EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 14 April 2021

Addressees
Registrants of JS_627-83-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
9 April 2013

Registered substance subject to this decision ("the Substance")
Substance name: Ethylene distearate
EC number: 211-014-3
CAS number: 627-83-8

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 ***19 October 2022***.

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

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

1. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1., Column 2)

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

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

1. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., Column 2)

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

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

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

Reasons for the request(s) are explained in the following appendix/appendices:

- Appendix entitled "Reasons common to several requests";
- Appendix/Appendices entitled "Reasons to request information required under Annexes VII to IX of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- 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, VIII and IX to REACH, for registration at 100-1000 tpa;

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

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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 Christel Schilliger-Musset, Director of Hazard Assessment

[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 on Reasons common to several requests

1. Assessment of your read-across approach under Annex XI, Section 1.5.

In your registration dossier, you seek to adapt the information requirements for the following standard information requirements by grouping substances in the category and applying a read-across approach in accordance with Annex XI, Section 1.5:

- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

ECHA has considered the scientific and regulatory validity of your grouping and read-across approach in general before assessing the specific standard information requirements in the following appendices.

Grouping of substances and read-across approach

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 (addressed under 'Scope of the grouping'). 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 (addressed under 'Predictions for properties').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

A. Scope of the grouping

In your registration dossier you have formed a group (category) of 'Glycol Ester category'. You have provided a read-across justification document in IUCLID Section 13.

You provide the following reasoning for the grouping the substances: "*The Glycol Ester category covers* [redacted] *The fatty acid chains comprise carbon chain lengths ranging from* [redacted] *, mainly saturated but also mono unsaturated* [redacted] *.".*

You define the applicability domain of the category as follows: "*Depending on the degree of* [redacted] *with carbon chain length* [redacted] *(even numbered) linear and branched, mainly saturated but also unsaturated* [redacted] *are included into the category.*

In one case, there is an additional functional group (epoxy) attached to the alkyl chain ([redacted] *what does not eliminate this substance from the category because of similarities in properties and mode of action*".

ECHA understands that this is the applicability domain of the grouping and your predictions are assessed on this basis.

B. Predictions for properties

You have provided the following reasoning for the prediction of aquatic toxicity: *"the similarity is justified on basis of scope of variability and overlapping of composition, representative molecular structure, physico-chemical properties, tox-, ecotoxicological profiles and supported by various (Q)SAR methods"*.

For predictions of ecotoxicological properites, you explain that all the category members show similar absence of toxicity towards aquatic organisms. For prediction of toxicity to algae, you claim that *"the available studies are covering the variability of the category with different alcohol components and fatty acid chain lengths at the lower and upper end of the category"*. For the prediction of long-term toxicity on aquatic invertebrates you explain that fatty acid-1,3-butandiolester (CAS No. 853947-59-8) can be considered as a worst case as it is more water soluble and hence it is expected to have higher bioavailability.

Therefore, ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

For long-term toxicity on aquatic invertebrates, ECHA understands that the properties of your Substance are predicted based on a worst-case approach.

You intend to predict the aquatic toxicity properties of the Substance from information obtained from the following source substances:

Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- C8-C10-fatty acid-1,3-butandiolester (CAS No. 853947-59-8; source substance 1)
- C16-C18- Ethylene glycol (CAS No. 91031-31-1/EC No. 292-932-1; source substance 2)

Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)
- C8-C10-fatty acid-1,3-butandiolester (CAS No. 853947-59-8, source substance 1),

ECHA notes that with regards to prediction(s) of ecotoxicological properties there are issues that are common to all information requirements under consideration, common to some information requirements and also issues that are specific for these information requirements individually. Altogether they result in a failure to meet the requirement of Annex XI, 1.5. The common issues are set out here, while the specific issues are set out under the information requirement(s) concerned in the Appendices below.

Missing supporting information

Annex XI, Section 1.5 of the REACH Regulation states that *"physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)"*. For this purpose *"it is important to provide supporting information to strengthen the rationale for the read-across"*[2]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on other category members. Supporting information must include bridging studies to compare properties of the category members.

As indicated above, your read-across hypothesis is based on the assumption that (i) the

[2] ECHA Guidance R.6, Section R.6.2.2.1.f

structurally similar category members cause the same type of effect(s) and (ii) the source substance 1 constitutes a worst-case for the prediction of long-term toxicity on aquatic invertebrates for the Substance.

