EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 14 April 2021

Addressees
Registrant(s) of EO_JS_624-03-3 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
17 June 2017

Registered substance subject to this decision ("the Substance")
Substance name: Ethane-1,2-diyl palmitate
EC number: 210-826-5
CAS number: 624-03-3

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 ***22 July 2024***.

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)

D. Information required from all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit)

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) by oral route, in rats, specified as follows:
   - Ten weeks premating exposure duration for the parental (P0) generation;

- Dose level setting shall aim to induce systemic toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation

You must report the study performed according to the above specifications. Any expansion of the study must be scientifically justified.

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

- Appendix entitled "Reasons common to several requests";
- Appendix/Appendices entitled "Reasons to request information required under Annexes VII to X 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 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.

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:

- Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)
- 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]

You define the applicability domain of the category as follows: "*Depending on the degree of esterification,* [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

a. Prediction for toxicological properties

You have provided the following reasoning for the prediction of toxicological properties: *"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" and "that the constant pattern consists in a lack of potency change of properties across the category".*

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.

You intend to predict the reproductive toxicity properties for the category members from information obtained from the following source substance:

- C8-C10-fatty acid-1,3-butandiolester (CAS No. 853947-59-8; i.e. source substance 1).

ECHA notes the following shortcoming with regards to prediction of toxicological properties.

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 the source substance(s).

Supporting information must include for example bridging studies of comparable design and duration for the Substance and the source substances to confirm your read-across hypothesis.

As indicated above, your read-across hypothesis for toxicological properties including reproductive toxicity (fertility) is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substance cause the same type of effects, and are expected to be quantitatively similar.

You have reported the results from a two-generation reproductive toxicity study (OECD TG 416) conducted with the analogue substance C8-C10-fatty acid-1,3-butandiolester (CAS No. 853947-59-8). According to the robust study summary provided, *"In the high dose group an increased postimplantation loss (statistically significant at $p \leq 0.05$) The slight but statistically (at $p \leq 0.05$) significantly reduced live-born indices at 300 or 1000 mg/kg bw/day were regarded to be spontaneous"*.

This OECD TG 416 study constitutes the only available source of information for sexual function and fertility properties of the members of your category, including the Substance, and it shows potential for the effects on reproduction.

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

There is no bridging information addressing reproductive toxicity available within the category, and the comparison of the reproductive toxicity properties of the Substance and of the source substance C8-C10-fatty acid-1,3-butandiolester (CAS No. 853947-59-8) is not possible. It cannot be therefore confirmed that members of the category, including the Substance, would cause the same type of effects on reproductive toxicity. Also, it cannot be ruled out that the Substance may cause more severe effects on reproductive toxicity than the source substance C8-C10-fatty acid-1,3-butandiolester (CAS No. 853947-59-8). A prediction using the data to be generated on the source substance C8-C10-fatty acid-1,3-butandiolester (CAS No. 853947-59-8) could therefore underestimate the reproductive properties of the Substance.

In the absence of additional bridging information allowing a comparison of the reproductive toxicity (fertility and mating behaviour) of the Substance and of the source substance C8-C10-fatty acid-1,3-butandiolester (CAS No. 853947-59-8), the prediction from substance source substance C8-C10-fatty acid-1,3-butandiolester (CAS No. 853947-59-8) is not possible.

b. Predictions for ecotoxicological 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*"[3]. 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 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 invertebrate 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 (ethylene glycol, propylene glycol, butylene glycol). While the Substance contains 1.2-ethylene glycol, the source substance 1 contains 1.3-butylene glycol. In the absence of

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

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 within a 'Glycol Ester category'. 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 as provided in your registration dossier is rejected.

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. For 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:

A. 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 5.14E-010 mg/L.

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

B. 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.

The comments provided to the draft decision 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 deviation in the test concentrations 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 must be 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:

Reporting of the methodology and results:

- 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 studies 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 studies 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 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) 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 (5.14E-010 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:

- Two source studies according to OECD TG 203 on two analogues substances (CAS No 627-83-8 / EC No 211-014-3 and (CAS No 68958-54-3 / EC No 273-373-2).
- 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 5.14E-010 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 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.

