ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114300033-75-01/F Helsinki, 13 May 2015

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For hexamethyldisiloxane, CAS No 107-46-0 (EC No 203-492-7), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for hexamethyldisiloxane, CAS No 107-46-0 (EC No 203-492-7), submitted [redacted] (Registrant).

- Soil Microorganisms: Nitrogen Transformation Test (OECD Guideline 216) on the analogue substance Octamethyltrisiloxane (CAS No. 107-51-7, EC No 203-497-4);
- Earthworm Reproduction Test (Eisenia fetida/Eisenia Andrei) (OECD 222) on the analogue substance Octamethyltrisiloxane (CAS No. 107-51-7, EC No 203-497-4);
- Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test (OECD 208), on the analogue substance Octamethyltrisiloxane (CAS No. 107-51-7, EC No 203-497-4).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 05 March 2015, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his 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.

On 23 October 2013, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

On 11 April 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 9 May 2014 ECHA received comments from the Registrant on the draft decision. On 12 May 2014 and 1 July 2014 the Registrant updated his registration dossier [submission numbers [redacted], respectively].

The ECHA Secretariat considered the Registrant's comments and dossier updates. On basis of this information, only the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 5 March 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

The Registrant shall carry out the following additional tests pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test methods and the registered substance hexamethyldisiloxane, CAS No 107-46-0 (EC No 203-492-7):

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

2. Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222);

   or

   Test method: Collembolan reproduction test in soil (OECD 232);

3. Long-term toxicity testing on plants (Annex X, Section 9.4.6.; test method: Terrestrial plants, growth test, OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species;

while the originally proposed tests to be carried out using the analogue substance Octamethyltrisiloxane (CAS No. 107-51-7, EC No 203-497-4) are rejected pursuant to Article 40(3)(d) of the REACH Regulation.

The Registrant shall perform test 3 after the completion of tests 1 and 2. Any technical difficulties in performing the tests shall be addressed as further specified in section III.

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above terrestrial studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the terrestrial PNEC.

Note for consideration by the Registrant:

The Registrant 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 to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

4. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **22 August 2016** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

Effects on terrestrial organisms

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. Pursuant to Article 40(3)(d) of the REACH Regulation, ECHA may reject a proposed test.

With respect to the testing proposals subject to the present decision, the Registrant has used a read-across and grouping approach based on Annex XI, 1.5. of the REACH Regulation and proposed to perform the tests on the analogue substance Octamethyltrisiloxane (CAS No. 107-51-7, EC No 203-497-4). To the extent that all proposed testing relies upon an identical read-across hypothesis ECHA has considered the documentation and the scientific validity of the proposed read-across and grouping approach (Section 0, below), before assessing the testing proposals submitted for the three terrestrial endpoints according to Annexes IX and X of the REACH Regulation before assessing the testing proposed (Sections 1, 2 and 3 below).

ECHA notes that the present decision concerns the one-to-one read-across proposals from octamethyltrisiloxane (CAS 107-51-7; EC 203-497-4, source substance) to hexamethyldisiloxane (target substance), the substance subject to present decision, as submitted in the registration dossier for hexamethyldisiloxane for the three terrestrial endpoins concerned only. ECHA did not evaluate the read-across used in any other endpoints for compliance with the REACH information requirements. Such evaluation may be carried out in a compliance check under Article 41 of the REACH Regulation at a later stage.

0. Grouping of substances and read-across approach

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "*provided that the conditions set out in Annex XI are met*". As far as the testing proposals addressed in this decision are concerned, the Registrant has described an analogue approach of related substances and proposes to use information from a member

of this analogue approach to predict the terrestrial toxicity for the registered substance using read-across.
ECHA considers that the analogue approach and the read-across proposed by the Registrant, does not convincingly show how the relevant properties of the registered substance can be predicted from the information on properties of the analogue substance. More specifically, Annex XI, 1.5. of the REACH Regulation sets out the conditions to be met by grouping and read-across so that information requirements will be considered met. At present, the read across proposed by the Registrant does not fulfil those conditions, both in relation to the documentation provided (see section 0.1) and the scientific rationale of the read-across approach (see section 0.2).

