EUROPEAN CHEMICALS AGENCY

Helsinki, 14 December 2016

Addressee: [redacted]

Decision number: CCH-D-2114350442-58-01/F
Substance name: 2-(2H-benzotriazol-2-yl)-p-cresol
EC number: 219-470-5
CAS number: 2440-22-4
Registration number: [redacted]
Submission number: [redacted]
Submission date: 11.09.2013

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3; test method: OECD TG 476 or OECD TG 490) with the registered substance;**

2. **Growth inhibition study aquatic plants (Annex VII, section 9.1.2.; test method: Freshwater Alga and Cyanobacteria, Growth Inhibition Test, EU C.3./OECD TG 201) with the registered substance;**

3. **Robust study summary for the following study: Bioaccumulation: Test for the Degree of Bioconcentration in Fish according to test method OECD 305 C "National Institute of Technology and Evaluation (MITI, Japan), 1998" for meeting the information requirement of Annex IX, 9.3.2. of the REACH Regulation;**

4. **Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD TG 222, or Enchytraeid reproduction test, OECD TG 220, with the registered substance;**

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

6. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) with 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 **21 March 2018**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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 Kevin Pollard, Head of Unit, Evaluation E1

[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.

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Appendix 1: Reasons

1. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)**

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained. ECHA notes that the registration dossier contains negative results for both these information requirements. Therefore, adequate information *on in vitro* gene mutation in mammalian cells needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for a mammalian cell gene mutation assay (Anonymous, US-EPA, no year indicated). However, this study does not provide the information required by Annex VIII, Section 8.4.2., because the study is rated by yourself as supporting study and not assignable (Klimisch score 4) with respect to reliability. The submission information does not include the necessary data to judge on the reliability and outcome of the test. According to Article 13(3), a test 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 Agency as being appropriate. In the present case the data provided do not enable ECHA to judge whether the test is appropriate and of equal quality compared to a standard test according to an OECD test guideline. No data is provided e.g. on the test guideline used, GLP compliance, essential details of the test method applied and the results provided. Therefore, based on the deficits in reporting it is not possible to judge the relevance of the conclusion provided "presumably mutagenic". This reported conclusion however gives rise to a serious concern which needs clarification with a reliable and appropriate test.

Furthermore, you have sought to adapt this information requirement according to Annex VIII, Section 8.4.3., column 2. You provided the following justification for the adaptation:

"*In accordance with Annex VIII (8.4.3) of the REACH legislation, the test on mutagenicity in mammalian cells in vitro does not need to be conducted if adequate data from a reliable in vivo gene mutation assay is available. In this case, the substance was found to be non carcinogenic in two valid studies performed with both rats and mice.*"

These studies ([redacted] 1975 and [redacted], 1981) evaluated the chronic toxicity (OECD 452) and carcinogenicity (similar to OECD 451) of the substance, respectively, and have therefore design wise not the ability to clarify issues concerning gene mutation. Besides your above mentioned claim, you did not provide any convincing and toxicologically argued justification why a chronic toxicity and carcinogenicity study are suitable to waive an *in vitro* mammalian cell gene mutation test. Both, chronic toxicity and carcinogenicity tests do not represent a reliable *in vivo* mammalian gene mutation test.

ECHA notes further that your adaptation does not meet the specific rules for adaptation of Annex VIII, Section 8.4.3., column 2, because carcinogenicity and chronic toxicity studies are not in vivo mammalian gene mutation tests. Carcinogenicity and chronic toxicity studies are not evaluating specifically gene mutation as a study endpoint. Thus results of these studies are not adequate for waiving a standard information requirement of an *in vitro* mammalian cell gene mutation test.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the *in vitro* mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

ECHA notes that in your comments on the draft Decision, you agreed to carry out an OECD TG 476 study as requested.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490).

2. Growth inhibition study aquatic plants (Annex VII, section 9.1.2.).

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, section 9.1.2. 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.

In the technical dossier you have sought to adapt this information requirement according to Annex XI, Sections 1.2 (Weight of evidence) and 1.5 (Read-across approach) of the REACH Regulation.

