Helsinki, 28 July 2020

Addressees
Registrants of JS_Niobium_Metal listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
22 May 2017

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Niobium
EC number: 231-113-5
CAS number: 7440-03-1

Decision number: [Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)]

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***5 May 2022***.

A. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201) with the Substance

2. The long-term toxicity testing on aquatic invertebrates also requested at C.1. below (triggered by Annex VII, Section 9.1.1., column 2)

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. The long-term toxicity testing on fish also requested at C.2. below (triggered by Annex VIII, Section 9.1.3., column 2)

2. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.; Test method: OECD TG 209) with the Substance

C. Requirements applicable to all the Registrants subject to Annex IX of REACH

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

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.
To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annex VII of REACH, if you have registered a substance at 1-10 tonnes per annum (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- you have to comply with the requirements of Annexes VII and VIII of REACH, if you have registered a substance at 10-100 tpa;
- you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa;
- you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 1000 tpa.

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

When a study is required under several Annexes of REACH, the reasons are provided in the corresponding appendices of this decision. The registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants in accordance with Article 53 of REACH.

The Appendices A to C state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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

Appendix on general considerations

(i) Assessment of the read-across adaptations (Annex XI, Section 1.5.) proposed in your comments on the draft decision

In your comments on the draft decision, you explain that you intend to predict the properties of the Substance from information obtained from the following substances

- Niobium pentachloride (EC no. 233-059-8 / CAS no. 10026-12-7):
  - Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
  - Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
  - Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

- Dinobium pentoxide (EC no. 215-213-6 / CAS no. 1313-96-8):
  - Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.)

Annex XI, Section 1.5. specifies three conditions which must be fulfilled whenever a read-across approach is used:

(i) there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category;
(ii) it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group;
(iii) adequate and reliable documentation of the applied method must be provided.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[2] and related documents[3,4].

You provide the following reasoning for the prediction of ecotoxicological properties:

- As specified in the executive summary of the MISA 2 workshop (ECHA, 7 February 2019), you explain that the direct aquatic ecotoxicity testing of metals and sparingly soluble metal salts (SSMCs) is in principle not recommended. You state that Niobium pentachloride is well soluble in water and therefore constitute a valid alternative to the testing of the Substance.
- You indicate that following dissolution of Niobium pentachloride, dissolved Niobium species undergo rapid hydrolysis. You refer to a study conducted according to a Transformation/Dissolution protocol similar to the screening test of OECD GD 29 to show that the dissolution of the source leads to higher concentrations in dissolved Niobium compared to the Substance.
- You consider that the effects observed in some short-term toxicity study on Niobium pentachloride are not relevant for the Substance as they were observed at concentrations over the upper dissolution limit of the Substance.
- You state that "*one study testing the toxicity of the substance Niobium pentaoxide towards aquatic microorganisms is available*".

ECHA understands that you intend to predict the ecotoxicological properties of the Substance

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals. 2008 (May) ECHA, Helsinki. 134. pp. Available online: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9
[3] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)
[4] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

using a read-across hypothesis which is based on the similar structure and on the formation of the same dissolved Niobium forms. The properties of your Substance are predicted based on a based on a worst-case approach.

In principle, ECHA agrees that the aquatic ecotoxicity testing of a soluble form is to be preferred to the direct testing of metals or of sparingly soluble metal forms. We consider that the testing of Niobium pentachloride may provide relevant information to cover the information requirements for the Substance. However, concerning the predictions of ecotoxicological properties based on the data on Niobium pentachloride described in your comments on the draft decision, ECHA notes the following shortcomings:

1) Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*" (ECHA Guidance R.6, Section R.6.2.2.1.f). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include information to confirm your claimed worst-case prediction.

As indicated above, your read-across hypothesis is based on the transformation of the Substance and of the source substance to the same dissolved Niobium forms. In this context, reliable information characterising the rate and extent of the solubilisation of the Substance and of the source substance(s) is necessary to support your predictions. Therefore adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3) must be provided. For metals of sparingly soluble metal compounds, the Transformation/Dissolution study in aqueous media (Annex 10 of UN-GHS and OECD GD 29) is the recommended method (ECHA Guidance R7.a, Section R.7.1.1.1). This method requires that the following conditions are met:

- The test material must be representative of the Substance and must correspond to the smallest representative particle size on the market;
- The screening study is performed by adding the test substance in the aqueous medium at a single loading of 100 mg/L;
- The screening test must cover a pH range from 5.5 up to 8.5. The full test must be carried out at a pH that maximizes the concentration of the dissolved metal ions in solution.