0.1 Documentation of the read-across approach

It is a requirement of Annex XI, 1.5., that "*adequate and reliable documentation of the applied method shall be provided.*"

In Section 1.4 of the chemical safety report (CSR) the Registrant explains that "*the submission includes use of QSAR and read across, with exact details depending on the end point.*" He states further that the registered substance is "*part of an analogue group of linear and cyclic siloxanes with alkyl, aryl, vinyl, hydrogen or hydroxy attached to Si. Siloxanes with reactive functional groups in the side-chain are excluded. This analogue group (termed I-3 in the analogue overview report) has subdivisions based on lipophilicity. This is important for some endpoints".* Furthermore, the Registrant states that: "*The basis of the read across is the relevance of the chemical structure and physicochemical properties to the registered substance. The analogue methodology takes into account the properties of the substance and the choice of read-across substance is described on a case-by-case basis for individual endpoints*". In section 7 of the CSR the Registrant provides the following about the compositions of hexamethyldisiloxane (target) and octamethyltrisiloxane (source): "*registered substance, hexamethyldisiloxane (HMDS, CAS 107-46-0) and the surrogate substance octamethyltrisiloxane (L3, CAS 107-51-7) are linear siloxanes. HMDS is a linear siloxane with two trimethylated silicon atoms linked by one oxygen atom. L3 is a directly analogous structure with three silicon and two oxygen atoms.*" Additional documentation on the analogue approach has been provided in three separate documents attached to Section 13 of the IUCLID technical dossier and the relevant endpoint records.

In the IUCLID Endpoint study records for the three terrestrial endpoints for which testing is proposed the Registrant provides the following explanation for the read-across for the terrestrial endpoints: "*It is proposed that the study should be performed with the related substance octamethyltrisiloxane (L3, CAS 107-51-7) and read across to hexamethyldisiloxane (HMDS). Soil ecotoxicity testing for siloxanes presents considerable technical experimental difficulties, due to their potential for volatilisation from, and degradation in, soil. The fugacity properties of the analogous substance L3 are considerably more favourable in this respect than those of the registration substance HMDS. HMDS has a higher tendency to volatilise from soil compared to L3, based on its higher vapour pressure (5500 Pa versus 530 Pa at 25°C) and lower tendency to partition to organic matter (log Koc 3.0 versus 4.3) than L3. HMDS also has a faster homogeneous hydrolysis rate (t1/2 116 h versus 329 h at pH 7 and 25°C) than L3, and so is expected to degrade faster in soil. It is also well established that siloxanes undergo clay-catalyzed hydrolysis in soil ([redacted]), with half-lives increasing with increasing molecular size of the siloxane ([redacted]).*"

In section 6 Endpoint summary of IUCLID the Registrant has provided further discussion on the analogue approach applied and proposed specifically in the context of terrestrial toxicity.

With regards to the technical feasibility of testing it is further elaborated that: "*In the context of terrestrial toxicity: octamethyltrisiloxane is more likely to remain in the soil as the parent substance during the terrestrial toxicity studies, therefore the results may provide a more robust and conservative assessment of the terrestrial ecotoxicity of the siloxane form than HMDS. Terrestrial studies with siloxanes such as HMDS are considered to be technically difficult to conduct due to their high volatilisation potential (high Henry's Law Constant and low octanol-air partition coefficient) and the potential for degradation in soil. Soil testing according to guideline methods does not allow for a renewal of the substrate and hence re-application of test substance. Therefore, there is potential for the organisms to not be exposed to the test material for a sufficiently long period of time for effects to be expressed, as well as the difficulty of quantifying actual exposure concentrations. To avoid these uncertainties, the registrants recommend that octamethyltrisiloxane (L3, EC 203-497-4) be tested as a surrogate for HMDS*".

