EUROPEAN CHEMICALS AGENCY

Helsinki, 19 July 2018

Addressee: [redacted]

Decision number: TPE-D-2114422498-44-01/F
Substance name: octamethylcyclotetrasiloxane
EC number: 209-136-7
CAS number: 556-67-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 06/02/2017
Registered tonnage band: 1000+T

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.

While your originally proposed test for **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 analogue substance **decamethylcyclopentasiloxane (EC No 208-764-9; CAS No 541-02-6)** is rejected, you are requested to perform:

1. **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.**
2. **Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test, OECD TG 222) OR Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Enchytraeid reproduction test, OECD TG 220) OR Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Collembolan reproduction test in soil, OECD TG 232) using the registered substance.**
3. **Long-term toxicity testing on plants (Annex X, Section 9.4.6.; test method: Terrestrial plants, growth test, OECD TG 208) OR Long-term toxicity testing on plants (Annex X, Section 9.4.6.; test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030) 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 of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **26 April 2019**. You shall also update the chemical safety report, where relevant.

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

Appeal

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

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

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

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposal submitted by you for the registered substance octamethylcyclotetrasiloxane, CAS No 556-67-2 (EC No 209-136-7) (hereafter referred to as "target substance" or D4).

In relation to the testing proposal subject to the present decision, you propose a testing strategy intending to fulfil the standard information requirement for

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

In your testing strategy you propose to test the analogue substance Decamethylcyclopentasiloxane (hereafter referred to as source substance or D5) (CAS No 541-02-6; EC No 208-764-9).

The results from the structural analogue(s) will then be used to adapt the standard information requirements by using read-across and grouping approach following Annex XI, Section 1.5. of the REACH Regulation.

ECHA has considered first the scientific validity of the proposed read-across and grouping approach (preliminary considerations; Section 0, below), before assessing the testing proposed (Section 1, below) and the testing additionally required (Sections 2 and 3 below).

0. Grouping of substances and read-across approach

a. Legal Background on ECHA's assessment of the grouping of substances and read-across hypothesis

The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. To this end, it is necessary to consider whether programmes of testing proposed by you are appropriate to fulfil the relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting wherever possible the use of alternative means, where equivalent results to the prescribed test are provided on health and environmental hazards.

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping of substances and read-across), *"provided that the conditions set out in Annex XI are met"*.

The first Recital and the first Article of the REACH Regulation establish the *"promotion of alternative methods for assessment of hazards of substances"* as an objective pursued by the Regulation. In accordance with that objective, ECHA considers whether a prediction of the relevant properties of the substance subject to the present decision by using the results of the proposed tests is plausible based on the information currently available.

b. Description of the proposed grouping and read-across approach

You have provided the following arguments to justify the read-across approaches in general terms:

In your Siloxane analogue report you identify that the target substance is "*within the analogue group of siloxanes (alkyl, vinyl, aryl or hydrogen substituted) (defined in the analogue overview report as sub-class I-3)".*

In the Siloxane analogue report you identify that when choosing test substances you have considered "*The quality of read-across between individual source and target read-across substances, in terms of: a. Chemical structure, b. Physicochemical (partitioning and degradation) properties*".

You refine the read-across approach for the testing proposed as follows in the CSR under the ecotoxicological endpoints and in the technical dossier under endpoint summary of Terrestrial toxicity: "*There are no terrestrial data available for octamethylcyclotetrasiloxane (D4, CAS 556-67-2). D4 is a member of an analogue group of siloxanes. In view of the high potential to adsorb to soil for siloxane substances, and the lack of terrestrial toxicity testing across the analogue group, it is concluded that further testing is required".*