You have provided the following studies on the solubilisation of the Substance and of the source substance in water:

(i) a GLP compliant Transformation/Dissolution study according to OECD GD 29 with the Substance ([redacted] 2011) already included in your technical dossier,
(ii) a reference, in your comments on the draft decision, to a study conducted according to a Transformation/Dissolution protocol similar to the screening test of OECD GD 29 and performed with Niobium pentachloride,
(iii) a reference, in your comments on the draft decision, to a study conducted according to a Transformation/Dissolution protocol similar to the screening test of OECD GD 29 and performed with Diniobium pentoxide.

With regard to study (ii), you state that the preliminary study was conducted at a loading rate

of 11.5 to 14 g/L. You have not specified at which pH maximum solubilisation was achieved. We conclude that the test was conducted at extremely high loading rates with no justification and that you have not demonstrated that it was conducted at a pH that maximizes the concentration of the dissolved metal ions in solution

With regard to study (i) and (iii), the highest pH tested was 8 and therefore this study did not cover the mandotory pH range from 5.5 up to 8.5. As higher dissolution was observed with increasing pH, higher dissolution may be expected at pH 8.5.

In your comments, you acknowledge that "*the impact of the particle size of Niobium pentachloride was not reported*" in the study on the source substance. However you state that "*Niobium metal is marketed or used in compact form and as granular form. Dissolution testing of the substance with particle size of 1 mm is considered to be representative and a worst-case scenario according to the ECHA Guidance on the Application of the CLP Criteria (2017)*".

2) Reliability of the source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

In your comments on the draft decision, you refer to acute toxicity studies conducted on the source substance Niobium pentachloride, including a short-term toxicity study on aquatic invertebrates according to OECD TG 202, a growth inhibition study on aquatic plants according to OECD TG 201 and a short-term toxicity testing on fish according to OECD TG 203. You also refer to an activated sludge respiration inhibition test according to OECD TG 209 on Diniobium pentoxide. You have not provided a robust study summary for any of these studies.

In the absence of adequate reporting of the methodology and results obtained in these studies ECHA is not in a position to evaluate the adequacy and reliability of this information. In particular, for the aquatic toxicity studies, it is not possible to verify the identity of the test material used (including purity and presence of impurities), if an adequate experimental set-up was used (e.g. adequacy of the test medium, pH of the test medium during the test period, spacing factor between test concentrations, adequacy of the selected test organisms) and in general if the validity criteria of the corresponding test guidelines were fulfilled. Similarly the validity of the activated sludge respiration inhibition test cannot be verified.

3) Adequacy of the source studies

For poorly water soluble substances (e.g. water solubility below 1 mg/L or below the detection limit of the analytical method of the test substance) long-term toxicity study on aquatic invertebrates and on fish must be considered instead of acute tests as specified in Annex VII, Section 9.1.1., Column2).

With regard to the studies on aquatic toxicity on the source substance Niobium pentachloride, you explain that some effects were observed at very high loading rates for aquatic invertebrates and algae. However you report that EC/LC/IC50 concentrations were above the highest loading rate. While the highest loading rate in these studies were ≥ 100 mg/L, you report that measured concentration in dissolved Niobium were in the 1-10 µg/L range.

We note that measured concentrations in dissolved Niobium species were well below 1 mg/L. This information indicate that upon dissolution Niobium pentachloride is transformed into

poorly water soluble tantalum species. Poorly water soluble substances require longer time to reach steady-state conditions and therefore, the long-term test is required. You have not submitted long term studies and based on the limited information reported by you, the selected studies do not provide adequate information on aquatic toxicity to aquatic invertebrates and to fish for the source substance.

Conclusion:

Based on what was explained above, the information included in your comments on the source substance does not provide a reliable basis to predict the properties of the Substance. In the absence adequate and reliable information on the solubiliation of the source substance and of the Substance, you have not established that the source substance constitutes a worst-case for the prediction of the properties under consideration of the Substance. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Consequently, the proposed adaptations fail to comply with the general rules of adaptation as set out in Annex XI, Section 1.5 and are therefore rejected.

