Helsinki, 9 April 2018

Addressee: [redacted]

Decision number: TPE-D-2114397527-33-01/F
Substance name: potassium titanium oxide (K2Ti6O13)
EC number: 432-240-0
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 08/03/2017
Registered tonnage band: 100-1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposals are accepted and you are requested to carry out:

1. **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) using the registered substance.**
2. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD TG 216) using the registered substance.**

While your originally proposed test for Long-term toxicity testing on fish (Annex IX, Section 9.1.6.2.; test method: Fish, short-term toxicity test on embryo and sac-fry stages, EU C.15./OECD TG 212) using the registered substance is rejected, you are requested to perform:

3. **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) using the registered substance.**

While your originally proposed test for Short-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1.; test method: Earthworm acute toxicity test, EU C.8/OECD TG 207) using the registered substance is rejected, you are requested to perform:

4. **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1.column 2; test method: Earthworm reproduction test, OECD TG 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232) using the registered substance.**

While your originally proposed test for Short-term toxicity to plants (Annex IX, Section 9.4.3.; test method: Terrestrial plant test: seedling emergence and seedling growth test, OECD TG 208) using the registered substance is rejected, you are requested to perform:

5. **Long-term toxicity testing on plants (Annex IX, Section 9.4.3. column 2; test method: Terrestrial plants, growth test, OECD TG 208) using the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation.

To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and an adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by ***16 January 2020***. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons for 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.

When determining the design of the testing requested and reporting its results, you should pay particular attention to Appendix 3, Section 4, regarding the tested material identification.

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 Claudio Carlon, Head of Unit, Evaluation E2

[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

The decision of ECHA is based on the examination of the testing proposals submitted by you.

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

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"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. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on aquatic invertebrates *Daphnia magna* reproduction test, OECD TG 211 with the following justifications:

"The REACH Regulation does not provide (in this case) any adaptation possibilities but the testing proposal can only be addressed by the results of the chemical safety assessment. The substance under investigation is inorganic so, it is out of the applicability domain of the largest part of the models and no reliable predictions can be performed.

The duration of the test is 21 days for daphnids, 21 days is sufficient for maturation and the production of 3 broods.
Typically the 21 day study may report ECx/NOEC values for survival or reproductive endpoints."

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), 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. There were no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than aquatic invertebrates.
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, long-term fish testing may need to be conducted.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Long-term toxicity testing on aquatic invertebrates (test method: *Daphnia magna* reproduction test, EU C.20/OECD TG 211).

Note for consideration for aquatic testing

Due to the low solubility and particulate nature of your substance, you should consult the OECD document ENV/JM/MONO (2014)40/1. This may be more appropriate for your substance with regard to its specific properties (particles form and poorly water soluble), rather than the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 in general recommended for testing poorly soluble substances.

The OECD *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3, summarises aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity tests and for calculation and expression of the result of the test. In addition to this, ECHA would recommend that you consult Appendix R7-1 for nanomaterials (regardless of their shape and form) to the ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R7b, (Version 2.0 - May 2017), which may be relevant by analogy.

2. Effects on soil micro-organisms (Annex IX, Section 9.4.2)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

The information on "effects on soil micro-organisms" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the registered substance for effects on soil micro-organisms nitrogen transformation test (test method: EU C.21/OECD TG 216) with the following justification:
"The REACH Regulation provides some adaptation possibilities (Column 2 of Annex IX):
1) These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely: the direct or indirect exposure of the soil compartment cannot be excluded.
2) In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment: some information and some data are not available because the substance is inorganic. Because of previous considerations, an experimental study was planned.
The substance is not an agrochemical. According to ECHA Guideline R.7c, the OECD 216 method is would be reccommended because for most non-agrochemicals the nitrogen transformation test is considered sufficient as nitrate transformation takes place subsequent to the degradation of carbon-nitrogen bonds."
ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.4.2 of the REACH regulation.

To address this endpoint, either a nitrogen transformation test (test method: EU C.21/OECD TG 216) or a carbon transformation test (test method: EU C.22/OECD TG 217) could be performed. According to Section R.7.11.3.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals. For agrochemicals the carbon transformation test (EU: C.22/OECD TG 217) is also required.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216.

