the rules applicable for grouping of substances and read-across in accordance with Annex XI, Section 1.5.

2.2. Assessment of the information provided

2.2.1. Read-across adaptation rejected

42 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.

43 Therefore, the information requirement is not fulfilled.

2.3. Study design

44 When there is no information available neither for the 28-day repeated dose toxicity (OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

45 The study design is addressed in request 3.

3. Screening for reproductive/developmental toxicity

46 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1.

3.1. Information provided

47 You have adapted this information requirement by using Annex VIII, Section 8.7.1, column 2, based on the following experimental data from the source substances according to Annex XI, Section 1.5. (Grouping of substances and read-across approach):

(i) a prenatal developmental toxicity study (OECD TG 414, 1991) with the source substance 2-ethylhexanol, EC 203-234-3.

48 Given that your column 2 adaptation relies on a read-across approach, it will be assessed under the rules applicable for grouping of substances and read-across in accordance with Annex XI, Section 1.5.

3.2. Assessment of the information provided

3.2.1. Read-across adaptation rejected

49 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.

3.2.1.1. Inadequate or unreliable study on the source substance

50 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 must normally be performed for a particular information requirement, in this case OECD TG 414. Therefore, the following specifications must be met:

a) the highest dose level aims to induce toxicity or aims to reach the limit dose.

51 However, in study (i):

a) the highest dose levels tested was 191 mg/kg bw/d, which is below the limit dose of the test guideline, and no adverse effect were observed. Although you attempt to provide a rationale for this high dose setting by referring to effects observed in a developmental toxicity study with DEHP at equivalent dose levels of 2-ethylhexanol (1988), no such effects were observed in study (i).

52 The information provided does not cover the specification(s) required by the OECD TG 414.

53 Therefore, study (i) submitted in your adaptation does not provide an adequate and reliable coverage of the key parameter(s) of the corresponding OECD TG.

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

3.3. Study design

55 When there is no information available neither for the 28-day repeated dose toxicity study (OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

56 The information requirement for the 28-day repeated dose toxicity study is not fulfilled for the reasons explained under request 2.

57 Therefore, a study according to the test method EU B.64/OECD TG 422 must be performed in rats.

58 As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1., Column 1).

59 Therefore, the study must be conducted in rats with oral administration of the Substance.

4. Long-term toxicity testing on fish

60 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, Section 9.1.3. However, long-term toxicity testing on fish may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

4.1. Triggering of the information requirement

61 As already explained in request 1, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

4.2. Information provided

62 You have adapted this information requirement and provided the following justification:

(i) *"Registered tonnage to be reduced to 10 - 100 tonnes. Long term toxicity to fish is not a standard requirement according to Regulation (EC) No. 1907/2006, Annex VII – VIII"*.

4.3. Assessment of information provided

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

63 A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

64 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).

65 Long term testing is an information requirement at Annex VIII. Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH and the legal basis you are relying on for your intended adaptation is not apparent to ECHA.

66 Based on the above, you have not demonstrated that this information can be omitted.

67 Therefore, the information requirement is not fulfilled.

4.4. Study design

68 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.).

69 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 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 (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online: https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 12 April 2023.

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

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

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Addressee(s) of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third-party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1 Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries (https://echa.europa.eu/practical-guides).
(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2 Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/group of constituents on the test results for the endpoint to be assessed. For example, if a constituent/group of constituents of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/group of constituents.

(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 the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. 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.

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).