Appendix A: Reasons for the requests to comply with Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

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

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement based on Annex VII, Section 9.1.2., Column 2.

In support of your adaptation, you provided the following justification: "*In accordance with column 2 of Annex VII and VIII of Regulation (EC) No 1907/2006, short-term studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water*".

Based on the information provided in your dossier we have identified the following issue:

> Annex VII, Section 9.1.2., Column 2 indicates that information on water solubility may be used to support that aquatic toxicity is unlikely to occur if it shows that the substance is highly insoluble. There is no scientific basis to define a cut off limit value for solubility below which no toxicity could occur (ECHA Guidance R.7b, Section R.7.8.5.). For sparingly soluble metals, measured data on the dissolved fraction are always required for getting reliable toxicity test data (ECHA Guidance R.7b, Section R.7.8.4.1.). In this context it must be considered whether or not the solubility of the Substance permits to conduct a study at concentrations below the solubility limit of the Substance. The technique used to prepare test solutions must aim to achieve the maximum dissolved concentrations (ECHA Guidance R.7b, Table R.7.8-3).
>
> You have provided the results of a transformation/dissolution study according to OECD GD 29. The test was conducted a sample with a particle size of c.a. 1 mm which is adequate to cover the information requirement for the massive form of the Substance. You report that, at a loading of 100 mg/L, the test sample used to conduct the study has a water solubility of 0.104 µg/L at pH 8 after 7 days of stirring. Therefore, while the Substance is regarded as poorly water soluble, the dissolved fraction reaches concentrations that are high enough to be quantifiable. This indicates that, at least for that test sample, the Substance can be tested at concentrations below its solubility limit and that exposure concentrations can be monitored. Therefore, your adaptation according to Annex VII, Section 9.1.2., Column 2 is rejected.

In your comments on the draft decision you explain that you intend to cover this information through an adaptation according to Annex XI, Section 1.5 using information on the source substance Niobium pentachloride (EC no. 233-059-8 / CAS no. 10026-12-7). However, for the reasons explained under the Appendix on general considerations, your adaptation is rejected.

Therefore the information requirement is not fulfilled.

While selecting the test material you must take into account the impact of parameters relevant for the property to be tested. For the Substance, this includes the particle size. For the aquatic toxicity studies, you must justify that the selected test material properties constitute a

reasonable worst case to cover all the registrants of the Substance. Therefore the selected test material should correspond to the most soluble form of the substance taking into account the range of properties of the substance as registered under REACH.

2. The long-term toxicity testing on aquatic invertebrates also requested at C.1. below (triggered by Annex VII, Section 9.1.1., column 2)

"Short-term toxicity testing on aquatic invertebrates" is a standard information requirement in Annex VII to REACH. However, pursuant to Annex VII, section 9.1.1., Column 2, for poorly soluble substances the long-term aquatic toxicity study on aquatic invertebrates (Annex IX, Section 9.1.5.) must be considered.

You have adapted this information requirement based on Annex VIII, Section 9.1.1., Column 2. In support of your adaptation, you provided the following justification: "*In accordance with column 2 of Annex VII and VIII of Regulation (EC) No 1907/2006, short-term studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water*".

You have also provided a supporting study ([redacted] 2005) of the toxicity of the Substance on *Hyalella Azteca*. The study was not conducted according to any recommended guideline. You have not provided a key study for this endpoint.

Based on the information provided in your dossier we have identified the following issues:

A. Annex VII, Section 9.1.1., Column 2 specifies that this information requirement may be adapted if:
   1. there are mitigating factors indicating that aquatic toxicity is unlikely to occur (e.g. the substance is highly insoluble) or;
   2. a long-term toxicity study on aquatic invertebrates is available.

   As already explained under request A.1. above, the data provided in your dossier does not adequately support that aquatic toxicity is unlikely to occur. As explained under request C.1., you did not provide long-term toxicity study on aquatic invertebrates. Therefore, your adaptation according to Annex VII, Section 9.1.1., Column 2 is rejected.

B. To be considered compliant and therefore to enable concluding whether the Substance has dangerous properties and to support the determination of Predicted No-Effect Concentrations (PNECs) for relevant environmental compartments, a long-term toxicity study to aquatic invertebrates has to meet the requirements of EU Method C.20. / OECD TG 211. The key parameters of these test guidelines include:
   - adequate exposure duration (i.e. 21 days);
   - the study of sub-lethal endpoints (i.e. reproduction efficiency).