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.2.)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"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. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on fish: Fish, short-term toxicity test on embryo and sac-fry stages, EU C.15./OECD TG 212 with the following justification:
"*- No available GLP studies on the substance for the endpoint long-term toxicity to fish.*
- No available non-GLP studies on the substance for the endpoint long-term toxicity to fish.
- Historical human data: Human data are not applicable since the endpoint for which the testing is proposed is the long-term toxicity to fish.
- (Q)SAR: in general, the long-term toxicity to fish can be predicted by the model "Fish, ChV" that is contained in the software ECOSAR (US EPA), as reported in the ECHA document "Practical Guide - How to use and report (Q)SARs 3.1. 2016." at Table c. Ecotoxicological endpoints. However, ECOSAR cannot be used for all chemical substances. The intended application domain is organic chemicals so, inorganic chemicals are outside the applicability domain. Potassium hexatitanate is an inorganic substance so it is outside of the applicability domain of the models and the available models are not suitable to predict the long term toxicity to fish for an inorganic substance.
Others software, with others models or other models for the prediction of the long-term toxicity testing on fish are not available, as reported in "Practical Guide - How to use and report (Q)SARs 3.1. 2016", p.32.
- In vitro methods: In accordance with ECHA's guidance on the information requirements and chemical safety assessment, charpter R7b; at present, there are no EU/OECD guidelines for in vitro tests of relevance to aquatic toxicity.

There are ongoing efforts to develop and validate in vitro methods, which in future might be useful in a testing strategy for acute aquatic toxicity (e.g. ECVAM study on optimisation of cytotoxicity tests and CEFIC LRi study ECO 8 aiming to replacing the acute fish toxicity test using fish cell lines and fish embryos). The use of fish cells in environmental toxicology was

reviewed at the ECVAM workshop (Castano et al., 2003, ECVAM workshop report 47) and ECETOC (2005).
- Weight of evidence: according to ECHA guideline "Practical guide 10: How to avoid unnecessary testing on animals. 2010", this approach may be applied if there is sufficient information from several independent sources leading to the conclusion that a substance has (or has not) a particular dangerous property, while the information from each single source alone is regarded insufficient to support this assertion.
As detailed above, no studies and no information related to long term toxicity to fish are available so, a weight of evidence approach cannot be performed.
- Grouping and read-across: since no studies related to long-term toxicity to fish are available from the similar substance (i.e. potassium octatitanate CAS: 59766-31-3, EC: 261-919-2), the read-across approach is not applicable.
- Substance-tailored exposure driven testing: not applicable - substance is used in wide-dispersive uses.

The need to conduct further testing (other than short toxicity tests) may be triggered by the results from a qualitative assessment, where a possible risk should be confirmed/rejected, e.g. when due to low water solubility of a substance, short term toxicity tests do not reveal any toxicity, long-term tests are performed - as reported in ECHA Guidance document Chapter R.7b: endpoint specific guidance. V. 3.0. 2016.

The substance of interest is poorly water soluble; the test available and reported in the technical dossier was performed according EU Guideline and it is GLP compliant. Under the test conditions (Temp. 20 °C and pH 6.2) the water solubility is below 1 mg/L."

ECHA considers that the proposed study is in principle appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH regulation.

However, ECHA considers that the proposed guideline Fish, short-term toxicity test on embryo and sac-fry stages, EU C.15./OECD TG 212 is not the most sensitive for the purpose of addressing the information requirement of long-term toxicity to fish, nor is it long enough compared to OECD TG 210.
Indeed, ECHA considers that for the endpoint of long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, the FELS toxicity test according to OECD TG 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Figure R.7.8-4). The test method OECD TG 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 3.0, February 2016). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as more appropriate and suitable than the test proposed by the Registrant.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), 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.
There were no indications in the dossier from the short-term toxicity studies on aquatic species that fish would be substantially more sensitive than aquatic invertebrates or algae. Therefore both aquatic long term toxicity tests shall be performed in parallel.

Therefore, Article 40(3)(d) and (c) of the REACH Regulation, you are requested to carry out the following test using the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD TG 210).

Note for consideration for aquatic testing

Due to the low solubility and particulate nature of your substance, you should consult the OECD document ENV/JM/MONO (2014)40/1. This may be more appropriate for your substance with regard to its specific properties (particles form and poorly water soluble), rather than the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 in general recommended for testing poorly soluble substances.

The OECD *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3, summarises aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity tests and for calculation and expression of the result of the test. In addition to this, ECHA would recommend that you consult Appendix R7-1 for nanomaterials (regardless of their shape and form) to the ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R7b, (Version 2.0 - May 2017), which may be relevant by analogy.

4. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on "short-term and long-term toxicity to invertebrates" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a short-term toxicity test on terrestrial invertebrates Earthworm, Acute Toxicity Tests (EU C.8/OECD TG 207), with the following justification:

"The REACH Regulation provides some adaptation possibilities (Column 2 of Annex IX):
1) These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely: the direct or indirect exposure of the soil compartment cannot be excluded.
2) In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment: some information and some data are not available because the substance is inorganic.
Because of previous considerations, an experimental study was planned."

