ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114299623-38-01/F Helsinki, 20 May 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For tris(2,4-ditert-butylphenyl) phosphite, CAS No 31570-04-4 (EC No 250-709-6), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for tris(2,4-ditert-butylphenyl) phosphite, CAS No 31570-04-4 (EC No 250-709-6), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 3.5., Annex IX, Section 9.4. and Annex X, Sections 9.4 and 9.5.1. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration 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 submitted after 5 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 2 June 2014.

On 27 October 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 1 December 2014 ECHA received comments from the Registrant on the draft decision.

On 23 January 2015 the Registrant updated his registration dossier with the submission number [redacted].

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

On 5 March 2014 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. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annexes IX and X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Long-term toxicity testing on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232);

2. Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Terrestrial Plant Test: Seedling Emergence and Seedling Growth, 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);

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

4. Long-term toxicity to sediment organisms (Annex X, 9.5.1.); using one or more of the following test methods: Sediment-water Chironomid toxicity using spiked sediment (OECD 218) or Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225) or Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233)

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 sound 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, shall result in a notification to the Authorities of the Member States for enforcement.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall to ECHA by **28 November 2016** an update of the registration dossier containing the information

required by this decision, including an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII, VIII, IX, and X of the REACH Regulation.

1., 2 and 3. Effects on terrestrial organisms

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), 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.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

a) Terrestrial Invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

Toxicity to terrestrial invertebrates is a standard information requirement under Annex IX, 9.4.1. and Annex X, 9.4.4. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has proposed to adapt short- and long-term toxicity testing on effects on terrestrial invertebrates using the following justification: "*In accordance to column 2 of REACh Annex IX, and X, toxicity testing on terrestrial organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on terrestrial organisms.*
According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB.
The hazard assessment of tris(2,4-di-tert-butylphenyl) phosphite reveals neither a need to classify the substance as dangerous for the environment or human health, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. The substance is used typically as antioxidant and/or stabiliser for polymers in very low concentrations and will be included into the matrix. Therefore, it can be expected that the application of the substance during its life cycle does not result in direct exposure to soil and exposure to soil is regarded as negligible. Further, no risk for soil organisms can be expected, due to a considerable high PNEC of 7980000 mg/kg dw derived by EPM.
No study on terrestrial organisms is proposed."
ECHA notes that the Registrant has proposed to adapt the standard information requirements of Annex IX 9.4.1 and Annex X 9.4.4 claiming that as the substance is not shown to be a PBT/vPvB substance and is not classified the Chemical Safety Assessment

(CSA) indicates no need for studies on terrestrial organisms. Furthermore, the Registrant argues that substance uses during its life cycle would not lead to soil exposure. ECHA notes that in the dossier with submission number [redacted] based on which the initial draft decision (DD) was prepared, the Registrant had not specified the uses of the substance as required by Annex VI, Section 3.5. In an update with submission number [redacted] submitted on 25 January 2015 use descriptors were added as requested in the initial draft decision (DD).

However, as the Chemical Safety Report (CSR) submitted by the Registrant as part of the technical dossier does not contain the Exposure Assessment (EA) and the subsequent Risk Characterisation (RC) sections it is not possible to fully assess whether exposure of the soil environment may occur. No further information on the claim on no exposure was provided in the Registrants comments on the draft decision. Therefore, ECHA considers that the Registrant has not demonstrated that the conditions of this adaptation possibility are fulfilled.

In his proposed adaptation the Registrant claims further that "*no risk for soil organisms can be expected, due to a considerable high PNEC of 7980000 mg/kg dw derived by EPM*". The Registrant seems to consider that with the EPM leading to a high PNEC registrants could waive all five standard information requirements for effects on terrestrial organisms.

However, Column 2 of Annex IX, 9.4. does not state that the EPM alone is sufficient to justify the adaptation of the standard information requirements. The second subparagraph of that Column 2 provision needs to be read in its entirety. Its aim is to establish whether there is a possibility to waive some of the standard information requirements stemming from Column 1 of Annex IX, 9.4. In order for an adaptation of the Column 1 provisions to be justified, registrants would have to demonstrate by means of the CSR that the conditions of an adaptation possibility in Column 2 or Annex XI are fulfilled. In establishing this, in some cases, registrants may use the EPM. Upon such a basis, registrants can then depending on the case establish whether some taxonomic group(s) could be waived.

In this context registrants have to take into account the other relevant provisions in Column 2 of Annex IX. The last sub-paragraph of that provision states that when a substance has a high potential to adsorb to soil or is highly persistent, even for registrations at a tonnage level between 100 up to 1000 tonnes long-term testing shall be considered instead of short-term testing. For registrations at a tonnage level of 1000 tonnes this is a standard information requirement.