As part of a weight-of-evidence approach, you proposed read-across to a supporting Algal inhibition test (EU C.3.) using 2-tert-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4-methylphenol (EC 223-445-4), with the following justification:

"*The substance to be registered is of low water solubility and no signs of toxicity in the solubility range were observed in the available acute aquatic toxicity studies. It can be assumed that also there is no toxicity to algae. As the substance is difficult to test because of its low water solubility the available read across data from a similar substance were used to support this weight of evidence approach. In this study no toxic effects to algae were observed up to the solubility limit. The EC50 and NOEC were therefore based on the nominal concentration and the study is adequate and reliable with restrictions.*

For this endpoint available data on toxicity to aquatic algae on a similar substance were used to derive the EC50. 2-tert-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4-methylphenol has

the identical molecular base structure (phenolic benzotriazoles) as the substance to be registered, 2-(2H-benzotriazol-2-yl)-p-cresol. The read across substance is also of low water solubility and degradation and hydrolysis are not likely. Based on the two additional functional groups (Cl- and But-) of the read across substance it can be assumed that the water solubility is predicted to be even lower and the the log Pow higher. (logP 6.6, water solubility 4.7E-4g/l, ACD/Labs V.8.14)".

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".

Annex XI, Section 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation.

ECHA notes that a significant effect on parent mortality after 21 days was observed in a *Daphnia magna* reproduction test (OECD 211), which demonstrates that the substance has potential for aquatic toxicity contrary to what you have stated in your adaptation. Additionally, your justification for the proposed read-across does not adequately analyse the structural differences or the impurity profiles, and the impact of these elements on the properties of the substances. ECHA considers that your proposed read-across approach does not convincingly show how the relevant properties of the registered substance can be predicted from the information on properties of 2-tert-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4-methylphenol.

Consequently, your adaptation of the standard information requirement in the technical dossier, based on read-across, does not comply with the general rules for adaptation as set out in Annex XI, 1.5. and the weight of evidence justification using test results for 2-tert-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4-methylphenol (EC 223-445-4) cannot be accepted.

Furthermore, ECHA notes that the Algal inhibition test (EU C.3.) study, used in your read-across approach, did not include an analysis of test material concentration in solution and was performed using test concentrations above the water solubility of the substance.

Therefore, the adaptation is rejected and the information provided in the technical dossier is considered insufficient to address the standard information requirement of Annex Annex VII, section 9.1.2.

ECHA notes that in your comments on the draft Decision, you agreed to carry out an OECD 201 study as requested.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Freshwater Alga and Cyanobacteria, Growth Inhibition Test, EU C.3./OECD TG 201).

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3. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.).

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Bioaccumulation in aquatic species" is a standard information requirement as laid down in Annex IX, Section 9.3.2. 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.

In the technical dossier you have sought to adapt this information requirement according to Annex XI, Sections 1.2 (Weight of evidence) and 1.5 (Read-across approach) of the REACH Regulation.

As part of a weight-of-evidence approach, you proposed read-across to a supporting bioconcentration study (OECD 305 C) using 2-tert-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4-methylphenol (EC 223-445-4), with the following justification:

"For this endpoint available data on bioaccumulation on a similar substance were used to support the weight of evidence approach. 2-tert-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4-methylphenol (EC has the identical molecular base structure (phenolic benzotriazoles) as the substance to be registered, 2-(2H-benzotriazol-2-yl)-p-cresol. The read across substance is also of low water solubility and degradation and hydrolysis are not likely. Based on the two additional functional groups (Cl- and But-) of the read across substance it can be assumed that the water solubility is predicted to be even lower and the log Pow higher. (logP 6.6, water solubility 4.7E-4g/l, ACD/Labs V.8.14)".

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".

Annex XI, Section 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation.

Your justification for the proposed read-across does not adequately analyse the structural differences or the impurity profiles, and the impact of these elements on the properties of the substances. ECHA considers that your proposed read-across does not convincingly show how the relevant properties of the registered substance can be predicted from the information on properties of 2-tert-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4-methylphenol.

Consequently, this adaptation of the standard information requirement in the technical dossier, based on read-across, does not comply with the general rules for adaptation as set out in Annex XI, 1.5. Therefore, the adaptation is rejected and the information provided in the technical dossier using 2-tert-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4-methylphenol (EC 223-445-4) is considered insufficient to address the standard information requirement of Annex IX, Section 9.3.2.

Furthermore, you provided an abstract of a bioconcentration study (OECD 305 C) on the registered substance. ECHA notes that the results of this study may be sufficient to address the standard information requirements of Annex IX, Section 9.3.2.

However, the available abstract information does not provide sufficient information on the analytical methods or results (e.g. controls, mortalities and any observed abnormal behaviour). to allow a definitive conclusion to be made on the validity of this study.

Article 14(1) in conjunction with Annex I and Article 10(a)(vii) of the REACH Regulation requires to provide robust study summaries of the information derived from the application of Annexes VII to XI. In accordance with Article 3(28) of the REACH Regulation, a robust study summary is defined as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report." Guidance on the preparation of the robust study summaries is provided in Practical Guide 3: "How to report robust study summaries".

