ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 20 February 2018

Addressee: [redacted]

Decision number: CCH-D-2114392241-54-01/F
Substance name: tris(2-ethylhexyl) phosphate
EC number: 201-116-6
CAS number: 78-42-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 18.10.2013
Registered tonnage band: 1000+T

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. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species (rabbit), oral route with the registered substance;**

2. **Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance specified as follows:**
   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce some toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**
   - **Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;**

3. **Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD TG 222, or Enchytraeid reproduction test, OECD TG 220, or Collembolan reproduction test in soil, OECD TG 232) with the registered substance;**

4. **Long-term toxicity to plants (Annex X, Section 9.4.6.; 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;**

5. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) and carbon transformation test, EU C.22/OECD TG 217) 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 **27 August 2020**. 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.

Appendix 1: Reasons

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2) in a second species

Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route using the registered substance as test material.

However, there is no information provided for a pre-natal developmental toxicity study in a second species. Furthermore, The technical dossier does not contain an adaptation in accordance with column 2 of Annex X, Section 8.7.2. or with the general rules of Annex XI for this standard information requirement.

Hence, 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.

The test in the first species was carried out by using a rodent species (rat). According to the test method EU B.31./OECD 414, the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbit as a second species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

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: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species (rabbit) by the oral route.

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3)

The basic test design of an extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Further detailed guidance on study design and triggers is provided in the ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 6.0, July 2017).

Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

a) The information provided

You have not provided any study record of an extended one-generation reproductive toxicity study in the dossier that would meet the information requirement of Annex X, Section 8.7.3.

You have sought to adapt this information requirement according to Annex XI, Section 1.1.2., use of existing data, and Annex XI, Section 1.2., weight of evidence. Hence, ECHA has evaluated your adaptation with respect to those adaptations.
By using the criteria of Annex XI, Section 1.1.2., you have provided an assessment of the endpoint fertility on the basis of the following elements:

- Several oral subacute, sub-chronic and chronic toxicity studies performed with the registered substance (e.g., NTP 1984) for which you provided study summaries in IUCLID section 7.5.1.
- A pre-natal developmental toxicity study in rats performed with the registered substance ([redacted] 2008) for which you provided a study summary in IUCLID section 7.8.2.
- Literature references with regard to the value of histopathological examination of reproductive tissues in repeated dose toxicity studies for the evaluation of reproductive toxicity in males and females of substances other than the registered substance (Mangelsdorf et al. 2003, Ulbrich & Palmer 1995, Janer et al. 2007a, Dent 2007, Sanbuissho et al. 2009)
- Considerations on estrogen receptor binding based on QSAR Toolbox for which you did not provide a documentation.

You have acknowledged that certain fertility endpoints are not addressed in the subchronic and chronic toxicity studies.

You concluded that "*According to Annex XI Section 1.1.2. all conditions are met to conclude that the available data shall be considered sufficient for the endpoint fertility and no additional animal testing corresponding to test methods referred to in REACH regulation Article 13(3) are necessary to assess this endpoint.*

According to Annex XI chapter 1.2. there is sufficient weight of evidence to conclude that tris(2-ethylhexyl) phosphate has not a particular dangerous property for the endpoint fertility and further testing on vertebrate animals for that property shall be omitted". Evaluation of the adaptation according to Annex XI, Sections 1.1.2 and 1.2

ECHA notes that the criteria listed in Annex XI, Section 1.1.2., which you are referring to, are important aspects to be considered if a source of information is relevant, reliable and adequate for the purpose of the weight of evidence adaptation under Annex XI, Section 1.2, as indicated in ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.4.4. Hence, ECHA has evaluated your information within this context.

Evaluation of adaptation according to Annex XI, Section 1.2

Criteria applied

An adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property with respect to the information requirement in question.