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, 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: Reasons to request information required under Annex X of REACH

1. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

In the registration dossier, you have adapted the standard information requirements mentioned above according to Annex XI, Section 1.2. of REACH (weight of evidence).

In support of your adaptation, you have provided following sources of information for the 'Glycol Ester category' ('Glycol Ester category' described in the 'Appendix on Reasons common to several requests'):

i. Robust study summaries on rat pre-natal developmental toxicity (PNDT) studies (OECD TG 414) conducted with CAS Nos 91031-31-1, 68583-51-7, 853947-59-8, and 85883-73-4 [redacted], 1994; 1997; [redacted] 2007; [redacted], 2007)
ii. Robust study summary on rat 2-generation reproductive toxicity study (OECD TG 416) conducted with CAS No 853947-59-8 [redacted] 2005)
iii. Robust study summaries on rat sub-chronic toxicity studies (OECD TG 408) conducted with CAS Nos 1323-39-3, 151661-88-0 and 68583-51-7 [redacted], 1991; 1993; [redacted] 1967)
iv. Information on the toxicokinetics of glycol esters showing a common metabolic fate resulting in glycol alcohols and free fatty acids.

In addition, to further support your adaptation, you have provided:

v. Review of the utility of testing in a second species for pharmaceutical compounds based on a database analysing developmental toxicity studies of pharmaceuticals in rat and rabbit (Theunissen et al., 2014).
vi. Executive summary of the rabbit PNDT (OECD TG 414) conducted with ethylene glycol, CAS No 107-21-1 (Tyl et al., 1993)

Based on the presented sources of information, you argue that the available data gives sufficient information to conclude on the information required for pre-natal developmental toxicity in a second species, because *"Based on the available information from several independent sources, and based on the general toxicological profile derived from the available data, members of the Glycol Ester category are considered to exhibit no potential for toxicity to development and teratogenicity. No hazard for toxicity to development/teratogenicity was identified in the rat in developmental toxicity studies and the Two-generation study performed according to the current OECD guidelines. Also, taking into account the data available for ethylene glycol tested in rabbits, the data are considered to prove that there is no convincing difference in relative species sensitivity towards glycol fatty acid esters between the rat and rabbit, and hence, testing in a second species would not provide additional evidence relevant for hazard assessment of the Glycol Ester category. Furthermore, the preliminary results of a comparative analysis of data on pharmaceutical compounds suggest that the second species does not add significant information for the assessment of developmental effects."*

Annex XI, Section 1.2 states that there may be sufficient weight of evidence weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of

effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence adaptation.

You have provided a justification for the weight of evidence in IUCLID under section 7.8.2. Whilst this justification can be regarded as integrated summary of the data set, you have not communicated and documented in a robust and transparent manner your considerations on the relevance, relialibity of the individual sources of information. No critical assessment of their relative weight and of the overall adequacy of the data set in the context of these weight of evidence is included in the documentation of your adaptation. Therefore your weight of evidence adaptation is not supported by adequate documentation.

Furthermore, ECHA has identified the following deficiencies in your weight of evidence approach.

Relevance of the information

Relevant information that can be used to support weight of evidence adaptation for information required under Section 8.7.2 at Annex X includes similar information that is produced by the OECD TG 414 on a second species (two species taking the first species into account to address the potential species differences). The following aspects must be covered: 1) prenatal developmental toxicity in two species, including structural malformations and variations (external, visceral and skeletal) 2) maternal toxicity in two species, and 3) maintenance of pregnancy in two species.

The sources of information (i-iii) provide information for the first species (rodent/rat), but do not inform on the properties of the Substance in a second species, i.e. in a non-rodent species. In addition, these sources of information have the following limitations in the context of a weight of evidence approach intended to determine the pre-natal developmental toxicity properties of the Substance in a second species:

- the source of information (ii) provides relevant information on maternal toxicity and maintentance of pregnancy in rats, but does not inform on the developmental toxicity, specifically visceral and skeletal variations ;
- the source of information (iii) does not cover any of the key aspects of pre-natal developmental toxicity.