In this context, relevant, reliable and adequate information allowing to compare the properties of the category members is necessary to confirm that (i) the category members cause the same type of effects and (ii) the prediction of the long-term toxicity on aquatic invertebrates properties are conservative from the data on other category members. Such information can be obtained, for example, from bridging studies of comparable design and duration for the category members.

For toxicity to algae, you have provided the following studies:

- A study performed on the source substance 1 (according to EU Method C.3; Algal Inhibition test, [redacted] 1997).
- A study performed on the source substance 2 (according to DIN 38412, part 9; [redacted] 1994).

For Long-term toxicity on aquatic invertebrates, you have provided the following study:

- a key study on the source substance 1 (according to OECD 211; [redacted] 2001).

You have also provided short-term toxicity studies on aquatic invertebrates and fish conducted with analogue substances, as listed in section A.1 and B.1 (respectively).

The provided information has the following deficiencies:

- Regarding the short-term studies on aquatic invertebrates and fish, as explained in the Appendices below (in sections A.1 and B.1. respectively), due to the Substance properties these studies are not considered adequate to conclude on the hazard properties.
- Regarding the algae and long-term toxicity on aquatic invertebrates data, for the reasons explained in the Appendices below (sections A.2 and C.1 respectively) all these studies are considered as not adequate.

Consequently, since there are no adequate and reliable studies for the aquatic toxicity across the category, no comparison of toxicity can be made. In particular, ECHA notes that your justification does not address the structural variation within the category regarding the glycol group ([redacted]). While the Substance contains [redacted] In the absence of reliable supporting information relevant for the predicted properties, you have not demonstrated that the glycol group as well as the other structural variation does not affect the predicted ecotoxicological properties (i.e. toxicity to algae and long-term toxicity on aquatic invertebrates).

Therefore, you have not established that the category members show similar ecotoxicological properties nor that source substance 1 constitutes a worst-case for the prediction of long-term toxicity on aquatic invertebrates.

As explained above, the data set reported in the technical dossier does not include relevant, reliable and adequate information to support your read-across hypothesis.

In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties.

C. Conclusions on the grouping of substances and read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substances. Therefore, your adaptations do not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

In your comments to the draft decision, you have mentioed a group (category) of 'FEUC glycol esters category' including ethylene glycol and propylene glycol main subgroups. The proposed FEUC category includes some common members with the 'Glycol Ester category' evaluated above, but also some new category members.

In the comments, you present a strategy relying on the generation of additional "*common studies or bridging studies that will be necessary to support the category*".

As this strategy relies essentially on a category that has not yet been fully described and justified, as well as on data which is yet to be generated for the proposed category members (including common studies or bridging studies), no conclusion on the validity of the proposed category approach can currently be made.

Nevertheless, you agreed in your comments to the draft decsision to perform all requested studies.

Appendix A: Reasons to request information required under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). Long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

You have provided the following information:

A. For short-term toxicity : two source studies according to EU Method C.2 (Acute Toxicity for Daphnia), one performed on the source substance 1 and one on an analogue substance (CAS No 68583-51-7 / EC No 271-516-3).
B. Long-term toxicity : a study performed on the source substance 1 according to OECD TG 211.

We have assessed this information and identified the following issues:

1. Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7b, Section 7.8.5).

In your dossier the saturation concentration of the Substance in water was determined to be 4.24E-012 mg/L.

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

2. For the reasons explained under Appendix C.1 below, the long-term toxicity study on aquatic invertebrates included in your registration dossier does not meet the information requirement.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section C.1.

Your comments to the draft decision regarding this information requirement are addressed under section C.1 below.

2. Growth inhibition study aquatic plants

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

You have adapted this information requirement according to Annex XI, section 1.5 (Grouping of substances and read-across approach), providing the justification examined in the Appendix on Reasons common to several requests above.

You have provided the following information:

- A study performed on the source substance 1 (according to EU Method C.3; Algal Inhibition test [redacted] 1997); study (i).
- A study performed on the source substance 2 (according to DIN 38412, part 9; [redacted] 1994); study (ii).

We have assessed this information and identified the following issues:

A. Your adaptation in accordance with Annex XI, Section 1.5 is rejected already for the reasons explained in the Appendix on Reasons common to several requests above. Moreover, ECHA has identified an endpoint specific issue with regards to your adaptation that is addressed under point B below.

B. Adequacy and reliability of source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following requirements must be met:

Reporting of the methodology and results:

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

Validity criteria

- At least 16-fold increase in biomass is observed in the control cultures by the end of the test;
- The mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
- The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7%.