However, according to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. ECHA notes that, according to the evidence presented within the Registration dossier, the substance is considered very persistent, as it is an inorganic compound, which is default setting for not readily biodegradable substances, when value of the half-life in soil is not available and therefore meets the column 2 adaptation criteria of Annex IX, section 9.4. concerning the use of long-term testing instead of short-term. Therefore, considering the properties of the substance, ECHA concludes that only a long-term toxicity test on invertebrates (and not the short-term) will provide the adequate information.

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are required to carry out one of the following additional studies using the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232), while the short-term toxicity test on terrestrial invertebrates (OECD 207) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Notes for consideration by the Registrant

ECHA notes that you have also proposed toxicity test on fish and aquatic invertebrates and the results of these tests may subsequently allow the derivation of PNECwater. If the results of the proposed toxicity test on fish and aquatic invertebrates allow the subsequent derivation of a PNECwater, you may consider the ITS as recommended in section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), and determine the need for further testing on terrestrial organisms. If you include a justified proposal for adaptation of Annex IX, 9.4.3. or alternatively a proposal for adaptation of Annex IX, 9.4.1., in the registration dossier you will not be required to perform both the toxicity test on plants and on invertebrates.

5. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on "short-term or long-term toxicity to plants" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a short-term toxicity test on terrestrial plants (OECD 208), with the following justification:

"The REACH Regulation provides some adaptation possibilities (Column 2 of Annex IX):
1) These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely: the direct or indirect exposure of the soil compartment cannot be excluded.
2) In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment: some information and some data are not available because the substance is inorganic.
Because of previous considerations, an experimental study was planned."

However, according to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, and substances with a half-life >180 days are considered very persistent in soil. ECHA notes that, according to the evidence presented within the Registration dossier, the substance is considered very persistent, as it is an inorganic, which is the default setting for not readily biodegradable substances when the value of the half-life in soil is not available and therefore the substance meets the column 2 adaptation criteria of Annex IX, Section 9.4. concerning the use of long-term testing instead of short-term. Therefore, considering the properties of the substance, ECHA concludes that only a long-term toxicity test on plants (and not the short-term) will provide the necessary useful information.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum and testing shall be conducted, as a minimum with two monocotyledonous species and four dicotyledonous species. You should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 40(3)(b) of the REACH Regulation, you are required to carry out one of the following additional studies using the registered substance subject to the present decision: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

Notes for consideration by the Registrant

ECHA notes that you have also proposed toxicity test on fish and aquatic invertebrates and the results of these tests may subsequently allow the derivation of PNECwater. If the results of the proposed toxicity test on fish and aquatic invertebrates allow the subsequent derivation of a PNECwater, you may consider the ITS as recommended in section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), and determine the need for further testing on terrestrial organisms. If you include a justified proposal for adaptation of Annex IX, 9.4.3. or alternatively a proposal for adaptation of Annex IX, 9.4.1., in the registration dossier, you will not be required to perform both the toxicity test on plants and on invertebrates.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 9 March 2017.

ECHA held a third party consultation for the testing proposals from 17 May 2017 until 3 July 2017. ECHA did not receive information from third parties.

This decision does not take into account any updates after **10 November 2017**, 30 calendar days after the end of the commenting period.

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

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

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

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

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

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2017.

2. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

3. 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.

4. In relation to the information required in relation to Annex VII-XI data requirements, 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.

   Finally there must be adequate information on substance identity for the sample tested and the substance registered to enable the relevance of the tests to be assessed. For each study record reported, adequate information on the test material used to generate the data needs to be documented in the test material record linked to the EndPoint Study Record. The test material record will document as a minimum the constituent concentration values and any other parameter that is relevant (for instance the size, the shape and the surface chemistry of the particles). The registrants' rationale for the choice of each representative test material will be given in sufficient detail so that its relevance and representativeness for the registered substance can be independently verified. Technical instructions are available in the Manual "How to prepare registration and PPORD dossiers" on the ECHA website https://echa.europa.eu/documents/10162/22308542/manual_regis_and_ppord_en.pdf.

   The registration dossier suggests that it might include various forms of the registered substances (e.g., numerical identifiers (EC number) refers to both fibrous and non-fibrous forms of the substance). Therefore, when applying this section, the Registrant is advised to consider whether fibre form is relevant and, if so, whether the fibre form and the size affect the outcome of the study.