ECHA noted that the need for further terrestrial testing has been also discussed in the report named "[redacted]" dated March 2013 submitted as a supporting document of the analogue approach in the registration dossier with submission number [redacted]. With regards to further terrestrial testing requirements on page 51 of that report it was written that: "*The two top priority substances to test are D5 (for which several studies are already available) and L2* (ECHA note L2=hexamethyldisiloxane, the registered (target) substance*). It is noted that particular problems with volatility are expected for L2 (see below section on testing methods). The third substance to test is a longer chain linear siloxane: either L4 or L5. Read-across of L3* (ECHA note: L3=octamethyltrisiloxane (source)) *and HL3 from L4 rather than L2 (which would be the closest compound if L5 were tested), is preferred due to the aquatic toxicity observed for L2. However, L5 is the better choice in terms of covering the physicochemical property space of the category, having higher log KOW, lower water solubility and higher molecular weight than L4 and being more different from D5 in terms of these properties. The final decision will be made when the soil testing results for L2 are available.*"

ECHA noted that in the registration dossier with submission number [redacted], the proposed read-across and testing approach for terrestrial toxicity was discussed both in the technical dossier and in the document [redacted] attached to section 13 of IUCLID. With regards to the scientific validity of the read-across, in the documentation submitted the Registrant gave conflicting information as to which of the two substances would be most suited for terrestrial testing.

In the updated dossier with submission number [redacted], the Registrant has attached a revised version of the report named [redacted] dated January 2014. In this report, the Registrant has revised the criteria for selection of substances to be tested. The criteria related to aquatic ecotoxicity data has now been removed, while a new criteria related to the feasibility of testing has been introduced. In the paragraph "testing method – technical challenges", the Registrant appears to claim an adaptation of the standard information requirements according to Annex XI, section 2, where due to the volatility of the registered substance testing may not be technically feasible. However, in the technical dossier, the adaptation is still according to Annex XI, 1.5. The pre-condition of testing the stability of D5 (for which several studies are already available) and L3 (as a representative short-chain linear siloxane) first before any terrestrial testing, still remains in the read across approach report.

In the revised report, the conflicting information provided regarding the above mentioned read across as highlighted in the draft decision were resolved. The Registrant maintains in the updated dossier that "The two top priority substances to test are D5 (for which several

studies are already available) and L3 (as a representative short-chain linear siloxane). These substances are also the candidates chosen to conduct preliminary stability tests. This is in contradiction to the Registrant's comments to the draft decision, whereby the Registrant agreed to attempt testing with the registered substance L2 (this aspect will be further discussed in section 2 below).

In conclusion of the above, ECHA considered that there is now no conflicting information in the updated dossier and ECHA considers, regarding the read-across, that the requirement of Annex XI section 1.5. of "*adequate and reliable documentation of the applied method shall be provided*", has now been met. However, there is still a contradiction between the Registrants comments which accepts the testing of the registered substance but also acknowledges this will be difficult due to the properties of the registered substance and the updated dossier which outlines a read across approach and in addition outlines the difficulties in testing the registered substance.

0.2 Scientific assessment of the analogue approach

ECHA notes that as far as the present decision is concerned, the scientific assessment of the read-across concerns only the analogue approach proposed for the three terrestrial testing proposals.

Section 1.5. of Annex XI states: *Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances.*

ECHA notes that in the current case, the Registrant did not use a group approach but an one-to-one analogue approach. For the analogue approach Annex XI, 1.5. provides:
The similarities may be based on:

(1) a common functional group;
(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or
(3) a constant pattern in the changing of the potency of the properties across the category.