In this specific case, ECHA notes that the Registrant has not justified an adaptation pursuant to Column 2 or Annex XI. A statement that the EPM leads to a high PNEC does not fulfil the conditions of any adaptation rule in REACH.

ECHA notes that the Registrant has not demonstrated that available data would lead to the conclusion that the substance is or is not toxic to soil organisms (Annex XI, 1.2.). In fact, based on the information available in the dossier on the environmental fate 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 1.1., November 2012), ECHA considers that there is indication for high persistence of the substance in soil. ECHA also notices that the Registrant for his PBT assessment concludes that the test substance has to be considered as p/vP. According to the abovementioned section of the Guidance, the EPM-method is not sufficient to assess the hazard to soil for substances for which there is indication for high persistence of the substance in soil. Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial invertebrates.

Based on the indication for high persistence in soil, ECHA notes that even if the substance was only registered at a tonnage of 100 to 1000 tonnes, long-term testing instead of short-term testing should have been considered.

Based on the indication for high persistence in soil, ECHA also considers that the column II adaptation for Annex IX, section 9.4., regarding long-term testing instead of short-term testing, is applicable to this substance.

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.1., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

ECHA notes that in the comments to the draft decision the Registrant has agreed to carry out the earthworm reproduction test (OECD 222). The agreement to conduct this study has also been added to the adapatation provided for this endpoint in the latest technical dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD 222), or Enchytraeid reproduction test (test method: OECD 220), or Collembolan reproduction test in soil (test method: OECD 232).

b) Toxicity testing on terrestrial plants (Annex IX, 9.4.3. and Annex X, 9.4.6.)

Toxicity to terrestrial plants is a standard information requirement under Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has proposed to adapt short- and long-term toxicity testing on effects on terrestrial plants using the following justification:

"In accordance to column 2 of REACh Annex IX, and X, toxicity testing on terrestrial organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on terrestrial organisms.
According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB.
The hazard assessment of tris(2,4-di-tert-butylphenyl) phosphite reveals neither a need to classify the substance as dangerous for the environment or human health, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. The substance is used typically as antioxidant and/or stabiliser for polymers in very low concentrations and will be included into the matrix. Therefore, it can be expected that the application of the substance during its life cycle does not result in direct exposure to soil and exposure to soil is regarded as negligible. Further, no risk for soil organisms can be expected, due to a considerable high PNEC of 7980000 mg/kg dw derived by EPM.
No study on terrestrial organisms is proposed."

As it is explained above under III."1.,2. and 3."a), the information available on these endpoints for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial plants.

In his comments to the draft decision and in the updated adaptation for this endpoint in the latest technical dossier, the Registrant has reasoned that studies on plants and soil microorganisms are not scientifically justified. The Registrant states that as plant and microorganism species are mainly exposed via the soil pore water due to substance properties of low water solubility, high partitioning and high persistence the substance would not enter soil pore water. The Registrant quotes sections of Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., November 2012), where it is discussed that for such substances studies on soil ingesting species is preferred. ECHA notes that as stated by the Registrant for strongly adsorbing or binding substances soil-dwelling organisms that feed on soil particles (e.g. earthworms) are most relevant. However, ECHA notes further that even if based on substance properties the main exposure would be via soil particles, there is no data to show that none of the substance would be available in the soil pore water. Furthermore, even if plants and microorganisms are primarily exposed via the soil pore water, some exposure via the soil particles may also occur. ECHA hence considers this proposed justification as not scientifically valid.

However, ECHA notes further that, as also expressed in the "Note for consideration by the Registrant" under point d) below, the Registrant has been given the option to choose whether to carry out the long-term terrestrial invertebrates or the plant study first. ECHA agrees with the Registrant that the earthworm study should be conducted first. Once the results of this study are available, the Registrant shall consider whether the plant study is needed in addition. Together with the results of the earthworm study, the EPM and any other relevant line of evidence, the Registrant may wish to build a weight of evidence approach to fully justify why the plant study would not be needed in addition. ECHA notes that as a line of evidence the Registrant may wish to use the weight-of-evidence (WoE) approach outlined in ECHA Guidance on information requirements and chemical safety assessment R.7.c (Version 1.1., November 2012, p. 124) where the following is specified: "The absence of chronic or long-term effects in aquatic organisms up to the substance solubility limit, or of acute effects within the solubility range above 10 mg/l can be used as part of a Weight of Evidence argument to modify/waive the data requirements of Annex IX and X".

