EUROPEAN CHEMICALS AGENCY

Helsinki, 28 May 2019

Addressee: [redacted]

Decision number: CCH-D-2114470723-47-01/F
Substance name: Triiron phosphide
EC number: 234-682-8
CAS number: 12023-53-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 27 March 2013
Registered tonnage band: 10-100
Joint submission tonnage band: 100 – 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. **Description of the analytical methods (Annex VI, Section 2.3.7.) ;**
   - **Identification and quantification of the constituents**
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 test material representative of the registered substance;**
3. **Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: Fish, acute toxicity test, OECD TG 203) with test material representative of the registered substance;**
4. **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 test material representative of the registered substance;**
5. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with test material representative of the registered substance.**

You have to submit the requested information in an updated registration dossier by **8 March 2021**. You shall also 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, Hazard Assessment C4

[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

INFORMATION ON SUBSTANCE IDENTITY

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.

1. Description of the analytical methods (Annex VI, Section 2.3.7.)

Annex VI, section 2.3.7 of the REACH Regulation requires that each registration dossier contains a sufficiently detailed description of the analytical method used for establishing the composition of the registered substance and therefore its identity. This information shall be sufficient to allow the method to be reproduced. According to chapter 4.2.1 of the Guidance for identification and naming of substances under REACH and CLP (Version 2.1 May 2017) available on the ECHA website, for inorganic substances, the use of methods such as X-Ray Diffraction (XRD) or X-Ray Fluorescence (XRF) or Atomic Absorption Spectroscopy (AAS) may be more suitable to confirm their structure and therefore identity.

You have provided results of an elemental analysis of your substance that includes information on the content of iron, phosphorous and impurities (attachment [redacted] in IUCLID section 1.4). However, you have not provided the description of the analytical methods used for that analysis. Furthermore, no XRD analysis of your substance has been provided in section 1.4 of your dossier. Therefore, your dossier does not have sufficient information to verify the reported composition of the registered substance and therefore its identity.

Accordingly, you are required to provide the description of the analytical method used on the identification and quantification of the main constituent and impurities, including the descriptions of the elemental analysis methods reported in the attachment [redacted]. You will also need to include an XRD pattern recorded on the substance, or data from a suitable alternative method that can provide the same information (e.g. a record that enables the characterisation of the atomic structure of the substance, showing for the match of the identified absorption bands or emission wavelengths of a sample of your substance vs. that of a certified standard reference).

The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained. Please note that for XRD you will need to include details of sample/standard preparation, voltage, current, X-ray source and define the refinement method for quantitative XRD

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

In your comments to the draft decision you agreed to provide requested descriptions and results of the XRD analysis as part of an updated dossier.

ECOTOXICOLOGICAL INFORMATION

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier covering information requirements at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

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

"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 VII, Section 9.1.2., column 2. You provided the following justification for the adaptation: "*In accordance with Annex VII Column 2 of the REACH Regulation, this study does not need to be conducted if the substance is highly insoluble in water. Fe3P was found to have a water solubility of less than 1 mg/L at 20°C (refer to section 4.8 of the registration dossier) and is considered to be highly insoluble in water. On this basis this study is considered unnecessary.*"

ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex VII, Section 9.1.2., column 2 due to the following. You base your justification for waiving on the results obtained from the OECD TG 105 water solubility study while you also have data from a transformation/dissolution study (OECD GD 29) available. ECHA notes that as your substance is inorganic, the results from the transformation/dissolution study are most relevant in determining its solubility in aquatic test media and its aquatic toxicity potential (ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7a* (version 6.0, July 2017). ECHA acknowledges that the concentrations of iron, phosphorous, and orthophosphate, measured after 7 and 28 days, are low, however for instance effects on phosphorous could occur at these concentrations when compared to its aquatic effect values publicly available on the ECHA dissemination website. ECHA therefore considers that there is a need to evaluate the aquatic toxicity potential of the registered substance further.

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.

In your comments on the draft decision (DD) you agreed to conduct an algae study and indicate that effects would be assessed "*in the filtrate of test media to which different loadings of Fe3P will be added (cfr. WSF-methodology)*" rather than following the standard approach for sparingly soluble metal compounds, such as your substance, as discussed further below.

In your general comments for the ecotoxicological tests requested in this decision, you discuss that the hazard and risk assessment for a sparingly soluble inorganic compound should be carried out either 1) by comparing the dissolved fractions of each element as obtained from a transformation/dissolution study with existing acute/chronic Ecotoxicity

Reference Values (ERVs), or 2) by conducting ecotoxicity tests in aqueous media spiked with the elemental composition/speciation determined in the transformation/dissolution study. You indicate that 1) is not possible due to the unknown speciation of the non ortophosphate P-fraction and that due to this unknown speciation 2) cannot be followed as it is not possible to generate a test medium that reflects the exact composition/speciation of the transformation/dissolution medium.

