EUROPEAN CHEMICALS AGENCY

Helsinki, 3 September 2018

Addressee: [redacted]

Decision number: CCH-D-2114440251-64-01/F
Substance name: TRIBUTYLAMINE
EC number: =
CAS number: 102-82-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10/04/2018
Registered tonnage band: 100-1000 T

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. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats with the registered substance;**

2. **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;**

3. **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;**

4. **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;**

5. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment: generate an exposure assessment for all relevant exposure scenarios and revise the risk characterisation accordingly.**

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 of the REACH Regulation. In order 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 an adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **10 December 2020**. 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. Advice and further observations are provided in Appendix 3.

ECHA
EUROPEAN CHEMICALS AGENCY

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, shall 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. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

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.

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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.

In your dossier based on which the initial Draft Decision (DD) was prepared you had sought to adapt this information requirement according to Annex XI, Section 1.5 of the REACH regulation. In your comments on the DD you agreed with ECHA's rejection of the read-across approach. In the updated technical dossier you have deleted the read-across approach and have concluded that the available information do not fulfill current test guideline requirements and as such are not sufficient for evaluation of repeated dose toxicity of the registered substance.

ECHA acknowledges your intention to conduct a study on the registered substance to fulfil the present information requirement.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. ECHA notes that the substance is toxic by the inhalation route (Fatal if inhaled) and skin irritant. In addition the substance is liquid with vapour pressure 0.18hPa. ECHA considers that for the purpose of generating useful properties information for classification and labelling for target organ toxicity, the substance should be tested via the oral route due to its potential irritant properties via the inhalation route. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

In your comments to the DD, you have proposed to perform this study via the inhalation route according to OECD 413. You have indicated that although the route of administration proposed by ECHA in the DD is in line with the ECHA Guidance, you consider that the inhalation route is more appropriate due to:

1. Higher toxicity in the acute inhalation studies compared to the acute oral studies that you consider is of concern for route-specific effects
2. The necessity to derive a specific DNEL (hazard via the inhalation route, long term exposure, local and systemic effects)

You have further provided a justification document within your updated registration dossier explaining your proposal to test the neutralised form of tributylamine (tributylamine hydrochloride) in order to avoid irritating effects and allow testing higher doses/concentrations.

ECHA considered that in order to achieve meaningful concentrations to assess the systemic toxicity potential the oral route is preferred over the inhalation route due to its properties (irritant and fatal if inhaled).

ECHA considered that local effects in a sub-chronic toxicity study might mask other systemic toxicity effects or induce unnecessary stress to the animals with consequences to the outcome of the study.

ECHA notes that the higher toxicity observed in the acute inhalation toxicity studies compared to the acute oral studies might be due to local effects via inhalation since the studies were performed with the registered substance and not with the neutralised form (e.g. tributylamine HCL). In addition, the available toxicokinetic information indicate that the registered substance is completely absorbed via the oral route whereas there is no specific toxicokinetic information available to indicate differences when comparing the oral versus the inhalation route. Therefore, ECHA does not agree that the higher toxicity observed in the acute inhalation studies compared to the acute oral studies provide sufficient evidence that there are route-specific effects for systemic toxicity apart from the observed local effects.

Regarding derivation of a specific DNEL for local effects, ECHA considers that the current approach presented in the dossier appears to be protective for the local effects (low threshold value used for risk assessment and adequate risk management measures reported in the Chemical Safety Report). The proposal for testing with the neutralised form of the registered substance would also not allow for derivation of a specific DNEL for local effects.

Furthermore, since the requested 90-day repeated-dose toxicity study includes parameters to investigate potential triggers for extended-one generation reproductive toxicity study, ECHA notes that the latter would have to, if triggered, be performed via the oral route (as per ECHA Guidance CSA/IR R.7a for EOGRTs for strong irritants). Therefore, the oral route for the repeated-dose toxicity study would be more useful for the design, if needed, of the EOGRTs study.

For the reasons outlined above, ECHA does not agree to change the route of administration from oral to inhalation and has not amended the decision.