Characterisation of exposure

- A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;
- 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;
- The test media prepared specifically for analysis of exposure concentrations during the test is treated identically to those used for testing (i.e. inoculated with algae and incubated under identical conditions);

Additional requirements applicable to difficult to test substances:

- If the test material is poorly water soluble, evidence must be provided that the test solution preparation allowed achieving the maximum dissolved concentration under test conditions;
- A justification for, or validation of, the separation technique is provided, especially if filtration is used, as it can cause losses due to adsorption onto the filter matrix.

As mentioned above your registration dossier provides two source studies (study i and ii) performed on the source substance 1 and 2, respectively; showing the following:

- The results of algal biomass determined in each flask at least daily during the test period are not reported for any of the studies;

Validity criteria

- For study (i), you have not provided data related to the biomass . Therefore you have not demonstrated at least 16-fold increase in biomass in the controls by the end of the test.
- You have not provided in any of the study the section-by-section growth rates in the control cultures. Therefore you have not demonstrated that the mean coefficient of variation is ≤ 35%
- You have not provided in any of the study the coefficient of variation of average specific growth rates during the test. Therefore you have not demonstrated that the variation in the control is ≤ 7%.

Characterisation of exposure

- For study (i), you have carried out total organic carbon (TOC) analyses to determine exposure concentrations. You have not provided performance parameters of the analytical method (e.g. LOD, LOQ, recovery). You reported nominal concentrations of 1000 mg/L for study (i) and measured concentration of 3 mg/L.
- For study (ii) no analytical monitoring of exposure was conducted;
- For study (i), the test media prepared specifically for analysis of exposure concentrations was not inoculated with algae.

Additional requirements applicable to difficult to test substances

- For study (i) (limit study), you report that the test solution (1000 mg/L nominal) was prepared, stirred for 18 h and filtered.
- For study (ii), you report that the test solutions were prepared by direct weight of the test substance to dilution water.
- You have not provided any justification for the methods used to prepare the test solutions for any of the studies.

Based on the above, there are critical methodological deficiencies resulting in the rejection of the studies included in your registration dossier. More, specifically:

- For studies (i) and (ii), in the absence of data related to biomass, you have not demonstrated that the validity criteria as defined above are met.
- In study (i), as the deviation in exposure concentrations was not maintained within 20 % of the nominal concentration throughout the test, you have used measured concentrations to derive the EC50. You used the total organic carbon (TOC) method for analytical monitoring of exposure concentrations but you did not provide performance parameters for this method, including limit of detection. While the performance of the method cannot be currently assessed based on the information submitted, the TOC is considered as a nonspecific method with low sensitivity. Therefore the TOC method used may not be reliable to measure the substance in test solution.
- In study (ii) you did not monitor the exposure concentrations during the test and you have not demonstrated that the deviation in exposure concentrations were maintained within 20 % of the nominal concentration throughout the test. Hence for neither studies, it is not possible to conclude if the algae were exposed to the test material nor if the exposure was satisfactorly maintained during the test.

Furthermore, the Substance and selected analogue substances are expected to be difficult to test due to low water solubility. A solubility below 100 mg/L in the test medium is indicative that a test material may be difficult to test according to OECD GD 23. You have reported a solubility in water for the Substance of 4.24E-012 mg/L. In your read-across justification document you have reported water solubility values below 0.01 mg/L (based on QSAR) and 0.05 mg/L (based on experimental study) for the source substances 1 and 2, respectively, which is orders of magnitude below 100 mg/L. On this basis, the substances are expected to

be difficult to test. In the submitted aquatic toxicity studies, there are critical methodological deficiencies related to low solubility of the substances. More specifically:

- you have not justified nor demonstrated that the method applied in test media preparation allowed achieving maximum dissolved concentrations, including the use of filter as a separation method in study (i).

Therefore, the requirements of OECD TG 201 are not met and therefore these studies are not considered adequate for the purpose of classification and labelling and/or risk assessment.

On this basis, the information requirement is not fulfilled.

In your comments on the draft decision you agree to conduct the requested test as specified in the decision.

Study design

The Substance is difficult to test due to the low water solubility (4.24E-012 mg/L). 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 the 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.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Long-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

You have provided the following information:

- A key study according to OECD TG 203 on the Substance.
- You have adapted the information requirement on long-term toxicity on fish in your registration dossier.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7b, Section 7.8.5).