Ad (1): Both substances contain the same chemical elements and the majority of their functional groups are the same. However, in L3 (source) there is a group where a silicon is attached to two oxygen atoms, this structure is not present in L2 (target). The two substances hence have common functional groups as well as differences.
Ad (2): ECHA notes that both substances hydrolyse in soil to similar products. Hexamethyldisiloxane hydrolyses to trimethylsilanol, octamethyltrisiloxane to trimethylsilanol and dimethylsilanediol.
Ad (3): ECHA notes that even if the registrant considers that given the similar properties, structural similarities, and expected mode of action it is valid to read-across data from octamethyltrisiloxane to hexamethyldisiloxane (HMDS) constant pattern in the toxicity potency of the two analogues is not reliably demonstrated as further discussed below.

ECHA understands that in the case of terrestrial toxicity, the read-across relies on the physicochemical similarity of the two substances. However, as shown in the data submitted in the technical dossier for the registered substance adverse effects were observed in the aquatic studies performed whereas no effects were observed in the aquatic studies performed on the analogue substance as shown in the data submitted in the technical dossier for octamethyltrisiloxane with submission number [redacted]. This indicates that

the physical-chemical properties such as solubility differ in a way that makes the read across uncertain, since it would appear that octamethyltrisiloxane is not sufficiently available to exert such toxic effects. Furthermore due to the difference in the observed aquatic toxicities between the two substances the registered substance is classified for environment whereas no such classification exists for octamethyltrisiloxane. Pore water is a main exposure route for soil organisms. Therefore, and because of the uncertainty regarding the similarity in exposure to soil organisms, adverse effects cannot be predicted with confidence for the registered substance. On that basis ECHA concludes that the lack of constant pattern in the aquatic toxicity potency between the analogues has been reliably demonstrated and therefore the read-across can not be accepted.

The Registrant has furthermore justified the read-across by arguing that testing octamethyltrisiloxane is more feasible technically since "*octamethyltrisiloxane is more likely to remain in the soil as the parent substance during the terrestrial toxicity studies, therefore the results may provide a more robust and conservative assessment of the terrestrial ecotoxicity of the siloxane form than HMDS*". In the IUCLID Endpoint study records for the three terrestrial endpoints for which testing is proposed, the Registrant states further that "*HMDS has a higher tendency to volatilise from soil compared to L3, based on its higher vapour pressure (5500 Pa versus 530 Pa at 25°C) and lower tendency to partition to organic matter (log Koc 3.0 versus 4.3) than L3".*

ECHA notes that based on the physicochemical properties octamethyltrisiloxane seems to have a higher Henry's law constant. Consequently the volatilisation potential of octamethyltrisiloxane from soil may be higher than that of hexamethyltrisiloxane. ECHA hence considers that this contradicts the argument made by the Registrant that testing of the proposed read-across substance would be technically more feasible. ECHA acknowledges that there may be difficulties in testing either of the substances in the terrestrial environment. Also for the source substance the Registrant proposes the following: "*stability of test substance concentrations in the soil under realistic test conditions must be explored as part of method development. Subsequent toxicity testing is subject to satisfactory results from the stability studies. It may be necessary to modify the standard guidelines to allow test substance concentrations to be maintained (for example the most appropriate type of soil and test substance delivery mechanism will be considered)".* ECHA notes that it is the Registrants responsibility to design the test in such a way that the effects to terrestrial organisms are adequately assessed.

In the comments to the draft decision, the Registrant acknowledges that the proposed read across had some uncertainty. As stated above, adverse effects were observed in the short-term fish, algal and long-term aquatic invertebrate studies performed with the registered substance (L2), whereas no effects were observed up to the limit of solubility of the source substance (L3) in the corresponding aquatic studies. The Registrant also has explained why he originally proposed to test L3 (Octamethyltrisiloxane) and has highlighted the physico-chemical properties that led to choose to test that substance and to read across the results to the registered substance, among these properties, the Henry's law constant and the vapour pressure. ECHA agrees that these properties are important to determine the behaviour of the substance. However, ECHA notes that the dissipation from soil is not only linked to volatilisation. Other factors, for example water solubility and adsorption may also play an important role in establishing whether the substance might be retained or not in the terrestrial compartment. In addition, the Registrant has further emphasized the differences in LogKoc, vapour pressure and hydrolysis rate between the source and target substance and he has indicated that L2 is expected to be degraded faster in soil.