As explained above, the documentation of the study is insufficient and does not allow an independent assessment of whether the information available on this endpoint for the registered substance in the technical dossier meets the information requirement. Consequently you are requested to provide a robust study summary for the bioconcentration study (OECD 305 C) on the registered substance including the missing information on the analytical methods and results (e.g. controls, mortalities, and any observed abnormal behaviour).

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have sought to adapt this information requirement according to Annex IX, Section 9.4., column 2. You provided the following justification for the adaptation:

"*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. An environmental exposure assessment was performed in order to determine possible risks of the test compound to the environment. According to the results of the exposure assessment, all the relevant uses of the test substance are considered to be safe with a Risk Characterization Ratio below 1. Therefore, studies on the toxicity of the test substance to terrestrial organisms are not provided*".

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.4., column 2 because a statement that the Equilibrium Partitioning Method (EPM) leads to an Risk Characterisation Ratio below 1 is not sufficient to fulfil the conditions of any adaptation for this endpoint. Furthermore, ECHA notes that you have not demonstrated that available data would lead to the conclusion whether the substance is toxic to soil organisms and that you have concluded within the CSR that the substance is very persistent. Consequently, you have not adequately demonstrated by means of the CSR that the conditions of an adaptation possibility in Annex IX, Section 9.4., column 2 are fulfilled.

Furthermore, according to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the (EPM) approach.

ECHA notes that the results from the toxicity test(s) on algae requested in point 2 of the present Decision may lead to a revision of the currently derived PNECaquatic. Therefore, ECHA considers that accurate allocation of an appropriate soil hazard category according to table R7.11-2, of the abovementioned guidance, is not possible at this time. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4. Since a screening assessment for terrestrial organisms is not possible, testing for effects on all terrestrial organisms indicated in section 9.4 of Annex IX is considered necessary.

According to section R.7.11.5.3., Chapter R.7c of the above mentioned guidance, substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance is likely to be very persistent. Therefore 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.

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 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

As explained above, the information provided 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 this endpoint.

ECHA notes that in your comments on the draft decision, you agreed to carry out a long-term toxicity to terrestrial invertebrates study (OECD 222) as requested providing the following reasons: "*reasonable considering the substance's physical-chemical properties - The substance has a low water solubility of 0.173 mg/L and a logKow of 4.20. Furthermore, due to its logKoc of > 3 it is expected to bind to the solid soil phase. According to ECHA's Information Requirements and Chemical Safety Assessment, Chapter R.7c: Endpoint specific guidance the assessment of the toxicity to terrestrial organisms shall take into account the different routes by which terrestrial organisms may be exposed to substances. According to Table R.7.11-1 several exposure routes can be distinguished between the different organism groups. Invertebrates ..have several exposure pathways strongly depending on the specific habitat these species are living in. The requested OECD 222 study uses the earthworm Eisenia fetida as test organism. … This species belongs to the family of Lumbricidae and is adapted to decaying organic material. That means that it is exposed to the test substance by different exposure pathways. On the one hand it is exposed to the vast amount of substance adsorbed to the solid soil phase both due to skin contact to the soil material and mostly via ingested soil material. Moreover, the earthworms are even exposed via skin contact to the small amount of dissolved substance in the pore water. In summary, it can*

be stated that Eisenia fetida clearly represents a species which is exposed via different routes to the maximal amount of substance present in the soil compartment. However, a long-term toxicity study to terrestrial invertebrates according to OECD TG 222 is clearly regarded as suitable and sufficient to cover the main exposure pathway of the compound"

ECHA considers both the earthworm reproduction test (OECD 222) and Enchytraeid reproduction test (OECD 220) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA acknowledges your indicated species selection and your reasoning to undertake testing on the earthworm reproduction testing. However, both OECD guidlelines are still provided as options in the draft decision.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 222), or Enchytraeid reproduction test (test method: OECD TG 220).

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have sought to adapt this information requirement according to Annex IX, Section 9.4., column 2 with the justification as explained in section 4. However, as noted above, this adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.4., column 2 .