   The study by [redacted] (2005) reports the results of toxicity tests on *Hyalella azteca* for sixty-three metals at two levels of water hardness (18 and 124 mg $CaCO_3$/L) following 7 days of exposure. In soft water, the 7d-LC50 was determined at 26 µg/L (based on measured values) for Niobium, which is among the lowest 7d-LC50 determined in this study. You consider this study non reliable as the method is not standardized and that insufficient documentation is reported to evaluate the test performance. You state that there was a large variability in the age of test organisms at test initiation (1-11 days) and you consider that the reliability of the reported effect values is low. You conclude that this study should only be used as an indicator for the

toxicity range of several metal species.

While no reference to any guideline is reported, we note that the study design is very similar to the short-term test of ASTM E 1706-05. The endpoint monitored is mortality. As specified in ECHA Guidance R.7b., Section R.7.8.9.1. this type of test is considered valid to provide information on toxicity to sediment organisms. Furthermore, considering the short exposure time (7 days), the study must be regarded as a short-term test. Accordingly this study does not provide equivalent information to long-term toxicity study to aquatic invertebrates.

In your comments on the draft decision, you refer to a publication by [redacted] (2005) which reports the results of toxicity tests on *Hyalella azteca* following 7 days of exposure. You considerthat this study *"confirm*[s] *the low toxicity of Niobium species and reveal that no effects are expected by Diniobium pentaoxide towards aquatic invertebrates"*.

We have assessed the information provided in your comments on the draft decision and we identified the following issue:

As already explained under issue A. above, the Substance is poorly water soluble and therefore information on long-term toxicity to aquatic invertebrates must be provided. Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). Among others, the OECD TG 211 requires that the following conditions are met:
- the exposure duration is 21 days,
- the key parameter investigated is the reproduction output of parent animals.

In the study by [redacted] (2005), the exposure duration was 7 days and the parameter monitored was mortality.

Hence this study does not provide an adequate coverage of the key parameters foreseen to be investigated in an OECD TG 211 study and is therefore not relevant to cover this information requirement.

In your comments on the draft decision you also explain that you intend to cover this information through an adaptation according to Annex XI, Section 1.5 using information on the source substance Niobium pentachloride (EC no. 215-213-6 / CAS no. 1313-96-8). However, for the reasons explained under the Appendix on general considerations, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances. Therefore, a long-term test must be conducted. Consequently, a long-term aquatic toxicity study on aquatic invertebrates triggered by Annex VII, section 9.1.1., Column 2 must be performed. This test is already required under request C.1. in accordance with Annex IX, Section 9.1.5.

Appendix B: Reasons for the requests to comply with Annex VIII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. The long-term toxicity testing on fish also requested at C.2. below (triggered by Annex VIII, Section 9.1.3., column 2)

"Short-term toxicity testing on fish" is a standard information requirement in Annex VIII to REACH. However, pursuant to Annex VIII, section 9.1.3., column 2, for poorly soluble substances the long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6.) must be considered.

You have adapted this information requirement based on Annex VIII, Section 9.1.3., Column 2. In support of your adaptation, you provided the following justification: "*In accordance with column 2 of Annex VII and VIII of Regulation (EC) No 1907/2006, short-term studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water*".

Based on the information provided in your dossier we have identified the following issue:

Annex VIII, Section 9.1.3., Column 2 specifies that this information requirement may be adapted if:

- there are mitigating factors indicating that aquatic toxicity is unlikely to occur (e.g. the substance is highly insoluble) or;
- a long-term toxicity study on fish is available.

As already explained under request A.1. above, the data provided in your dossier does not adequately support that aquatic toxicity is unlikely to occur. As explained under request C.2., you did not provide long-term toxicity study on fish. Therefore, your adaptation according to Annex VII, Section 9.1.3., Column 2 is rejected.

In your comments on the draft decision you explain that you intend to cover this information requirement through an adaptation according to Annex XI, Section 1.5 using information on the source substance Niobium pentachloride (EC no. 233-059-8 / CAS no. 10026-12-7). However, for the reasons explained under the Appendix on general considerations, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances. Therefore, a long-term test must be conducted. Consequently, a long-term aquatic toxicity study on fish triggered by Annex VIII, section 9.1.3., column 2 must be performed. This test is already required under request C.2. in accordance with Annex IX, Section 9.1.6.

2. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.).

Activated sludge respiration inhibition testing is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement based on Annex VIII, Section 9.1.4., Column 2. In support of your adaptation, you provided the following justification: "*According to the Regulation (EC) No 1907/2006 (REACH) Annex VIII 9.1.4 column 2, the toxicity to microorganisms in water does not need to be determined if the substance is highly insoluble in water. Tests on water solubility of niobium have shown that the substance is highly insoluble 0.8 µg/L). If released into the STP, the insoluble niobium will be mostly removed in the primary settling tank and thus will not reach the activated sludge*".

Annex VIII, Section 9.1.4., Column 2 specifies that this information requirement may be adapted if:

- there are mitigating factors indicating that aquatic toxicity is unlikely to occur (e.g. the substance is highly insoluble) or;
- there is no emission to a sewage treatment plant.

As already explained under request A.1. above, the data provided in your dossier does not adequately support that aquatic toxicity is unlikely to occur. Furthermore, your dossier does not demonstrate that no emission to a sewage treatment plant are expected. Hence your adaptation according to Annex VIII, Section 9.1.4., Column 2 is rejected.

In your comments on the draft decision you explain that you intend to cover this information requirement through an adaptation according to Annex XI, Section 1.5 using information on the source substance Diniobium pentoxide (EC no. 233-059-8 / CAS no. 10026-12-7). However, for the reasons explained under the Appendix on general considerations, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

While selecting the test material you must take into account the impact of parameters relevant for the property to be tested. For the Substance, this includes the particle size. For the aquatic toxicity studies, you must justify that the selected test material properties constitute a reasonable worst case to cover all the registrants of the Substance. Therefore the selected test material should correspond to the most soluble form of the substance taking into account the range of properties of the substance as registered under REACH.

Appendix C: Reasons for the requests to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

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

and

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

Long-term toxicity testing on aquatic invertebrates and on fish are standard information requirements in Annex IX to REACH.

You have adapted this information requirement and you provided the following justification: "*For niobium metal the highest water solubility detected is 0.8 µg/L. Furthermore, Transformation-Dissolution tests performed with niobium in its massive or granular form (FeNb) revealed likewise low solubility's. In addition, these test showed that no metal transformation took place within 28 days. Thus, it can be concluded, that niobium remains stable and thus biologically inert during this time. In consequence, equally to acute aquatic toxicity tests, chronic aquatic toxicity tests are of no use for the assessment of niobium*".

We have assessed the information provided in your dossier based on Annex IX, Section 9.1, Column 2 and we have identified the following issue:

In order to adapt the information requirement for long-term toxicity testing on aquatic invertebrates and on fish based on Annex IX, Section 9.1, Column 2, the Chemical Safety Assessment needs to demonstrate that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The Chemical Safety Assessment needs to assess and document that risks arising from the Substance are controlled and demonstrate that there is no need to conduct further testing (Annex I, Section 0.1; Annex IX, Section 9.1, Column 2).

In particular, you need to take into account the following elements in your justification:
- all relevant hazard information from your registration dossier,
- the outcome of the exposure assessment in relation to the uses of the Substance,
- the outcome of the PBT/vPvB assessment including information on relevant constituents present in concentration at or above 0.1% (w/w).

In addition, for poorly water soluble substances (e.g. water solubility below 1 mg/L or below the detection limit of the analytical method of the test substance) long-term toxicity study on aquatic invertebrates and on fish) must be considered instead of an acute test (Column 2 of Annex VII, Section 9.1.1. and Annex VIII, Section 9.1.3.).

However, you not provided any justification that the risks arising from the Substance are controlled, taking account all of the elements above.

As already explained under request A.1., the Substance is poorly water soluble and can be tested at concentrations below its solubility limit.

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances and the long-term test is required. Hence, in the absence of long-term testing on aquatic organisms your dossier does not include any relevant hazard information. Furthermore, you did not conduct an exposure assessment in relation to the uses of the Substance.