In conclusion ECHA considers whilst the the Registrant has resolved all the conflicting

information about the proposed analogue approach and the read-across for terrestrial endpoints in the documentation attached in section 13 of IUCLID of the updated dossier with submission number [redacted] there is still considerable uncertainty that with the proposed read-across the hazard potential can be estimated due to the difference in effects observed in the aquatic toxicity studies and the resulting differences in environmental classification of the source and target substances.

ECHA concludes that the Registrant has not demonstrated that the effects of the registered substance "may be predicted" from the analogue substance for terrestrial toxicity and that the requirements for general rules for adaptation of Annex XI, 1.5. – for the reasons specified above in sections 0.1 and 0.2 – have not been met.

Therefore, the adaptation of the information requirements suggested by the Registrant is not accepted.

Examination of testing proposals per endpoint

In order to fulfil the standard information requirements set out in Annexes IX and X, section 9.4. of the REACH Regulation, at 1000 tonnes and above per annum the Registrant must address the following endpoints for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), and long-term toxicity testing on plants (Annex X, section 9.4.6.).

The information on the endpoint 'effects on terrestrial organisms' is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

1. Soil microorganisms (Annex IX, section 9.4.2.)

The Registrant proposed a soil microorganisms test (OECD 216) to be carried out with the read-across substance octamethyltrisiloxane (CAS No. 107-51-7, EC No 203-497-4), with the following justification: "*A soil microorganisms study is planned for the related test substance octamethyltrisiloxane (CAS 107-51-7; EC 203-497-4). The registrant plans to read across the results of this study to hexamethyldisiloxane. Justification for planned read-across is given in the Endpoint Summary for Ecotoxicological information*".

As elaborated above in section III. 0 the proposed read-across does not meet the requirements of Annex XI section 1.5. and is therefore rejected together with the respective testing proposal as non-compliant with the REACH Regulation (Article 40(3)(d) of the REACH Regulation).

Nevertheless, a nitrogen transformation test is suitable to address the information requirement of Annex X, section 9.4.2.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216), using the registered substance hexamethyldisiloxane.

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.

2. Terrestrial Invertebrates (Annex X, 9.4.4.)

In the technical dossier, the Registrant proposed a long-term toxicity test on terrestrial invertebrates (OECD 222), with the following justification: "*An earthworm reproduction study is planned for the related test substance octamethyltrisiloxane (CAS 107-51-7; EC 203-497-4). The registrant plans to read across the results of this study to hexamethyldisiloxane. Justification for planned read-across is given in the Endpoint Summary for Ecotoxicological information*".

As elaborated above in section III. 0 the proposed read-across does not meet the requirements of Annex XI section 1.5. and is therefore rejected together with the respective testing proposal as non-compliant with the REACH Regulation (Article 40(3)(d) of the REACH Regulation).

In the comments to the draft decision, the Registrant claims that the OECD guidelines OECD 222 and OECD 232 explicitly indicate that those methods are not applicable to substances with high volatility (vapour pressure exceeding 0.0133 Pa at 25 C) (like the registered substance). The Registrant has acknowledged that the study design for the terrestrial toxicity studies will need to be discussed extensively with the laboratory, and ECHA acknowledges that the testing of the registered substance will be challenging.

ECHA notes that on page 70 of the analogue report [redacted] submitted as part of the updated IUCLID dossier as well as in the comments to the draft decision, the Registrant indicated that the OECD 232 is difficult to run properly and interpreting the results is problematic, therefore he will attempt to perform the OECD 222. However, to provide most flexibility to the Registrant both guidelines are maintained.

