EUROPEAN CHEMICALS AGENCY

Helsinki, 18 July 2017

Addressee: [redacted]

Decision number: CCH-D-2114366658-33-01/F
Substance name: PROPANOIC ACID, 2-HYDROXY-, 2-ETHYLHEXYL ESTER, (2S)-
EC number: 606-097-1
CAS number: 186817-80-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 11/12/2015
Registered tonnage band: Over 1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate) (Annex VI, Section 2.2.2.);**

2. **Spectral data (Annex VI, Section 2.3.5.);**

3. **Robust study summary (RSS) for key study, "Short-term toxicity to aquatic invertebrates.001", Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1. in conjunction with Annex I, Section 3.1.5);**

4. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD TG 201) with the registered substance;**

5. **Robust study summary (RSS) for key study, "Short-term toxicity to fish.001", Short-term toxicity testing on fish (Annex VIII, Section 9.1.3. in conjunction with Annex I, Section 3.1.5);**

6. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**

7. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance.

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **25 October 2019**. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

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

Appendix 1: Reasons

1. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate) (Annex VI, Section 2.2.2.)

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the identification of the registered substance.

"Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)" is an information requirement as laid down in Annex VI, Section 2.2.2. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

Based on the substance identity information provided in IUCLID section 1.1 and 1.2, the registered substance refers to an ester containing the (S)-lactate and the racemic alcohol moieties. In IUCLID section 1.4 you did not provide information on the optical activity of the substance, instead you included in the remarks field the following statement: "*based on optical activity of the lactate feedstock*". No value for the "optical activiy of the lactate feedstock" was provided, and furthermore no additional information on how the chirality of the substance has been determined was provided in the registration dossier.

Due to the missing information on the "optical activity of the lactate feedstock" and the absence of other analytical information (e.g. chiral chromatography, etc.) that would allow to clearly establish the stereochemistry of the substance, it is not possible to verify that the substance is the (S)-isomer.

Therefore, you should provide information on how the stereochemistry of the substance subject to this decision has been determined. This may include the optical activity of the substance itself, or any other analytical method that can confirm the stereochemistry of your substance (e.g. chiral chromatography). Alternatively, you can provide the optical activity of the lactate feedstock together with a statement clarifying that the stereochemistry of the lactate feedstock does not change during the manufacturing process.

As for the reporting in the registration dossier, the information requested above should be included in IUCLID section 1.4.

2. Spectral data (Annex VI, Section 2.3.5.)

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the identification of the registered substance.

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The current registration does not contain the full set of analytical data for the registered substance, as only a Mass Spectrum (MS) has been provided. The Ultra-violet (UV) and

Infra-red (IR) spectra are missing in section 1.4 of the IUCLID dossier, and a scientifically based justification for not including this information has not been provided.

ECHA points out that the identity of the substance cannot be confirmed based exclusively on the MS and considers that the IR and the UV spectra are necessary for the identification of the substance. The IR spectrum displays characteristic vibration bands for the covalent bonds of organic compounds such as the registered substance. The UV spectrum displays the absorption in the UV range due to the presence of the chromophores in the structure of the substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit an IR and UV spectra generated on the substance subject to the present decision. You shall ensure that the description of the analytical methods used for recording the spectra are specified in the dossier in such detail to allow the methods to be reproduced, in line with the requirements under Annex VI Section 2.3.7 of the REACH Regulation. You shall ensure that the information is consistent with the information provided throughout the dossier.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID section 1.4.

3. Robust study summary (RSS) for key study, "Short-term toxicity to aquatic invertebrates 001", Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1. in conjunction with Annex I, Section 3.1.5)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Pursuant to Articles 10(a)(vii) of the REACH Regulation, the information set out in Annexes VII to XI must be provided in the form of robust study summary, if required under Annex I. Article 3(28) defines a robust study summary (RSS) as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the ECHA Practical Guide 3: 'How to report robust study summaries'.

"Short-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex VII, Section 9.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 3.1.5. if there are several studies addressing the same effect, the study or studies giving rise to the highest concern shall be used to draw the conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust study summaries are required for all key data used in the hazard assessment.
In the technical dossier, under IUCLID section 6.1.3. "Short-term toxicity to aquatic invertebrates", you have provided the following study record to fulfil the standard information requirement of Annex VII, Section 9.1.1.:

- Key study, reliability 2, GLP not specified, test method: OECD Guideline 202 (*Daphnia sp.* Acute Immobilisation Test) with the registered substance. Data source: publication ("The ecotoxicity and the biodegradability of lactic acid, alkyl lactate esters and lactate salts", Bowmer CT, Hooftman RN, Hanstveit AO, Venderbosch PWM, van der Hoeven N (1998), Chemosphere 37: 1317-1333).

ECHA notes that in the RSS you have indicated in the relevant IUCLID field that the validity criteria have been fulfilled. However, you have not provided sufficient information in the RSS, or elsewhere in the technical dossier, to allow verification of the reliability of this study, as further discussed below.