"An integrated terrestrial toxicity testing strategy for the analogue group is proposed to validate the use of read-across (or equilibrium partitioning) within the analogue group (PFA, 2015i). There is a limited amount of data available. Terrestrial studies with siloxanes are considered to be difficult to conduct due to their high volatilisation potential (high HLC) and the potential for degradation in soil. Decamethylcyclopentasiloxane (D5, CAS 541-02-6) is the only substance with terrestrial toxicity data from which it has been possible to derive a PNEC. Terrestrial data gaps within the siloxane analogue group have been filled in by either read-across from D5 or by deriving a PNEC from the aquatic data and applying the Equilibrium Partitioning Model (EqP). Due to the high adsorption potential of substances having a log Kow ≥8, read-across from D5 has been used in these instances. The behaviour of a substance in the environment and once ingested is considered to be dominated by the high log Kow. A substance is not expected to be readily desorbed from particles or to be taken up by organisms when the log Kow reaches values of 8 or more. For lower log Kow substances the EqP is thought to be sufficiently valid to conduct an interim risk characterisation. However, further validation of the EqP method within the siloxanes group is considered to be needed."

In the Siloxane analogue report you identify that D5 is a "*top priority*" substance to test because it is stated "*several toxicity studies are already available*".

c. Information submitted to support the grouping and read-across approach

You have provided a Siloxane analogue report ("[redacted] as a separate attachment in IUCLID, Section 13. In ECHA's understanding, it "*sets out the analogue methods applicable to linear/branched and cyclic siloxanes*" and presents the substances within the analogue group of siloxanes (alkyl, vinyl, aryl or hydrogen substituted). In addition, in ECHA's understanding, the document describes the existing data, intended and proposed analogue methods regarding physicochemical, degradation, bioaccumulation and ecotoxicological properties in pelagic, benthic and terrestrial compartments.

Apart from the above general information, in ECHA's understanding, you have provided general information on the testing strategy for environmental hazard assessment, in the technical dossier, under the endpoint summary for Terrestrial toxicity, in Section 6.3 and in the Chemical Safety Report (CSR) in section 7.0.

This information includes description of the properties of substances in the class of siloxanes in general terms, followed by information regarding the read-across approaches proposed to be applied to terrestrial toxicity.

d. ECHA analysis of the grouping approach and read-across hypothesis in light of the requirements of Annex XI, 1.5.

ECHA notes that the registrants of siloxanes (alkyl, vinyl, aryl or hydrogen substituted) have grouped the substances in 'analogue group', including the substance subject to the current decision. Based on the substance specific justification for read-across approach provided by you for the registered substance, ECHA understands that no category hypothesis /justification has been included and the proposed prediction is based on the analogue approach using decamethylcyclopentasiloxane (D5; CAS No 541-02-6) as a source substance.

According to ECHA's understanding you suggest that the proposed read-across and selection of test substances is based on similar physicochemical properties and on structural similarity.

In the following, ECHA examines whether the substances have indeed similar properties or that they would follow a regular pattern in their properties.

(i) Substance characterisation of source and target substances

The substance characterisation of the source substance(s) need to be sufficiently detailed in order to assess whether the attempted prediction is not compromised by the composition and/or impurities. In the ECHA practical guide 6 "How to report on Read-Across" it is recommended to follow the ECHA Guidance for identification and naming of substances under REACH and CLP (version 1.3, February 2014) also for the source substances. This ensures that the identity of the source substance and its impurity profile allows an assessment of the suitability of the substances for read-across purposes.

In your CSR you identify D5 as one of the impurities of D4 and indicate that its concentration in D4 is [redacted] %. However, no information on the composition or impurities of the test substance has been provided in the technical dossier of the target substance. Consequently, ECHA notes that the source substance has been solely characterised by its chemical name and CAS/EC No.

ECHA considers that currently the composition and the impurity profile of the source and target substances cannot be adequately compared using the information provided in the registration dossier. Therefore, ECHA cannot analyse the impact of the possible differences in the composition and impurity profiles that the source and target substances may have on the proposed prediction. Hence ECHA cannot reach a conclusion that the source substance can be used to predict properties for the registered substance.