You note that attempts have been made in recent years to determine the potential presence of phosphine in Fe_3P solutions, however the attempts were unsuccessful "*due to several technical reasons related to low solubility and high volatility of phosphine, but also related to safety requirements that were related to the measurements of the highly neurotoxin phosphine (i.e. phosphine is needed as calibration gas for the gas-chromatographic analytical method)*".

ECHA however considers that the difficulties described by you are not substantiated and notes that methods of analysis of phosphine are described e.g. in relation to the use of the pesticide aluminium phosphide (e.g assessment report p. 43 accessible at https://echa.europa.eu/information-on-chemicals/biocidal-active-substances/-/disas/factsheet/4/PT14). Furthermore, in your comments you describe a number of other compounds that could be the "non ortophosphate P-fraction" but you have not indicated whether you have attempted to analyse the presence of these compounds in the transformation/dissolution medium to show whether the unknown P fraction could relate to these. ECHA therefore considers that with the information provided you have not justified why it is not possible to analytically identify which soluble P-compound the "unknown P-fraction" obtained from the transformation/dissolution study refers to.

You agree that depending on the speciation of the unknown P-fraction, toxic effects may occur and have quoted effect values for different P-compounds obtained from ECHA dissemination website. ECHA has not evaluated the validity of the studies quoted by you, but notes that both phosphorus and phosphine have harmonised classifications due to their acute toxicity to fish, also shown in the data quoted by you.

You indicate that due to the difficulties in identifying the speciation of the unknown P-fraction you will conduct the algae study requested with the Water Soluble Fraction (WSF), i.e. you will prepare a stock solution using the Water Accommodated Fraction method (WAF) and subsequently filter it to remove any undissolved components. However, you also acknowledge that such approach should normally not be used for sparingly soluble metal compounds. As discussed above, ECHA does not consider that the attempts at identifying the speciation of unknown P-fraction have been adequate. ECHA therefore considers it not justified, with the current information, to deviate from the standard approach for inorganic substances.

ECHA also considers the WAF/WSF method in general inappropriate for inorganic substances such as your substance for the following reasons. Firstly, the WAF method does not take into account the influence of pH nor the surface properties of the test material which would be required to be able to compare the toxicity results obtained with the results obtained for the solubility as determined in the transformation/dissolution study reflecting the availability of the inorganic compound in the environment. Secondly, also other differences in the test media preparations, such as stirring, filtering, the time samples are left to equilibrate, make it not possible to compare the results obtained from a WAF/WSF study with the solubility in a transformation dissolution study. Thirdly, results from a WAF/WSF study are usually given

in nominal concentrations whereas according to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) for sparingly soluble metals measured data on the dissolved fraction(s) is always required for getting reliable toxicity test data and test results where solubility is exceeded must be considered unreliable. Furthermore, precipitation and other reactions potentially caused by high loading, commonly used in WAF/WSF approach, may mask toxicity. For the above reasons the WAF method does not accurately estimate potential hazard of inorganic substances and should not be used to generate data.

As part of your comments you have also submitted a short-term fish study (OECD 203) conducted using the WSF method to assess whether the unknown P-fraction would cause toxic effects. ECHA has assessed this study under section 3 below and for the reasons explained therein, as well as the limitations on the WAF/WSF method given in the previous paragraph, considers that the study cannot be used to conclude on the potential toxicity of the registered substance to fish.

Lastly, in your comments you consider that as no request for an acute daphnia study is made in this decision, the OECD 202 limit test, also conducted using a WAF/WSF method, available in the registration dossier is considered acceptable and therefore new studies can be conducted using the same approach. However, as described above, and further in section 3 below, ECHA does not agree that new data should be generated with the WAF/WSF method. Also it may still be necessary to provide further data on aquatic invertebrates (please refer to section 4).

In conclusion, ECHA considers that you have not adequately justified why it is not possible to identify the "unknown P-fraction" and consequently ECHA does not consider that deviation from the standard practice of assessing the aquatic toxicity of a metal compound is justified.

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. You are to carry out the test in a way that that maximises the concentration of dissolved ions in solution and that expresses the highest toxicity. Any advice given in the specific guideline, here the OECD TG 201, for testing of inorganics should be followed. Analytical monitoring of the exposure concentrations, for the three main components iron, phosphorus and orthophosphate is necessary to demonstrate that the concentrations of the soluble ions tested are in a similar range to the concentrations found in the transformation/dissolution study submitted within the dossier. You are to provide data that is usable for hazard and risk assessment and for classification and labelling. Any substance specific considerations you may use in your hazard and risk assessment need to be fully justified and the approach chosen needs to cover the whole substance as registered including, for instance, the counter-ion and any impurities.
Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with test material representative of the registered substance subject to the present decision: Algae growth inhibition test, EU C.3./OECD TG 201).