As it is also explained above under point a), ECHA considers that the column II adaptation for Annex IX, section 9.4., regarding long-term testing instead of short-term testing, is applicable to this substance.

Both the Terrestrial plants, growth test (OECD 208, in the configuration as explained below) and the Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) are considered capable of generating information appropriate for the fulfilment of the information requirement for long-term toxicity testing on plants. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.3., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

OECD guideline 208 (Terrestrial Plant Test: Seedling Emergence and Seedling Growth) 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 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Terrestrial Plant Test: Seedling Emergence and Seedling Growth (test method: 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 (test method: ISO 22030).

c) Soil micro-organisms (Annex IX, section 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation. The registration dossier does not contain data for this endpoint. Instead, the Registrant has proposed to adapt testing on effects on soil microorganisms using the following justification:

"In accordance to column 2 of REACh Annex IX, and X, toxicity testing on terrestrial organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on terrestrial organisms.
According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB.
The hazard assessment of tris(2,4-di-tert-butylphenyl) phosphite reveals neither a need to classify the substance as dangerous for the environment or human health, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. The substance is used typically as antioxidant and/or stabiliser for polymers in very low concentrations and will be included into the matrix. Therefore, it can be expected that the application of the substance during its life cycle does not result in direct exposure to soil and exposure to soil is regarded as negligible. Further, no risk for soil organisms can be expected, due to a considerable high PNEC of 7980000 mg/kg dw derived by EPM.
No study on terrestrial organisms is proposed."

In his comments and the updated adaptation for this endpoint in the latest technical dossier, the Registrant refers to an acute toxicity test on microorganisms (OECD 209 Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation)) where no inhibition was observed. According to ECHA Guidance R.7.C. (Version 1.1., November 2012, p. 125) "where inhibition of sewage sludge microbial activity has been observed in Annex VIII testing, a test on soil microbial activity will additionally be necessary for a valid PNEC to be derived." ECHA notes that the Guidance does not give the possibility to adapt the standard information requirement of Annex IX section 9.4.3. based on no inhibition of sewage sludge microbial activity. ECHA notes that absence of inhibition of sewage sludge microbial activity may be used as a line of evidence in a WoE approach. Furthermore, in the comments and updated adaptation the Registrant reasons that studies on plants and soil microorganisms are not scientifically justified. However, as fully discussed under point b)

above the first line of evidence of tests on toxity to plants and microorganisms not being scientifcally justified cannot be accepted. Hence ECHA considers that overall the WoE approach proposed does not fulfill the requirements of Annex XI section 1.2. If the Registrant had other evidence of low toxicity to microorganisms, the Registrant may wish to improve the WoE approach.

As it is already explained above under point a), the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for toxicity for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), Chapter R.7C, Section R.7.11.3.1., p. 115, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD 216).

d) Note for consideration by the Registrant

As stated above, based on the information currently available in the technical dossier on environmental fate and physio-chemical properties, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012), ECHA considers that there is indication for high persistence and adsorption of the substance in soil. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. ECHA notes that in his comments to the DD and in the updated dossier, the Registrant has indicated that he wishes to conduct the long-term invertebrates study requested under section II.1. first. ECHA agrees with the Registrant that the OECD 222 study is to be conducted first. Once the results of the requested long-term soil toxicity test as well as the results from the toxicity test on soil microorganisms have become available the Registrant may be able to justify an adaptation of the other requested long-term soil toxicity test, the plant study. Specifically he could examine whether or not screening assessment based on Predicted No Effect Concentration (PNEC) for soil organisms (derived by using Equilibrium Partitioning Method (EPM)) with additional safety factor of 10 applied indicates the risk to soil compartment when compared to relevant environmental concentrations in soil and whether or not performed toxicity tests with terrestrial organisms indicate a risk to the tested organisms. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly arguing why – from weight of evidence considerations – taking into account the new information it is justified to adapt the information requirement for the second long-term soil toxicity test.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method. Therefore the potential weight of evidence adaptation possibility outlined in the Guidance (based on EPM and other data that is available for the substance) does not apply for the present endpoint.

4. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.)

"Long-term toxicity to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant has sought to adapt the long-term toxicity testing on sediment organisms using the following justification: *"In accordance to column 2 of REACh Annex X, long-term toxicity testing on sediment organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on sediment organisms.*
According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB.
The hazard assessment of tris(2,4-di-tert-butylphenyl) phosphite reveals neither a need to classify the substance as dangerous for the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. Due to a considerable high PNEC of 40000000 mg/kg dw derived by EPM, no risk for sediment organisms can be expected. Additionally, the application of the substance during its life cycle does not result in direct exposure to sediment.
No study onsediment organisms is proposed."