As also established within section 4 above, it is not currently possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4. OECD TG 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. 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 TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

In your comments on the draft decision, you considered that the requested long-term toxicity study to plants (OECD TG 208) is not necessary for the following reasons: *"...to carry out an Growth inhibition study aquatic plants ....Invertebrates ..have several exposure pathways strongly depending on the specific habitat these species are living in. The requested OECD 222 study uses the earthworm Eisenia fetida as test organism. .....This species belongs to the family of Lumbricidae and is adapted to decaying organic material. That means that it is exposed to the test substance by different exposure pathways. On the one hand it is exposed to the vast amount of substance adsorbed to the solid soil phase both due to skin contact to the soil material and mostly via ingested soil material. Moreover,*

the earthworms are even exposed via skin contact to the small amount of dissolved substance in the pore water. In summary, it can be stated that Eisenia fetida clearly represents a species which is exposed via different routes to the maximal amount of substance present in the soil compartment. However, a long-term toxicity study to terrestrial invertebrates according to OECD TG 222 is clearly regarded as suitable and sufficient to cover the main exposure pathway of the compound……considering the substance's physical-chemical properties. …. The substance has a low water solubility of 0.173 mg/L and a logKow of 4.20. Furthermore, due to its logKoc of > 3 it is expected to bind to the solid soil phase.

According to ECHA's Information Requirements and Chemical Safety Assessment, Chapter R.7c: Endpoint specific guidance the assessment of the toxicity to terrestrial organisms shall take into account the different routes by which terrestrial organisms may be exposed to substances. According to Table R.7.11-1 several exposure routes can be distinguished between the different organism groups. Plants as primary producers are mainly exposed by soil pore water due to root uptake… As mentioned above the compound has a very low water solubility and a high potential to adsorb to the solid soil phase. Therefore, the amount of substance present in the pore water is expected to be negligible. In summary, it can be stated that Eisenia fetida clearly represents a species which is exposed via different routes to the maximal amount of substance present in the soil compartment. In contrast to the multiple exposure pathways of Lumbricidae terrestrial plants are only affected by the compound via root uptake of the pore water. The pore water is not expected to be the main "micro-compartment" for the present substance due to its low solubility and high adsorption potential. Therefore, root uptake of pore water seems to be a negligible exposure pathway and it definitely does not represent the worst case situation. ….In conclusion, neither… terrestrial plants …are expected to adequately cover the main exposure route of the present compound and are therefore not considered necessary for the assessment of the terrestrial toxicity of the substance. ….However further terrestrial studies are scientifically not justified".

ECHA acknowledges your agreement to perform the Growth inhibition study aquatic plants. Also, your preferred Earthworm reproduction testing using the OECD 222. And, also in accordance to section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), as indicated in Section 4 above in the draft decision submitted to you: where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, to use this PNEC in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach, considering an accurate allocation of an appropriate soil hazard category according to table R7.11-2, of the abovementioned guidance, is possible, to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4.

Currently, due to the available information, it is not possible to allocate the substance to a soil hazard category and to adapt some of the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4. Since a screening assessment for terrestrial organisms is not possible, testing for effects on all terrestrial organisms indicated in section 9.4 of Annex IX is considered necessary, this includes Terrestrial plants, section 9.4.3.

As indicated in the notes for consideration in Section 6 below in the draft decision, ECHA notes that if the results of the proposed test on Growth inhibition study aquatic plants allow the subsequent derivation of a PNECwater, you may consider the ITS as recommended in

section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), and determine the need for further testing on terrestrial organisms.

Also, following the completion of the preferred Earthworm reproduction testing using the OECD 222, you may adapt the terrestrial plant 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. Any adaptation will be evaluated by ECHA at the follow-up stage. However, if it is not possible to adapt the terrestrial plant testing requested, the testing request will need to be fulfilled as per this decision.

According to section R.7.11.5.3., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), substances that have a log Kow/Koc >5 are considered highly adsorptive. You indicated in your comments on the draft decision, the registered substance has a log Koc of > 3. Based on these properties of the registered substance, ECHA agrees that the registered substance is expected to adsorb, however, without any provided evidence, it is to difficult to quantify the extent of any adsorption, at this stage. You have provided no evidence in your comments to the draft decision or in the techncial dossier to the following statement, "...the amount of substance present in the pore water is expected to be negligible". Based on the technical dossier, direct and indirect exposure wide dispersive professional and consumer uses are reported for the registered substance.

According to section R.7.11.1., Table R.7.11-1, Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), it recognises all relevant soil exposure pathways required for a comprehensive effect assessment of substances in soils. There is no indication that one pathway needs/should be more relevant than another and that this could be used as a justification not to test a particular organism group. Also, you acknowledge there is some soil exposure to earthworms via the soil pore water expected, "M*oreover, the earthworms are even exposed via skin contact to the small amount of dissolved substance in the pore water."*

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Terrestrial plants, growth test (test method: OECD TG 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).

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.
You have sought to adapt this information requirement according to Annex IX, Section 9.4., column 2 with the justification as explained in section 4.

However, your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.4., column 2, as established within section 4 above.