(ii) Structural (dis)similarities and their impact on prediction

Structural similarity is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general or this specific case that structural similarity *per se* is sufficient to enable the prediction of ecotoxicological properties of a substance, since structural similarity does not always lead to predictable or similar ecotoxicological properties. It has to be justified why such prediction is possible in view of the identified structural differences and the provided evidence has to support such explanation. In particular, the structural similarities must be linked to a scientific explanation of how and why a prediction is possible.

ECHA notes that you have not described whether you consider the target and source substances to be structurally similar. You note, in general, that you have considered the quality of read-across between individual source and target read-across substances, in terms of "*chemical structure*" and "*physicochemical (partitioning and degradation) properties*". You consider that D5 is a "*top priority*" substance to test because "*several toxicity studies are already available*".

Even though no description on potential structural similarity/dissimilarity is provided by you, ECHA notes the following. Both the target and source substances are cyclic siloxanes and both are monoconstituents. They differ from one another in chain length, only.

You further intend to support the structural similarity in the Siloxane analogue report. You state that the choice of substances for testing is based on e.g., "*structural similarity, represented by the Tanimoto similarity index using an enhanced MDL fingerprint for the representation of Si-compounds*". ECHA acknowledges that molecular similarity indexes (e.g. the Tanimoto similarity index) can be considered when searching for relevant source chemicals for comparison. However, ECHA considers that such approaches give only an indication regarding potential similarity and do not provide a justification for the structural *differences between the target and source substances and how they influence the property to be predicted.*

ECHA notes that you have not provided any description on how the structural differences between the target and source substances may impact the toxicity of the substances and thus affect the possibility to predict properties of the target substance from the data obtained with the source substances.

(iii) Similar properties or regular pattern as a result of structural similarity

Annex XI, Section 1.5. provides that "*substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances*". One prerequisite for a prediction based on read-across therefore is that the substances involved are structural similar and are likely to have similar properties. One important aspect in this regard is the analysis of the data matrix to compare the properties of source and target substances and to establish whether indeed they are similar or follow a regular pattern.

In your general read-across justification you state that you have considered the physicochemical properties when choosing the proposed source substances. However, you provide no discussion on the physico-chemical parameters/properties of the target and source substance specifically. You report in your attached analogue report the log Kow values (6.2 for D4, 8.02 for D5), the log Koc values (4.22 for D4, 5.17 for D5), molecular weight (296.62 for D4, 370.8 for D5, water solubility (0.0562 mg/L for D4, 0.017 mg/L for D5), and vapour pressure values (132 Pa for D4, 33.2 Pa for D5).

ECHA observes that there are differences in the physicochemcial properties between the target and source substances, which have impact on your hypothesis, for example, the Log Kow values are 6.2 for D4 and 8.02 for D5. ECHA notes that you define applicability boundaries for using read-across data from D5 by *"Due to the high adsorption potential of substances having a log Kow ≥8, read-across from D5 has been used in these instances".* In light of your reasoning on the impact of Kow on toxicity, the proposed read-across from D5 to D4 appears not justified, as the logKow of the target is 6.2 and therefore out of the boundary you defined (≥8). Furthermore, you did not justify and provide evidence for the definition of such applicability boundary.

Therefore, ECHA notes that you have not addressed how the different physicochemical properties of the substances will influence their stabilty in soil, bioavailability of the substances to the target organisms and thus their toxic potential in the time course of terrestrial toxicity testing, and in the terrestrial environment. ECHA notes that you have not adequately explained how the presented differences affect the prediction

In your read-across justification you indicate that you have considered degradation properties when choosing the proposed source substances. However, ECHA notes that you provide no further discussion on the degradation properties of the target and source substance and whether you consider them to be similar. Nevertheless ECHA notes that as the testing proposed concerns terrestrial environments and both substances have potential to adsorb, their degradation potential in soil may be the most relevant property to address in assessing whether they have similar fate in the test media.