In your comments on the draft decision, you indicate that you disagree with the request to perform long-term toxicity tests with aquatic invertebrates and fish and you provide the following justification:

- No effects were observed in a short-term toxicity study on fish according to OECD TG 203 with the source substance Niobium pentachloride. Similarly, no effects were observed in a short-term toxicity to *Daphnia magna* according to OECD guideline 202 up to the limit of solubility of Niobium pentachloride ([redacted] 2014);
- You refer to T/D tests according to OECD guideline 29 on the Substance and the source substance Niobium pentachloride which shows that for both subsances measured dissolved concentrations in Niobium are in the µg/L range or below;
- Based on the above, you conclude that toxicity to aquatic organisms is unlikely. You further state that dissolved Niobium species undergo rapid hydrolysis to insoluble forms and the "*physical effects to the tested organisms during a long-term test cannot be excluded*".

As a consequence, we understand that you still intend to adapt these information requirements according to Annex IX, Section 9.1., Column 2. You now intend to support your adaptation by providing information on the source substance Niobium pentachloride.

However, for the reasons explained under the General consideration section, your read-across adaptation based on Annex XI, Section 1.5 is rejected.

Based on the above, the information provided in your comments on the source substance Niobium pentachloride does not further substantiate that the risks of the Substance are adequately controlled.

Therefore, your adaptation according to Annex IX, Section 9.1., Column 2 is rejected.

Based on the above, the information requirements on long-term toxicity testing on aquatic invertebrates and on fish set out in Annex IX Section 9.1.5 and 9.1.6.1, respectively, are not fulfilled.

While selecting the test material you must take into account the impact of parameters relevant for the property to be tested. For the Substance, this includes the particle size. For the aquatic toxicity studies, you must justify that the selected test material properties constitute a reasonable worst case to cover all the registrants of the Substance. Therefore the selected test material should correspond to the most soluble form of the substance taking into account the range of properties of the substance as registered under REACH.

Appendix D: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 26 March 2019.

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 within 30 days of the notification.

ECHA took into account your comments and did not amend the requests.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix E: Observations and technical guidance

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

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 the Member States.

3. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

   Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries'[5].

4. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/ impurity.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values and other parameters relevant for the property to be tested, in this case the particle size. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

[5] https://echa.europa.eu/practical-guides

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[6].

5. List of references of the ECHA Guidance and other guidance/ reference documents[7]

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

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

ECHA Read-across assessment framework (RAAF, March 2017)[8]

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

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

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

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

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

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

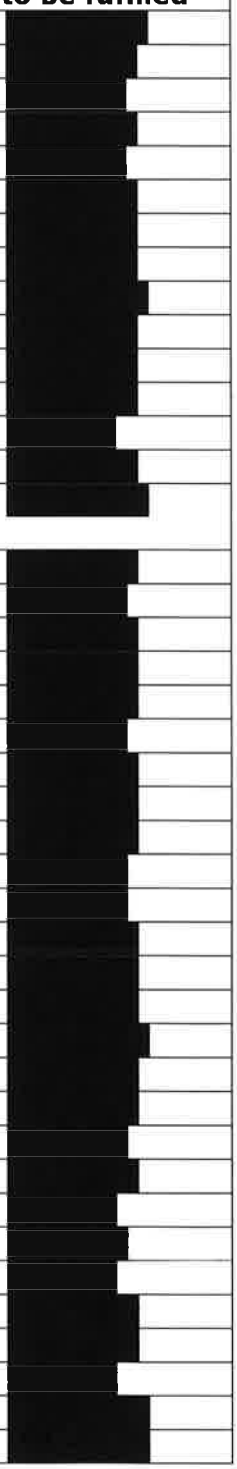
PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

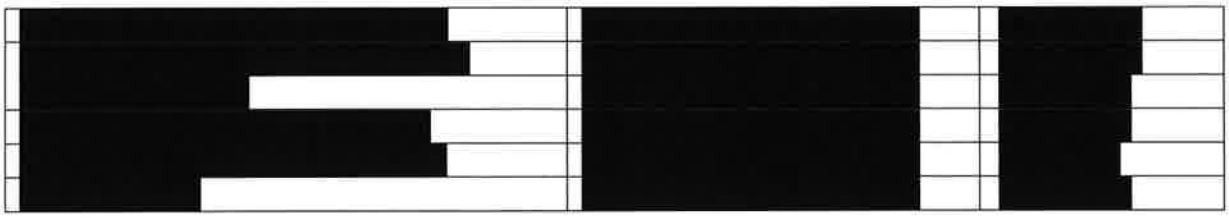
Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

OECD Guidance documents[9]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

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

Appendix F: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
		



Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.