According to the validity criteria described in the OECD TG 202 (2004), paragraph 6, a test is valid when (1) in the control, including the control containing the solubilising agent, not more that 10 percent of the daphnids has been immobilised; (2) the dissolved oxygen concentration at the end of the test is ≥ 3 mg/L in the control and test vessels. However, concerning these validity criteria, ECHA notes that in your RSS you have not provided the following elements as defined in paragraph 27 of the OECD TG 202:

- Results on the number and percentage of daphnids that were immobilised or showed any adverse effects (including abnormal behaviour) in the controls at each observation time.
- Measurements of the dissolved oxygen concentration made during the test.

In absence of this information, it is not possible for ECHA to evaluate whether the validity criteria of this study have been fulfilled.

Furthermore, also the following elements, needed to verify the reliability of the results, are not reported in the RSS submitted:

- The age of the test species, *Daphnia magna*. As described in OECD TG 202 (2004), paragraph 3, the test organisms shall be less than 24 hours old at the beginning of the test.
- The number and percentage of daphnids that were immobilised or showed any adverse effects (including abnormal behaviour) in each treatment group, at each observation time and a description of the nature of the effects observed, as given in paragraph 27 of OECD TG 202 (2004).
- The nominal test concentrations and, preferably, the result of all analyses to determine the concentration of the test substance in the test vessels, as given in paragraph 27 of OECD TG 202 (2004).

Therefore, ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard/risk assessment.

In order to allow an independent assessment of the study submitted, pursuant to Article 41(1) and (3) of the REACH Regulation you are requested to provide a complete robust study summary with the above missing elements for the key study.

4. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.3.. You provided the following justification for the adaptation: *"QSAR calculation, based on generally accepted model (ECOSAR), supported by publication based on slightly different input data."*

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI; Section 1.3. ECHA notes the following concerning the validity of the predictions submitted. ECHA has compared the QSAR information provided for 2-ethylhexyl-S-lactate (CAS No 186817-80-1, EC No 606-097-1) with the requirements set for acceptance of QSAR models in Annex XI, section 1.3 as follows:

- Adequate and reliable documentation of the applied method is provided: You have submitted a QPRF for the ECOSAR prediction.
- Results are derived from a (Q)SAR model whose scientific validity has been established: The ECOSAR model for esters used for prediction is scientifically valid.
- The substance falls within the applicability domain of the (Q)SAR model: the predictions for the 2-ethylhexyl-S-lactate (CAS No 186817-80-1, EC No 606-097-1) fall within the applicability domain of the ECOSAR model.
- Results are adequate for the purpose of classification and labelling and/or risk assessment: ECHA notes that the prediction provided for algal growth inhibition (96h EC50 = 7.9 mg/L) was obtained using an estimated octanol water partition coefficient (Log Kow) of 2.69, *"calculated using the computer program, KOWWIN (Version 1.67)."* However, in your dossier you have provided a valid experimental Log Kow value of 3.3 (OECD 117/EU A.8) for the registered substance. ECHA notes that using the valid experimental Log Kow as input to the model the 96h EC50 estimate for algae would be 2.95 mg/L. This value is lower than the prediction for algal growth inhibition provided in the registration dossier, thus ECHA concludes that the provided information is not the most conservative approach. ECHA notes that the prediction for algal growth inhibition provided in the registration dossier was used with an AF of 1000 to calculate a PNEC of 0.008 mg/L. However, if for example the most conservative prediction was used, the PNEC would be 0.003 mg/L, leading to freshwater RCRs of above 1 for some exposure scenarios (e.g. in exposure scenario 7 - F3).

Regarding the use of QSAR results for PNEC derivation, ECHA notes that, according to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017), Section 7.8.4.1, when deciding on the validity of a model, also the regulatory context of the decision needs to be considered. In ECHA's *Practical Guide - How to use and report (Q)SARs* (version 3.1, July 2016), section 2.5, it is in general recommended to use (Q)SAR results as part of a weight of evidence (WoE) approach or as supporting information. Furthermore, according to ECHA's *Guidance on information requirements and chemical safety assessment, Chapter R.10* (May 2008), Appendix R.10-1, the results from QSAR models should be used in combination with results from different models and approaches. ECHA hence considers that the above approach given in the ECHA Guidance is best suited for a QSAR result to be adequate for the purpose of risk assessment.

ECHA hence concludes that taking into account a conservative approach, the predictions are considered not adequate for the purpose of risk assessment as required by Annex XI, section 1.3.

In conclusion, the QSAR information submitted is currently not sufficient to fulfil the requirements of Annex XI, section 1.3.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA's *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Algae growth inhibition test, EU C.3./OECD TG 201).

5. Robust study summary (RSS) for key study, "Short-term toxicity to fish.001", Short-term toxicity testing on fish (Annex VIII, Section 9.1.3. in conjunction with Annex I, Section 3.1.5);

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Pursuant to Articles 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of robust study summary, if required under Annex I. Article 3(28) defines a robust study summary (RSS) as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the ECHA Practical Guide 3: 'How to report robust study summaries'.