ECHA notes that in the technical dossier result for a D4 non-standard soil simulation study is given, and according to the Siloxane analogue report similar soil degradation data is available for the source substance. The half-lifes for D4 are reported to range between 0.04 and 5.25 days in different soils of different physicochemical properties, whereas for D5 a half-life of 0.08 day is reported. The transformation products are identified to be *"Siloxane diols"* and *"Dimethylsilanediol"*. ECHA notes that there are uncertainties related to the reporting and reliability of these studies which do not allow reliable soil degradation half-lives to be derived. It is, for example, not clear whether the reported half-lives refer to the first step of transformation or to the ultimate degradation of the substances. Also the information given on metabolities is not specific enough and no further evaluation of the fate of the degradation products is provided. ECHA considers it not possible to reach a conclusion on whether degradation between the target and source substances are similar. Based on the information provided it is also not possible to verify to what degree the organisms would be exposed to the target and source substances during toxicity testing, and to what degree they would be exposed to any potential (unidentified) degradation products.

In summary, ECHA considers that you have not provided adequate and relevant information on the degradation of the target and source substances. ECHA notes that you have not explained how the potential differences in degradation will influence the substances' stabilty in soil, production and impact of degradation products, and how the potential differences in degradation affect the prediction.

Finally, ECHA notes that you have not considered ecotoxic potential of target and source substances. However, based on data provided ECHA considers that there is no indication that the aquatic toxicity potency between the target and the source substance are likely to be similar. Specifically, for aquatic toxicity of D4 in your CSR you consider that "*The long-term effects reported for D4 indicate that the substance meets the definitive criteria for toxicity (T) in the environment*", whereas based on the data provided in the analogue report there was no indication of toxic effects in aquatic long-term toxicity studies up to the water solubility limit in the exposure to the source substance D5. Therefore, ECHA considers that the aquatic toxicity indicates higher toxic potential of the target substance in the aquatic compartment and in absence of terrestrial data on D4 there is no evidence to the contrary for the terrestrial compartment.

Indeed, as discussed above, the pysicochemical and degradation properties of the target and source substances are different, which may be reflected in differences in toxic potential. ECHA considers that you did not demonstrate similarity in bioavailability and bioaccumulation properties among the substances (and their degradation products), and did not address how the potential differences in these properties do not influence the toxic potential of the substances.

In summary, ECHA concludes that based on the presented information it is not possible to confirm that the substances would have similar properties or they would follow a regular pattern in their properties regarding terrestrial toxicity. In the absence of such information there is not an adequate basis for predicting the properties of the target substance from the data obtained with the source substance.

e. Conclusion on the read-across approach

Based on the above considerations ECHA concludes that you have not provided adequate and reliable information to demonstrate that the proposed read-across approach is plausible for the environmental endpoint(s) in consideration.

ECHA therefore concludes that the criteria of Annex XI, Section 1.5, are not met, and consequently the testing proposed on the read-across substance(s) is not appropriate to fulfil the information requirement(s)of the substance subject to the present decision.

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

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.).

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.

In your dossier, you have submitted the following adaptation as a separate endpoint study record: "*In accordance with Section 1 of REACH Annex XI, the study does not need to be conducted because application of the equilibrium partitioning method indicates that the substance is of low risk to soil microorganisms.*" ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.3. does not apply for the present endpoint.

Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal to study the effects on soil micro-organisms (*Soil Microorganisms: Nitrogen Transformation Test*, OECD TG 216) with the analogue substance decamethylcyclopentasiloxane (D5; CAS 541-02-6).with the following justification: "*A soil microorganisms study is planned for the related test substance decamethylcyclopentasiloxane (CAS 541-02-6; EC 208-764-9). Should no toxicity be observed in this test, no microbial assay with octamethylcyclotetrasiloxane (D4, CAS 556-67-2) will be proposed. The approach will be reconsidered once the relevant stability and toxicity studies are complete*".