In his proposed adaptation the Registrant claims that there is no need to investigate the effects on sedment organisms further as since the substance is not shown to be a PBT/vPvB substance and is not classified the Chemical Safety Assessment (CSA) indicates no need for studies on sediment organisms. Furthermore, the Registrant argues that substance uses during its life cycle would not lead to soil exposure. ECHA notes that in the dossier with submission number [redacted] based on which the initial draft decision (DD) was prepared and as fully discussed in III.1. above, the Registrant had not specified the uses of the substance as required by Annex VI, Section 3.5. In an update with submission number [redacted] submitted on 25 January 2015 use descriptors were added as requested in the initial draft decision (DD).

However, as the Chemical Safety Report (CSR) submitted by the Registrant as part of the technical dossier does not contain the Exposure Assessment (EA) and the subsequent Risk Characterisation (RC) sectionsit is not possible to fully assess whether exposure of the sediment may occur. No further information on the claim of no exposure was provided in the comments. Therefore, ECHA considers that the Registrant has not demonstrated the lack of sediment exposure.

In the adaptation the Registrant argues further that *"Due to a considerable high PNEC of 40000000 mg/kg dw derived by EPM, no risk for sediment organisms can be expected."* ECHA notes further that in order for an adaptation of Annex X, 9.5.1. Column 1 provisions to be justified, the Registrant would have to demonstrate by means of the CSR that the conditions of an adaptation possibility (Annex XI) are fulfilled. In establishing this, in some cases and as explained in ECHA *Guidance on information requirements and chemical safety assessment* (R.7.B, version 1.2. November 2012, Section R.7.8.7.), Registrants may use the EPM as part of a weight-of-evidence to adapt the standard information requirement.

However, according to ECHA *Guidance on information requirements and chemical safety assessment* (R.7.B, version 1.2. November 2012, Section R.7.8.7., p. 140) the EPM cannot be used in a weight of evidence approach for substances that are highly insoluble and for which no effects are observed in aquatic studies. For such substances at least one sediment study has to be performed. ECHA notes that as is shown in the aquatic studies in the

technical dossier no effects were observed in any of the aquatic studies performed. In addition, as the substance has a reported water solubility of <5 µg/L ECHA considers that long-term sediment testing is indicated for the registered substance.

In his comments to the DD and the updated adpatation for this endpoint in the latest technical dossier, the Registrant has stated that he intends to determine the need for the sediment study based on the results of the terrestrial invertebrate study and the subsequent chemical safety assessment update. ECHA notes that as indicated in the section above, the sediment study is required based on substance properties and lack of effects in aquatic studies. According to ECHA Guidance (R.7.B, version 1.2. November 2012, Section R.7.8.7., p. 140) in such cases at least one sediment study is to be provided. ECHA notes further that under the REACH Regulation there are separate information requirements for testing sediment and terrestrial organisms as both are defined as two separate compartments and testing uses different organisms. Therefore, the results of the soil organisms testing alone cannot be used to adapt the information requirement of sediment organisms.

ECHA notes that the Registrant has not demonstrated that available data would lead to the conclusion that the substance is or is not toxic to sediment organisms (Annex XI, 1.2.). In fact, the present substance has a high potential to adsorb to sediment. Therefore, as the standard information requirements for long-term sediment testing have not been adapted in a justified manner, testing is required.

Therefore, in this specific case, ECHA notes that the Registrant has not justified an adaptation.

Therefore, pursuant to Article 41(1)(a) and (b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

- Sediment-water Chironomid toxicity using spiked sediment (Test method: OECD 218) OR
- Sediment-water Lumbriculus toxicity test using spiked sediment (Test method: OECD 225) OR
- Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233)

Note for consideration by the Registrant

The Sediment-water Chironomid toxicity using spiked sediment (OECD 218), Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225) and Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233) are in principle each considered capable of generating information appropriate for the fulfilment of the information requirements for sediment long-term toxicity testing. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity,substance properties and uses. ECHA considers that it is the Registrants responsibility to choose the most appropriate test protocol and to give a justification for the choice. The Registrant may carry out more than one of the sediment tests defined in Section II above if he considers that further testing is required. While ECHA at this stage only requires one test, based on newly available data it may consider whether further tests are required to fulfil the standard information requirement.

Furthermore, both water and sediment exposure scenarios are described in the OECD 233 Test Guideline. The Registrant is advised to consult the OECD 233 Test Guideline and the

ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section R.7.8.10.1) for the selection of the appropriate method of spiking.

IV. Adequate identification of the composition of the tested material

The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

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. 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on 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]
Guilhem de Seze
Head of Unit, Evaluation