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 3.1.5. if there are several studies addressing the same effect, the study or studies giving rise to the highest concern shall be used to draw the conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust study summaries will be required of all key data used in the hazard assessment.

In the technical dossier, under IUCLID section 6.1.1. "Short-term toxicity to fish", you have provided the following study record to fulfil the standard information requirement of Annex VIII, Section 9.1.3.:

- Key study, reliability 2, GLP not specified, test method equivalent or similar to OECD Guideline 203 (Fish, Acute Toxicity Test) with the registered substance. Data sources: publication ("The ecotoxicity and the biodegradability of lactic acid, alkyl lactate esters and lactate salts", Bowmer CT, Hooftman RN, Hanstveit AO, Venderbosch PWM, van der Hoeven N (1998), Chemosphere 37: 1317-1333) and study report ("Semi-static acure toxicity test with 2-ethylhexyl lactate and the fathead minnow", [redacted] (1993), Report no. IMW-R 93/206).

ECHA notes that in the RSS you have indicated in the relevant IUCLID field that the validity criteria have been fulfilled. However, you have not provided sufficient information in the RSS, or elsewhere in the technical dossier, to allow verification of the reliability of this study, as further discussed below.

The OECD TG 203 (1992) lists four validity criteria that need to be fulfilled in order for a study to be considered valid. One of these, given in paragraph 6 of the guideline, describes that 1)the mortality in the control(s) must not exceed 10% (or one fish if less than 10 fish are used) at the end of the test. ECHA notes that in the RSS submitted, you have not provided any information on mortality in controls, as also required in paragraph 23 of the guideline. In absence of this information it is not possible to evaluate whether all of the validity criteria given in the OECD TG 203 have been fulfilled in the study submitted.

Therefore, ECHA notes that, contrary to Article 3 (28) of the REACH Regulation, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard/risk assessment.

In order to allow an independent assessment of the study submitted, pursuant to Article 41(1) and (3) of the REACH Regulation you are requested to provide a complete robust study summary with the above missing elements for the key study.

6. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.5., column 2. You provided the following justification for the adaptation: "*The hazard assessment and the risk characterisation are currently based on acute aquatic toxicity data. In accordance with REACH Annex IX, column 2, "long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms". The chemical safety assessment for 2-ethylhexyl-S-lactate does not indicate the need for further testing since all uses are identified as safe. Therefore, waiving of a long-term study in aquatic invertebrates is justified.*"

However, ECHA notes that currently your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2. In your Chemical safety Assessment (CSA) you have used the results for Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1), Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.) and Short-term toxicity testing on fish (Annex VIII, Section 9.1.3). First, ECHA notes that the studies on short-term aquatic invertebrates and on short-term fish used in the CSA cannot currently be assessed, as discussed in sections 3. and 5. above. Consequently, their use in the CSA is currently not reliable. Second, ECHA notes that you have used the result of the study on Growth inhibition study aquatic plants to calculate the PNEC. However, as discussed in section 4. above, this study is not valid. As a result, also the PNEC derivation and consequent risk characterisation are currently not reliable. Therefore, the CSA cannot currently be used to adapt the current information requirement.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

7. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.6., column 2. You provided the following justification for the adaptation "*The hazard assessment and the risk characterisation are currently based on acute aquatic toxicity data. In accordance with REACH Annex IX, column 2, "long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms". The chemical safety assessment for 2-ethylhexyl-S-lactate does not indicate the need for further testing since all uses are identified as safe. Therefore, waiving of a long-term study in fish is justified.*"

However, ECHA notes that currently your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2. As already discussed in section 6. above, the PNEC derivation and consequent risk characterisation are currently not reliable. Therefore, the CSA cannot be used at this stage to adapt the current information requirement.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R.7b, Figure R.7.8-4)*.

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R.7b,* version 4.0, June 2017).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration for requests (4, 6-7)

Before conducting the tests requested above under points 6. and 7., you shall consult the ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R.7b, Section R.7.8.5 to determine the necessity to conduct the long-term toxicity testing on aquatic invertebrates and on fish.

Concerning the order of studies to be conducted, you may first complete the robust study summary requirements made under requests 3. and 5., and carry out the Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.) requested under point 4 and subsequently update the CSA according to Annex I of the REACH Regulation.
If you come to the conclusion that no further investigation of chronic effects on aquatic organisms is required, you shall update your technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.5 and 9.1.6. taking into account the new data generated by the growth inhibition study requested by the present decision and exposure assessment and risk characterisation.
On the other hand, if after the update of the CSA you come to the conclusion that the long-term toxicity tests are still required to refine the risk assessment, you should further consider Integrated Testing Strategy (ITS) for aquatic toxicity as described in ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R.7b (Section R.7.8.5., including Figure R.7.8-4).

According to the ITS, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially less sensitive than other trophic levels (i.e. fish, invertebrates, algae), long-term studies may be required on both fish and invertebrates. In such case, according to the ITS, the long-term *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 25 January 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

ECHA did not receive any comments by the end of the commenting period.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.