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

"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.

You have sought to adapt this information requirement according to Annex VIII, Section 9.1.3., column 2. You provided the following justification for the adaptation: "*In accordance with Annex VIII Column 2 of the REACH Regulation, this study does not need to be conducted if the substance is highly insoluble in water. Fe3P was found to have a water solubility of less than 1 mg/L at 20°C (refer to section 4.8 of the registration dossier) and is considered to be highly insoluble in water. On this basis this study is considered unnecessary.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex VIII, Section 9.1.3., column 2. The justification you provided for this endpoint is identical to that addressed in section 2. above. Your adaptation for the present endpoint is also rejected for the reasons explained in section 2. above.

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

In your comments you indicate that a short-term fish study according to OECD 203 has been conducted with the registered substance in 2013 (test species *Pimephales prolemas*, study at pH 6) but has not been included in the registration dossier. ECHA reminds you of your responsibility to keep your registration dossier up to date as laid down in Article 22 of REACH.

In your comments you have included a summary of the above study (a IUCLID format Robust Study Summary (RSS)). You again refer to the limitations of the standard approach of preparing a reconstituted medium since the speciation of the non-ortophosphate P-fraction is unknown (addressed in ECHA's reply under section 2.) and indicate that the study has therefore been conducted using the [redacted] as starting material. The study has been conducted using the WSF method with 100 mg/L loading. For dissolved iron you provide the following analytically determined concentrations "*new: 3893.5 µg/L*" and "*old 1279.0 µg/L*", however for orthophosphate only the following single concentration is provided "*0.33 mg/L reactive phosphorus*". For total Fe a measured value of 4976 µg/L is given. No unknown P-fraction is identified.

Under the section "*Overall remarks, attachments*" you discuss that the short-term fish study was necessary to be conducted to clarify a concern raised by the "*level and nature of the P concentration formed*" in the transformation/dissolution test. You indicate also that "*the formation of toxic P species for P alloys is a very relevant concern given proven for certain metal-P couples*". You continue that "*The total P levels measured in the transformation/dissolution tests indicated clearly that acute fish toxicity would be spotted in case traces of phosphine would be formed without quick transformation to orthophosphates*".

ECHA considers the discussion and the information provided on test material concentrations as contradictory for the following reasons. Firstly, you note that the short-term fish study has been conducted to clarify the concern of the unknown speciation of P as identified in the transformation/dissolution, but the results provided do not allow comparison with the transformation/dissolution data since in the short-term fish study only concentrations of iron and orthophosphate are provided. Secondly, the discussion implies that if at all present, any

phosphine would be quickly transformed to ortophosphate, however in the transformation/dissolution study not all P has been in the orthophosphate form as results have been given separately for phosphorus and orthophosphate. ECHA accordingly considers that currently the short-term fish study provided as part of your comments cannot be used to prove that the unknown P-fraction is of no ecotoxicological concern.

In section 2. ECHA has assessed why in general the WAF/WSF method is not applicable for your substance. Under "Conclusions" in the RSS of the short-term fish study you indicate that the study was a validation study, by which ECHA understands that you may refer to the option described in the OECD GD 29 (p. 12, footnote 1) where it is described that the aqueous medium from a completed transformation/dissolution study may in some cases for data validation be used directly for an OECD 203 test. While you have not explicitly stated that such approach was followed, ECHA acknowledges that after preparation the stock solution was left to equilibrate and stirred at 200 rpm for 7 days. The solution was then filtered through a 0.45 µm filter to remove the undissolved prior to study initiation. The agitation and equilibration time correlate with those given in the OECD GD 29 for the short-term study. While a smaller filter size (e.g. 0.2 µm) is in general recommended in the OECD GD 29 (paragraph 23), the choice of the appropriate filter size depends on the size of the particles tested. No information on the surface area/size of the particles tested in the short-term fish study is provided, nor is the filter size given in the transformation dissolution study in the dossier. It is therefore not possible to assess whether the test material preparation is comparable. Wrong filter size could also lead to physical effects which may mask real toxicity as discussed below and hence make a study not reliable.

Furthermore, you indicate that in the study "*a small but statistically significant difference in survival was observed between the control and the 100 % WSF exposure*". You consider that the effects observed were "*presumably more corresponding with physical effects at the fish gill due to very high Fe concentrations*" however no proof nor other discussion of precipitation nor of physical effects is provided. As discussed in section 2. above one of the reasons why the WAF/WSF method is not acceptable to inorganics is that precipitation and other reactions potentially caused by high loading may mask toxicity. According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) results from tests where a visual precipitation is observed should be discarded however the absence of a visual precipitation does not exclude that colloids may be present that could affect the test results. ECHA hence notes that there is no proof that the effects observed were physical effects, however ECHA also notes that a study with physical effects cannot be considered reliable due to the potential masking effect.