ECHA has evaluated your proposal to test the analogue substance. As explained above in Section 0 of this decision, the proposed read-across cannot be accepted. Hence there is a need to test the registered substance.

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 3.0, June 2017), 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.

ECHA notes that no agrochemical uses have been identified for this substance in the technical dossier. Therefore, the proposed test *Soil Microorganisms: Nitrogen Transformation Test*, OECD TG 216 is suitable to address the information requirement of Annex IX, section 9.4.2.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the following test using the registered substance: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216, while your originally proposed test for Soil microorganisms: nitrogen transformation test (OECD TG 216) using the analogue substance

decamethylcyclopentasiloxane (D5; CAS 541-02-6) is rejected according to Article 40(3)(d) of the REACH Regulation.

2. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1. Annex X, Section 9.4.4.)

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX and X, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX and X, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.).

The information on "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.

The test requested by ECHA under point (1) above is not sufficient by itself to address the standard information requirements of Annex IX, section 9.4.1. ECHA notes that the registration dossier does not contain data for this endpoint.

You have proposed to adapt this standard information requirement by the following: "*In accordance with Section 1 of REACH Annex XI, the study does not need to be conducted because application of the equilibrium partitioning method indicates that the substance is of low risk to soil macroorganisms.*"

However, the adapation cannot be accepted, for the following reasons. Based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), ECHA considers that the substance would fall into soil hazard category 4. For such substances it is not possible to adapt the present standard information requirement depending on the results of the other long-term study for soil requested by the present decision and an initial screening assessment based upon the Equilibrium Partitioning Method (EPM). The Guidance foresees that long-term toxicity tests according to the standard information requirements of Annex X should be carried out and that the lowest value obtained should be used to derive the PNEC soil.

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. You are to apply the most appropriate and suitable test guideline among those listed above. However ECHA notes that when log Kow >5 and log Koc >4, as

in this case, the test OECD 232 may not be the most appropriate as the dominant route of exposure for Collembolans is via pore water.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out one of the following additional studies using the registered substance: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232.

3. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3. and Annex X, Section 9.4.6.)

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"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 "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.

The test requested by ECHA under point (1) above is not sufficient by itself to address the standard information requirements of Annex IX, section 9.4.3. and Annex X, section 9.4.6. ECHA notes that the registration dossier does not contain data for this endpoint.

You have proposed to adapt this standard information requirement by the following: "*In accordance with Section 1 of REACH Annex XI, the study does not need to be conducted because application of the equilibrium partitioning method indicates that the substance is of low risk to terrestrial plants.*"

However, the adapation cannot be accepted, for the following reasons. Based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), ECHA considers that the substance would fall into soil hazard category 4.

For such substances it is not possible to adapt the present standard information requirement depending on the results of the other long-term study for soil requested by the present decision and an initial screening assessment based upon the Equilibrium Partitioning Method (EPM). The Guidance foresees that long-term toxicity tests according to the information requirements of Annex X should be carried out and that the lowest value obtained should be used to derive the PNEC soil.

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)(c) of the REACH Regulation, you are required to carry out one of the following additional studies using the registered substance: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).

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal(s) for examination pursuant to Article 40(1) on 1 December 2015.

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.

You were notified that the draft decision does not take into account any updates after 06 July 2016, 30 calendar days after the end of the commenting period. However, following your request and justification provided (including interlinked read-across testing strategy on several supposedly related registered substances) ECHA has exceptionally granted you additional time until 30 June 2017 for the update.

Before 30 June 2017 you updated your registration dossier on 15 November 2016 (submission number [redacted]) and again on 06 February 2017 (submission number [redacted]). In the updated dossiers, you did not modify the testing proposals addressed in this decision. ECHA notes that any dossier updates submitted after the extended deadline of 30 June 2017 have not been considered for this decision. ECHA took your comments into account, and did not amend the draft decision.

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

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

Appendix 3: Further information, observations and technical guidance

1. This 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.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

3. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.