In your dossier the saturation concentration of the Substance in water was determined to be 4.24E-012 mg/L.

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

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section C.2.

Your comments to the draft decision regarding this information requirement are addressed under section C.2 below.

Appendix C: Reasons to request information required under Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

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

You have adapted this information requirement according to Annex XI, section 1.5 (Grouping of substances and read-across approach), providing the justification examined in the Appendix on Reasons common to several requests above and providing a key study (according to OECD 211) that was performed on the source substance 1.

We have assessed this information and identified the following issues:

A. Your adaptation in accordance with Annex XI, Section 1.5. is rejected already for the reasons explained in the Appendix on Reasons common to several requests. Moreover, ECHA has identified an endpoint specific issue with regards to your adaptation that is addressed under point B below.

B. Adequacy and reliability of source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

To fulfil the information requirement, a source study must comply with the OECD TG 211 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following requirements must be met:

Reporting of the methodology and results:
- The full record of the daily production of living offspring during the test by each parent animal is provided;

Validity criteria:
- The mean number of living offspring produced per parent animal surviving is ≥ 60 at the end of the test;

Additional requirements applicable to difficult to test substances:
- If the test material is poorly water soluble, evidence must be provided that the test solution preparation allowed achieving the maximum dissolved concentration under test conditions.
- A justification for, or validation of, the separation technique is provided, especially if filtration is used, as it can cause losses due to adsorption onto the filter matrix.

Your registration dossier provides an OECD TG 211 showing the following:

Reporting of the methodology and results and Validity criteria :
- You have not provided any information on the mean number of living offspring. Therefore you have not demonstrated that the mean number of living offspring produced per parent animal surviving at the end of the test is above 60.

Additional requirements applicable to difficult to test substances:
- You report that the test solution (100 mg/L nominal) was prepared by addition of the

test substance to test water, followed by ultrasonication for 15 minutes, stirring for 48-73 h and filtration using a cellulose nitrate filter (pore size 0.45 µm). The test solutions of the lower test concentrations were prepared by diluting the stock solution with test water. You have not provided any justification for the methods used to prepare the test solutions.

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

- in the absence of data on the daily production of living offspring, you have not demonstrated that the validity criteria as defined above are met.

Furthermore, the Substance and selected analogue substance are expected to be difficult to test due to low water solubility. A solubility below 100 mg/L in the test medium is indicative that a test material may be difficult to test according to OECD GD 23. You have reported a solubility in water for the Substance of 5.14E-010 mg/L. In your read-across justification document you have reported water solubility values below 0.01 mg/L (based on QSAR) for the source substance 1, which is orders of magnitude below 100 mg/L. On this basis, the substances are expected to be difficult to test. In the submitted aquatic toxicity study, there are critical methodological deficiencies related to low solubility of the substances. More specifically:

- you have not justified nor demonstrated that the method applied in test media preparation allowed achieving maximum dissolved concentrations, including the use of filter as a separation method in the study.

Therefore, the requirements of OECD TG 211 are not met and therefore this study is not adequate for the purpose of classification and labelling and/or risk assessment.
On this basis, the information requirement is not fulfilled.

In your comments on the draft decision you agree to conduct the requested test as specified in the decision.

Study design

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' under Appendix A.2.

2. Long-term toxicity testing on fish

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

You have provided the following information:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1, Column 2. In support of your adaptation, you provided the following justification: "*CSA does not indicate need for further investigations*".

We have assessed this information and identified the following issue:

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

Your adaptation is therefore rejected.

In your comments on the draft decision you agree to conduct the requested test as specified in the decision.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

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 Appendix A.2.

Appendix D: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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[3].

B. Test material

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

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[4].

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

Appendix E: 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 21 April 2020.

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

ECHA took into account your comments and did not amend the request(s), but amended the deadline.

Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In your comments on the draft decision you requested ECHA to extend the standard granted time to a total of 15 months to allow time to perform the requested studies and for development of the suitable analytical measurements and preparation of test solutions due to substance characteristics (poorly water soluble). Furthermore, you considered that the the extension to 15 months is needed to allow coordination between registrants within the FEUC glycol ester category.

ECHA took this information into account and granted 3 months extension to the original deadline for development of analytical methods and preparation of test solutions. Therefore, the deadline is set to 15 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 F: List of references - ECHA Guidance[5] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[6]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[6]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[7]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[5] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[6] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix G: Addressees of this decision and their corresponding information requirements

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[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.