The source of information (iv) indicates that the glycol esters have a common metabolic fate resulting in glycol alcohols and free fatty acids and the metabolic fate would be expected to be similar in rats, rabbits and humans. Whilst similarities in metabolic fate leads to formation of similar metabolic products across the species, this does not establish that the toxicological impact of exposure to these metabolic products is similar across the species. Therefore, this information is not relevant for the purpose of hazard identification, and does not contribute to the assessment whether a substance has a particular dangerous property.

The source of information (v) discusses at a general level the utility of testing in a second species for pharmaceutical compounds. However, it does not provide any of the required specific information on effects of the Substance on structural malformations and variations, maternal toxicity or maintentance of pregnancy in a second species.

The source of information (vi) provides relevant information on the pre-natal developmental toxicity in the second species (rabbit) for one of the hydrolysis product of the glycol esters, the ethylene glycol (CAS 107-21-1). Your rationale is that *"Ethylene glycol is one of the hydrolysis products considered relevant for the Glycol Ester category based on the common metabolic fate of glycol esters resulting in glycol alcohols [...] and the respective free fatty acids.",* and that *"taking into account the data available for ethylene glycol tested in rabbits, the data are considered to prove that there is no convincing difference in relative species sensitivity towards glycol fatty acid esters between the rat and rabbit."*

Missing relevant information on the impact of all hydrolysis products

Based on the ECHA Guidance R.4, Section R.4.3.2.2., a scientific justification needs to establish why the toxicological or ecotoxicological properties of the Substance can be determined from information on the similar substances. As indicated above, your rationale is based on the assumption that the Substance and the (bio)transformation product(s) of the Substance will cause the same type of effect(s). In this context, exposure to the Substance will lead to exposure to all of its (bio)transformation product(s). For the prediction of properties of the Substance, the impact of exposure to all (bio)transformation products needs to be considered to ensure that a reliable prediction can be made.

In your dossier, you have provided information on the common metabolic fate of the glycol esters, including the Substance, resulting in structurally similar chemicals, glycol alcohols and the respective free fatty acids. You have provided pre-natal developmental toxicity studies in rats conducted with the glycol esters (i) and in rabbit conducted with the ethylene glycol (vi). You propose that based on this information, there is no difference expected in the pre-natal developmental toxicity of the Substance between the rat and the rabbit.

ECHA acknowledges that the toxicological properties of the Substance can be derived from the information on its (bio)transformation products, the glycol alcohol and the free fatty acid. For this purpose, the ethylene glycol (CAS 107-21-1) provides adequate and reliable information on the properties of the glycol alcohol formed from the hydrolysis of the Substance.

However, you have not provided adequate and reliable information on the pre-natal developmental toxicity in a second species of the free fatty acids formed as a result of exposure to the Substance.

Conclusion on weight of evidence

The information provided with the source substance ethylene glycol (CAS No. 107-21-1) alone is not sufficient to provide reliable information of the hazard properties of the Substance; and therefore, does not prove that there would not be differences in species sensitivity glycol fatty acid esters between the rat and rabbit. Therefore, you have not provided sufficient evidence for your weight of evidence adaptation.

In conclusion, none of the provided sources of information alone or together allows to conclude whether the Substance has or has not hazardous properties related to prenatal developmental toxicity in a second species. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

ECHA further observes the following on the information on the source studies.

Robust study summaries for the source studies not available

Under Article 10(a)(vii) of the REACH Regulation, a technical dossier must include "*robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I*". Annex I, Section 1.1.4/3.1.5 of REACH states that robust study summaries are "*required of all key data used in the hazard assessment*". The robust study summaries should contain detailed information on the methods, results and conclusions of the studies allowing for an independent assessment.

In your weight of evidence justification, you have provided a summary of the source study conducted with the ethylene glycol (CAS 107-21-1). However, the dossier does not contain a robust study summary containing detailed information on the methods, results and conclusions of the study.

In your comments to the draft decision, you do not agree to perfom the requested study. Instead, you indicate your intention to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

You refer to 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 under the Appendix 'Reasons common to several requests', but also some new category members.