ECHA notes that the earthworm reproduction test (OECD 222) and Collembolan reproduction test (OECD 232) are both 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.

Both of these tests are suitable to address the information requirement of Annex X, section 9.4.4. and at the same time that of Annex IX, section 9.4.1.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out either of the following additional studies: Long-term toxicity to terrestrial invertebrates (Annex X, 9.4.4.); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222 or Collembolan reproduction test in soil OECD 232), using the registered substance.

3. Terrestrial Plants (Annex X, 9.4.6.)

The Registrant proposed a long-term toxicity test on terrestrial plants (OECD 208), with the following justification: "*A terrestrial plants study is planned for the related test substance octamethyltrisiloxane (CAS 107-51-7; EC 203-497-4). The registrant plans to read across the results of this study to hexamethyldisiloxane. Justification for planned read-across is given in the Endpoint Summary for Ecotoxicological information.*"

As elaborated above in section III. 0 the proposed read-across does not meet the requirements of Annex XI section 1.5. and is therefore rejected together with the respective testing proposal as non-compliant with the REACH Regulation (Article 40(3)(d) of the REACH Regulation).

The OECD 208 is suitable to address the information requirement of Annex X, section 9.4.6. and at the same time that of Annex IX, section 9.4.3.

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 to achieve a reasonably broad selection. The long-term toxicity testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant 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, the Registrant is required to carry out the following additional study: Long-term toxicity testing on plants (Annex X, 9.4.6.); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species, using the registered substance.

Note for the consideration of the Registrant

ECHA notes that in the endpoint study records of the testing proposals submitted the Registrant has explained that: *"the stability of test substance concentrations in the soil under realistic test conditions must be explored as part of method development."* ECHA notes that this is an issue for both the proposed source substance and the registered substance on which testing are to be conducted. ECHA agrees with the Registrant that in this case it is necessary to study the stability of test concentrations in soil and it may be necessary to modify the standard guidelines to allow the test substance concentrations to be maintained. Furthermore, ECHA notes that it is the Registrant's responsibility to design the tests in such a way that the effects to terrestrial organisms are adequately assessed.

In the comments to the draft decision, the Registrant has repeated his arguments on the technical difficulties of testing the registered substance. ECHA acknowledges these challenges and has granted an extension of the deadline as further specified in section VI. In case of the test being technically not possible, the Registrant may omit the test pursuant to Annex XI, 2. In such case the Registrant shall provide a full documentation of the unfeasability of the test, and the reasons for the test not being technically possible in the registration dossier.

In his comments to the draft decision, the Registrant has also requested if ECHA would accept soil risk characterization based on equilibrium partitioning in the case the above tests could not be performed due to unfeasibility. According to Annex IX, 9.4 column 2, in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. ECHA considers that consequently the equilibrium partitioning method can be applied to derive a PNEC screening for the risk characterization. However, ECHA notes that the use of the equilibrium partitioning method provides only an uncertain assessment of risk (ECHA guidance Chapter R.7c: Endpoint specific guidance Version 2.0 – November 2014) and that this method cannot alone replace

toxicity data for soil organisms as indicated in ECHA Guidance Chapter R.10: Characterisation of dose [concentration]-response for environment (May 2008), e.g. as outlined above, the reasons for the tests being technically not possible need to be included in the dossier.

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal.

In relation to the proposed tests, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies 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 studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 9 months from the date of adoption of the decision. In his comments on the draft decision of 9 May 2014, the Registrant requested an extension of the timeline to 12-15 months stating difficulties expected in testing the registered substance, and proposing to conduct the open systems studies (invertebrates and plants) in sequence. ECHA has evaluated those arguments and considered the extension of the time required to

provide the tests justifiable, given the challenges in testing a substance with such high volatility and intrinsic properties. Therefore, ECHA has set the deadline to 15 months.

VII. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

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