ECHA notes that the tests requested under points 4 and 5 above are not sufficient to address this standard information requirement. ECHA concludes that the effects on soil micro-organisms need to be ascertained by performing a relevant test.

According to section R.7.11.3.1. of the above-mentioned guidance, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

In your comments on the draft Decision, you considered that the requested Soil microorganisms: nitrogen transformation test (OECD TG 215) is not necessary for the following reasons:

"……to carry out an Growth inhibition study aquatic plants ….Invertebrates ..have several exposure pathways strongly depending on the specific habitat these species are living in. The requested OECD 222 study uses the earthworm Eisenia fetida as test organism. …..This species belongs to the family of Lumbricidae and is adapted to decaying organic material. That means that it is exposed to the test substance by different exposure pathways. On the one hand it is exposed to the vast amount of substance adsorbed to the solid soil phase both due to skin contact to the soil material and mostly via ingested soil material. Moreover, the earthworms are even exposed via skin contact to the small amount of dissolved substance in the pore water.

In summary, it can be stated that Eisenia fetida clearly represents a species which is exposed via different routes to the maximal amount of substance present in the soil compartment. However, a long-term toxicity study to terrestrial invertebrates according to OECD TG 222 is clearly regarded as suitable and sufficient to cover the main exposure pathway of the compound… The substance has a low water solubility of 0.173 mg/L and a logKow of 4.20. Furthermore, due to its logKoc of > 3 it is expected to bind to the solid soil phase. ……As mentioned above the compound has a very low water solubility and a high potential to adsorb to the solid soil phase. Therefore, the amount of substance present in the pore water is expected to be negligible. ….The pore water is not expected to be the main "micro-compartment" for the present substance due to its low solubility and high adsorption potential. Therefore, root uptake of pore water seems to be a negligible exposure pathway and it definitely does not represent the worst case situation. The same applies for soil micro-organisms which are mainly exposed via soil pore water as well. Furthermore, a toxicity study to microorganisms from a representative sewage treatment plant conducted according to OECD TG 209 did not show any effect either. The IC50 was > 100 mg/L. Thus, effects on soil microorganisms are not expected…..In conclusion, neither ….soil micro-organisms are expected to adequately cover the main exposure route of the present compound and are therefore not considered necessary for the assessment of the terrestrial toxicity of the substance. …..However further terrestrial studies are scientifically not justified".

Please see Section 5 for the response to your similar comments to the draft decision for not undertaking the soil micro-organisms request. Please note, however, as already indicated to you in the note for consideration at the end of this section, ECHA considers 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. Therefore ECHA considers that it is not possible to waive the standard information requirement for soil microorganisms by using the EPM as part of the adaptation,

However, regarding your additonal comments to the draft decision, only to Section 6 soil micro-organisms, you have disagreed to perform the OECD 216 study on soil microorganisms due to available weight of evidence showing low toxicity to aquatic microorganisms. To substantiate the low-toxicity weight of evidence on soil microorganisms, you have raised the following study in your comments. This is available in the current dossier on the registered substance; activated sludge respiration inhibition (OECD 209).

Based on the above information and the submitted study in the technical dossier, ECHA agrees that you have provided some evidence in a weight of evidence (WoE) approach according to the general rules in Annex XI of the REACH Regulation and indicated that the level of toxicity to microorganisms appears to be > 100 mg/L (EC50 (3 h)). However, ECHA considers that only one line of evidence is indicated as activated sludge media is used in activated sludge respiration inhibition (OECD 209). For an acceptable WoE ECHA considers that further lines of evidence would be required. ECHA notes the Registrant could use in addition another line of separate evidence using results from a study conducted using another media.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 216).

Notes for your consideration

If the results of the requested toxicity test on algae allow the subsequent derivation of a PNECwater, you may consider the ITS as recommended in section R.7.11.6., of the above-mentioned *Guidance* and determine the need for further testing on terrestrial organisms. If you conclude that no further investigation of effects on terrestrial organisms is required, you should update your technical dossier by clearly stating the reasons for adapting the information requirements of section 9.4. of Annex IX, of the REACH Regulation.

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. does not apply for the present endpoint.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 14 October 2015.

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

In your comments you agreed to the draft decision requests of In vitro gene mutation study in mammalian cells, Robust study summary for the following study: Bioaccumulation, Growth inhibition study aquatic plants and Long-term toxicity to terrestrial invertebrates. ECHA took your comments into account and did not amend the request(s).

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

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

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

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

3. 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 eventually result in a notification to the enforcement authorities of your Member State.

4. In relation to the information required by the present decision, the sample of 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 substance composition 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 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.