ECHA acknowledges the intention to investigate additional parameters within the 90-day repeated dose toxicity study (e.g. sperm motility and estrous cycle).

ECHA acknowledges the intention to perform the test with the neutralised form of the registered substance (tributyalmine hydrochloride) and agrees with this approach.

According to the test method EU B.26./OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

Notes for your consideration

ECHA notes that a revised version of OECD TG 408 was adopted this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. You should test in accordance with the revised version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).

2. 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.

In your dossier based on which the initial Draft Decision (DD) was prepared you had sought to adapt this information requirement according to Annex XI, Section 1.5 of the REACH regulation. In your comments on the DD you agreed with ECHA's rejection of the read-across approach. In the updated technical dossier you have deleted the read-across approach and have provided the following information in an endpoint study record(ESR) in IUCLID section 6.1.5. Toxicity to aquatic algae and cyanobacteria: "*This information will be submitted later based on ECHA communication number CCH-D-2114375527-39-01/D.*" In addition you have provided the following ESRs:

a) Supporting study, "[redacted] (1987), (Reliability 2, GLP compliance: "*not specified*") Test method: German Industrial Standard DIN 38412, part 9 (draft), test species: *Scenedesmus subspicatus*,

b) Supporting study, "*Screening test: Stability of tributylamine in Elendt M4-medium according to OECD 201 without algae based on TOC-content*", (Reliability 2, not GLP) [redacted] 2014

c) Supporting study, "*Screening test: Stability of tributylamine in Elendt M4-medium according to OECD 201 without algae based on TOC-content*", (Reliability 2, not GLP)

ECHA acknowledges your intention to conduct a study on the registered substance to fulfil the present information requirement.

ECHA also acknowledges the information provided in the supporting studies a), b) and c). ECHA notes that tests on stability of substance without test organisms, studies b) and c), cannot be used to fulfil the present information requirement.

Regarding study a) above ECHA notes that you have submitted an algae study on the registered substance carried out according to the German Industrial Standard DIN 38412, part 9. In the ESR you have identified the following: "*Test procedure in accordance with*

national standard methods (DIN 38412, part 9); detailed study report not available; however, the data were peer-reviewed by BUA and have been used in a legally binding classification (KBwS, WGK 2); hence, effect values are considered as reliable". ECHA notes that the DIN 38412, part 9 is not one of the guidelines listed in ECHA's Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b, as an acceptable alternative to the OECD TG 201/ EU Method C.3 standard methods. According to ECHA guidance data observed from non-standard methods can be used for hazard assessment, however, such data should be particularly assessed for their adequacy (reliability and relevance) and completeness. ECHA therefore considers that for a study that has not been generated with an acceptable standard method, the robust study summary needs to be detailed enough to allow assessing the validity of the study. In this case ECHA notes that the DIN 38412, part 9, study is poorly reported and assessment of its validity is not possible due to the following.

In the study summary for the DIN 38412, part 9, study no information is given on details on test solution (other than a single value for pH). For results you have only provided effect values, EC10 and EC50 at 72 and 96 h. You have indicated that "*biomass growth rate as well as growth curves are not available*". In the ESR you define also that "*The effect data were presumably evaluated based on biomass, although there is no clear indication on the evaluation base.*" ECHA notes that as defined in ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) for algae studies "*The preferred observational endpoint in this study is algal growth rate inhibition because it is not dependent on the test design, whereas biomass depends both on growth rate of the test species as well as test duration and other elements of test design*". ECHA guidance also describes that the EC50 derived from biomass (EbC50) should not be used and "*Where only the EbC50 is reported, but primary data are available, a re-analysis of the data should therefore be carried out to determine the ErC50.*" Furthermore, "*if only an EbC50 is reported and no primary data are available, it should be considered to perform a new algae study to obtain a valid ErC50 and NOEC or ErC10 especially if algae are the most relevant species for the effects assessment.*"