In summary, albeit the limitations of the OECD 203 study identified above, ECHA notes that effects were observed. According to ECHA Guidance R. 7.b if mortality occurs at a limit test a full short-term study according to OECD 203, or a long-term toxicity study as appropriate (according to column 2, Annex VIII, a long-term study shall be considered if the substance is poorly water soluble, i.e. solubility <1 mg/L, TGD 2003), needs to be conducted. ECHA considers that the study provided in your comments cannot be used to conclude on toxicity to fish.

Lastly, ECHA notes that in your comments you have provided effect values obtained from short-term studies on fish for different P-compounds (as taken from ECHA website). While the quality of these data has not been evaluated by ECHA, ECHA notes that if the data on a P-compound would correspond to the speciation of P resulting from the transformation of the registered substance, you should consider whether the data can be used to fulfil the

current standard information requirement as per the agreed approach for sparingly soluble inorganic compounds. As discussed in section 2. above ECHA considers that clarifying the speciation of P is required for an accurate assessment of the potential risks of the registered substance. ECHA does not consider that with the information provided in your dossier and comments it can be concluded that no risks to the aquatic environment, and in particular fish, would occur.

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 acute toxicity test (test method EU C.1. / OECD TG 203) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.3.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with test material representative of the registered substance subject to the present decision: Fish, acute toxicity test (test method: EU C.1./OECD TG 203).

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

"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: "*In accordance with Annex IX, Column 2 of the REACH Regulation, this study may be proposed by registrants if the chemical safety assessment indicates a need to further investigate the effects on aquatic organisms. The available aquatic toxicity testing does not suggest any harmful effects on the aquatic environment (refer to dossier section 6.1.3), and it is noted that Fe3P is not sufficiently soluble in water to necessitate further short-term aquatic toxicity testing. A 28-day transformation-dissolution test was conducted to assess the release of Fe3P into the aqueous phase during long-term exposure (refer to dossier section 4.8); it was found that over the duration of the test, only very small quantities of iron, phorphorous, and orthophosphate were released into the aqueous medium and so Fe3P would not be anticipated to have any significant effect on the aquatic environment in the long term. On this basis long-term aquatic toxicity testing is considered unneccessary*."

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., Column 2. As already discussed in Section 2. above, while ECHA acknowledges that the concentrations of iron, phosphorous, and orthophosphate measured in the 28-d transformation/dissolution test are low, effects on phosphorous could occur at these concentrations when compared to its aquatic effect values publicly available on the ECHA dissemination website. ECHA therefore considers that there is a need to evaluate the aquatic toxicity potential of the registered substance further.

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.

In your comments you indicate that as the registered substance is not acutely toxic to invertebrates nor to fish and there is no need to assess the long-term hazard. ECHA however refers to the sections 2. and 3. and notes that the acute aquatic dataset is not yet complete and hence cannot be used to waive the current information requirement. ECHA also refers you to the aquatic ITS in the notes for your consideration below after section 5.

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 test material representative of the registered substance subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

5. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.)

"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. The justification you provided for this endpoint is identical to that addressed in Section 4. above. Your adaptation for the present endpoint is also rejected for the reasons explained in Section 4. above.

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.

ECHA notes that in your comments you indicate that as the registered substance is acutely not toxic to invertebrates nor to fish there is no need to assess the long-term hazard. ECHA however refers to the sections 2. and 3. and notes that the acute aquatic dataset is not yet complete and hence cannot be used to waive the current information requirement. ECHA also refers you to the aquatic ITS in the notes for your consideration below after section 5.

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) can be performed 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, Section R.7.8.4.1.*

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 test material representative of 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 sections 2. to 5.

Concerning the order of the aquatic studies (requests 2. to 5.) to be conducted, you may first fulfil the information requirements related to aquatic acute toxicity (requests 2. and 3.). 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.

If due to the properties of the substance to be tested you consider aquatic testing difficult you should consult the relevant sections of the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6/REV1(6 July 2018) and ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing

of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

Deadline to submit the requested information in this decision

The timeline indicated in the initial draft decision to provide the information requested was 12 months from the date of adoption of the decision. However, as indicated in the *Notes for your consideration* section above, you may first fulfil the information requirements for aquatic acute toxicity and then consider whether the chronic aquatic testing is needed in addition. The timeline has hence been extended to 21 months to allow for sequential testing.

Appendix 2: Procedural history

ECHA notes that the tonnage band of one member of the joint submission is 100 to 1 000 tonnes per year.

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 24 July 2018.

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 did not amend the request(s), but amended the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) 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.