You propose to read across from an analogue substance EC 292-932-1 using data from an OECD TG 414 (source study) which is yet to be conducted after being requested by ECHA in a separate compliance check decision. In addition, you intend to provide an OECD TG 422 conducted with the analogue substance EC 292-932-1 and similar studies on related substances within the ethylene glycol esters sub-category in order to demonstrate the adequacy of the read across approach.

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 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 source and bridging studies), no conclusion on the compliance can currently be made. Should you decide to pursue the strategy presented in your comments, ECHA will assess its compliance in the follow-up to dossier evaluation.

Information on study design

A PNDT study according to the OECD TG 414 should be performed in the rabbit or rat as the preferred species. The test in the first species was carried out by using a rodent species (rat). Therefore, a PNDT study in a second species must be performed in the rabbit as preferred non-rodent species with oral[4] administration of the Substance.

2. Extended one-generation reproductive toxicity study

The basic test design of an Extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is a standard information requirement under Annex X to REACH. Furthermore Column 2 of Section 8.7.3. defines when the study design needs to be expanded.

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

[4] ECHA Guidance R.7a, Section R.7.6.2.3.2.

You have provided two-generation reproductive toxicity study (OECD TG 416) conducted with an analogue substance C8-C10-fatty acid-1,3-butandiolester (CAS No. 853947-59-8) (Cordts, 2005).

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

As explained in the Appendix on Reasons common to several requests, your adaptations in accordance with Annex XI, Section 1.5. is rejected.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision, you do not agree to perfom the requested study. Instead, you confirm your intention to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

You refer to 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 under the Appendix 'Reasons common to several requests', but also some new category members.

You propose to read across from an analogue substance EC 292-932-1 using data from an OECD TG 443 (source study) which is yet to be conducted after being requested by ECHA in a separate compliance check decision. In addition, you intend to provide an OECD TG 422 conducted with the analogue substance EC 292-932-1 and similar studies on related substances within the ethylene glycol esters sub-category to demonstrate the adequacy of the read across approach.

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 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 source and bridging studies), no conclusion on the compliance can currently be made. Should you decide to pursue the strategy presented in your comments, ECHA will assess its compliance in the follow-up to dossier evaluation.

The specifications for the study design

Premating exposure duration and dose-level setting

The length of premating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required to obtain results adequate for classification and labelling and /or risk assessment. There is no substance specific information in the dossier supporting shorter premating exposure duration.[5]

Therefore, the requested premating exposure duration is ten weeks.

[5] ECHA Guidance R.7a, Section R.7.6.

In order to be compliant and not to be rejected due to too low dose levels, the highest dose level shall aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose level selection should be based upon the fertility effects. A descending sequence of dose levels should be selected in order to demonstrate any dose-related effect and to establish NOAELs.

If there is no relevant data to be used for dose level setting, it is recommended that range-finding results are reported with the main study.

You have to provide a justification with your study results that demonstrates that the dose level selection meets the conditions described above.

Cohorts 1A and 1B

Cohorts 1A and 1B belong to the basic study design and must be included.

Species and route selection

The study must be performed in rats with oral[6] administration.

Further expansion of the study design

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and/or Cohort 3 (developmental immunotoxicity)] were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if relevant information becomes available from other studies or during the conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in ECHA Guidance[7].

[6] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[7] ECHA Guidance R.7a, Section R.7.6.

Appendix E: 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[8].

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[9].

[8] https://echa.europa.eu/practical-guides
[9] https://echa.europa.eu/manuals

Appendix F: 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 requests, 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 30 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 36 months to allow time for the performance of the developmental toxicity (OECD 414) and reproduction toxicity (OECD 443) studies to allow time for the generation of appropriate bridging studies from the read across source substances to support the proposed FEUC glycol ester category. Additionally, you considered that 15 months would be required to perform the requested aquatic toxicity studies and for development of the suitable analytical measurements and preparation of test solutions due to substance characteristics (poorly water soluble). Finally, you considered that the the extension is needed to allow coordination between registrants within the FEUC glycol ester category.

ECHA took this into account and granted 6 months extension to the original deadline. Therefore, the deadline is set to 36 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 G: List of references - ECHA Guidance[10] 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)[11]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[11]

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[12]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[10] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[11] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[12] 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 H: 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]		

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.