Concerning whether the validity criteria have been fulfilled in the DIN 38412 study, you have indicated "*not specified*". ECHA notes that in the standard algae growth inhibition guidelines OECD test guideline 201/EU Method C.3 paragraph 11 a test is valid when: a) the biomass in the control cultures increases exponentially by a factor of at least 16 within the 72-hour test period (specific growth rate of 0.92 day^{-1}); b) 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 does not exceed 35%; c) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures does not exceed 7% in tests with *Pseudokirchneriella subcapitata* and *Desmodesmus subspicatus*. As only the effect values in the test medium has been provided, with the information provided it is not possible for ECHA to establish whether these validity criteria would be fulfilled. Furthermore, the dossier contains no information on the controls. All of this information is needed to verify the validity of the study.

ECHA therefore considers that from a combination of poor reporting and uncertainty on the parameter which the effect value is based on, ECHA cannot establish the validity of the study on the basis of the current information. ECHA hence considers that study a) listed above cannot be used to fulfil the information requirement of Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.) for the registered substance.

In conclusion for this endpoint, in your technical dossier you have not provided data on algae toxicity for the registered substance that ECHA could verify to be reliable.

Therefore, 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) 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).

3. 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.

In your dossier based on which the initial Draft Decision (DD) was prepared you had sought to adapt this information requirement according to Annex XI, Section 1.5 of the REACH regulation. In your comments on the DD you agreed with ECHA's rejection of the read-across approach. In the updated technical dossier you have deleted the read-across approach. Instead 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: "*In accordance with column 2 of REACH Annex IX, long-term 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. CSA resulted in RCRs below 1 for all environmental compartments, thus demonstrating safe use.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2 because of the following: You have not included an exposure assessment (EA) nor a risk characterisation (RC) for the environment in your CSA. Consequently it is not possible for ECHA to verify whether your claim of risk assessment not showing the need for long-term testing is valid. ECHA notes also that due to the absence of information on growth inhibition study aquatic plants (request 2 above) you currently do not have sufficient information to conduct an EA and RC for environment.

Therefore, your adaptation of the information requirement cannot be accepted. However, ECHA refers you to the *Notes for your consideration* section at the end of request 4. for possibility of fulfilling requests 2 to 4 in a tiered manner. In your comments on the DD you agreed to follow the approach as described.

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).

4. 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: "" *"In accordance with column 2 of REACH Annex IX, long-term 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. CSA resulted in RCRs below 1 for all environmental compartments, thus demonstrating safe use. Furthermore, the substance is not classified as dangerous to the environment according to Directive 67/548/EEC or Regulation (EC) No 1272/2008 or assessed as PBT / vPvB. Therefore and for reasons of animal welfare a long-term toxicity study with fish is not proposed."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 because your CSA is not complete as fully discussed in request 3. above. In addition, ECHA notes that substance not being classified and/or being assessed as PBT/vPvB are not acceptable waivers for the present endpoint Also, regarding your reasons for animal welfare, as explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement.

ECHA also considers that based on the short-term data provided in the technical dossier, it is not possible to conclude that fish would be significantly less sensitive than aquatic invertebrates and algae. Nevertheless, ECHA notes that the aquatic ITS given in ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) may be applied as further specified in the *Notes for your consideration* at the end of this section. In your comments on the DD you agreed to follow the approach as described.

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 R7b, 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 R7b,* 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 3 and 4

Before conducting the chronic aquatic tests requested above, you may first update the CSA according to Annex I of the REACH Regulation as discussed in section 5 below. If you come to the conclusion that no further investigation of effects on aquatic organisms is required, you shall update your technical dossier by clearly stating the reasons for adapting the standard information requirements of Annex IX, 9.1.5. and Annex IX, 9.1.6. taking into account the new exposure assessment and risk characterisation for environment.

On the other hand, if after the update of the CSA you come to the conclusion that further hazard data is required to refine the risk assessment you shall consult the ECHA *Guidance on information requirements and chemical safety assessment (*version 4.0, June 2017*)*, Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the *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.

5. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

Pursuant to Article 14(4), if the substance fulfils the criteria for any of the hazard classes listed in that provision or is assessed to be a PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative), the CSA shall include exposure assessment and risk characterisation.

Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Annex I, Section 6 of the REACH Regulation requires you to characterise the risk for each exposure scenario and to consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in Section 5 of the same Annex have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment, Section B.8.4. (pages 47 to 48) (version 2.1, December 2011) states that "*if no adverse effects have been observed in studies at the highest recommended concentration/doses tested, this would normally indicate that no hazard has been identified and no DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect or protection target would not be needed*".

ECHA notes that you have classified the substance as Acute Tox. 4 (H302), Acute Tox. 2 (H310), Acute Tox. 1 (H330) and Skin Irrit. 2 (H315) thus, fulfilling the criteria set out in Article 14(4) of the REACH Regulation to require an exposure assessment and a risk characterisation in the chemical safety assessment.

With regard to the scope of the required exposure assessment, as stated above and in accordance with Annex I, section 5.0., it has to cover all hazards that have been identified according to sections 1 to 4 of Annex I of REACH Regulation.

In the CSR that you provided, the exposure assessment for the environment is missing. You claimed that no exposure assessment is necessary for the environment by stating that "*In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an*

exposure estimation is not necessary. Consequently all identified uses of the substance are assessed as safe for the environment." In the latest dossier update submitted on 10 October 2016, based on which this draft decision is prepared, you have indicated that "*CSR not updated therefore not consistent with current IUCLID dossier - an appropriate update will be provided as soon as possible*". ECHA notes that no further update has been submitted.

Based on current available information from the technical dossier, ECHA notes that an adverse effect was observed in the valid short-term toxicity study to aquatic invertebrates where an EC50 of 8 mg/L was obtained. Therefore, exposure assessment and risk characterisation for environment are needed to address the hazard identified for the environment. As further outlined in Guidance *on information requirements and chemical safety assessment*, Part B: Hazard Assessment, Section B.8.1. (version 2.1, December 2011), such identified hazards (among others) necessitating exposure assessment are the *"hazards for which there are classification criteria and there is information on these properties of the substance showing that it does have these properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified".* Moreover, the above mentioned guidance specifies further (in Section 8.4.2.2.) that *"If there are ecotoxicity data showing effects in aquatic organisms, but the substance is not classified as dangerous for the aquatic environment, an aquatic PNEC can nevertheless be derived thus indicating a hazard to the aquatic environment.(...) Hence. quantitative exposure assessment, i.e. derivation of PECs, is mandatory for the water, sediment and soil environmental compartments."*

In your comments on the DD you agreed to provide the exposure assessment and risk characterisation for environment as requested. Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to generate an environmental exposure assessment for all relevant exposure scenarios and subsequently perform the risk characterisation for each exposure scenario to demonstrate the safe use of the substance, and update the dossier accordingly.

Appendix 2: Procedural history

You were notified that the draft 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. However, following your comments on the draft decision and the inter-related new and substantial information provided in the updated dossier, ECHA has taken into account all the updated information, relevant, to the draft decision. Based on the average production and/or import volumes for the three preceding calendar years, the tonnage band has been changed from 1000 + tonnes per year (submission number: [redacted]) to 100- 1000 tonnes per year (Latest submission number: [redacted]).

The compliance check was initiated on 16 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 took into account your comments and all the updated information of submission [redacted] As a result, the requests for information on Description of the analytical methods (Annex VI, Section 2.3.7.), Composition of the substance (Annex VI, Section 2.3.) Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species and Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.) were removed. For the requests for information on Sub-chronic toxicity study (90-day) oral route (Annex IX, Section 8.6.2.), Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.), Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.) and Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.), only Appendix 1 was modified.

As a consequence of removing some of the requests, the deadline for providing the information to meet the requests remaining in the decision has been set to 27 months.

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 request(s) in this decision, or to fulfil otherwise the information requirement(s) 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 test(s) 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 test(s) 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 test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.