To appropriately address the information requirement in question, your adaptation based on Annex XI, Section 1.2. needs to address the properties of the registered substance by covering the relevant elements investigated in an extended one-generation reproductive toxicity study (EU B.56./OECD TG 443) as requested in this decision. ECHA considers that this study type provides relevant information on two aspects, namely on sexual function and fertility in P and F1 generations (further referred to as 'sexual function and fertility') and on developmental toxicity observable peri- and postnatally in the F1 generation (further referred to as 'post-natal developmental toxicity'). Relevant elements for sexual function and fertility are in particular functional fertility (mating behaviour, conception, pregnancy, parturition, and lactation) in the parental generation after 10 weeks pre-mating exposure and histopathological examinations of reproductive organs in both P and F1 generations. Relevant elements for post-natal developmental toxicity are in particular peri- and post-natal investigations of the F1 generation up to adulthood (such as growth, survival/mortality, external malformations, sexual maturation).

Sexual function and fertility

With respect to the aspect of sexual function and fertility of P and F1 generation, you have provided reliable information on histopathological changes in major reproductive organs (e.g., repeated dose toxicity studies performed by NTP 1984). The information from prenatal developmental toxicity study in rats (OEC TG 414) is limited to maintenance of pregnancy from implantation up to close to the parturition.

ECHA notes that information regarding sexual function and fertility like mating behaviour, conception, pregnancy, parturition, and lactation, which are relevant elements to be investigated, are not provided.

The literature references cited in your adaptation justification do not contain information on the registered substance nor do you explain why and how the information on various aspects of reproduction provided by an extended one-reproductive toxicity could be replaced or predicted for your substance by histopathological examinations only.

Furthermore, the conclusion that the registered substance does not bind to estrogen receptor is not considered adequate to conclude on the absence of effects for the endpoint fertility.

Thus, the information you provided does not support your conclusion that the substance does not have a dangerous property with respect to sexual function and fertility.

Post-natal developmental toxicity

ECHA notes that your adaptation justification does not address post-natal developmental toxicity. The provided information does also not cover the key elements which need to be investigated in this regard. The studies according to OECD TG 414 in the rat provide information only on pre-natal developmental toxicity. Thus, you did not provide information to conclude on the hazardous property of the registered substance with respect to postnatal developmental toxicity.

Conclusion on your adaptation according to Annex XI, Section 1.1.2, and Section 1.2

ECHA concludes that with regard to the endpoint extended one-generation reproductive toxicity study, the conditions of Annex XI, Section 1.1.2., are not met due to lack of adequate and reliable coverage of key parameters foreseen to be investigated in the extended one-generation reproductive toxicity study.

For similar reasons, the information you provided to support you adaptation according to Annex XI, Section 1.2, considered individually or together, do not allow to assume/conclude that the substance does not have a particular dangerous (hazardous) property with respect to the information requirement for Annex X, Section 8.7.3.

Therefore, the general rules for adaptation laid down in Annex XI, Section 1.1.2 and 1.2 of the REACH Regulation are not met and your adaptations of the information requirement are rejected.

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. Thus, an extended one-generation reproductive toxicity study according Annex X, Section 8.7.3. is required. The following refers to the specifications of this required study.

b) *The specifications for the study design*

Premating exposure duration and dose-level setting

To ensure that the study design adequately addresses the fertility endpoint, the duration of the premating exposure period and the selection of the highest dose level are key aspects to be considered. According to the ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 6.0, July 2017), the starting point for deciding on the length of the premating exposure period should be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required because there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 6.0, July 2017).

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

If there is no existing relevant data to be used for dose level setting, it is recommended that results from a range-finding study (or range finding studies) are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

Species and route selection

According to the test method EU B.56./ OECD TG 443, the rat is the preferred species. On the basis of this default assumption, ECHA considers that testing should be performed in rats.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

c) Outcome

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: Extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);

Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation

Notes for your consideration:

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) were identified. You may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if new information becomes available after this decision is issued to justify such an inclusion.

Inclusion is justified if the available information, together with the new information shows triggers which are described in column 2 of Section 8.7.3., Annex X and further elaborated in ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6 (version 6.0, July 2017). You may also expand the study to address a concern identified during the conduct of the extended one-generation reproduction toxicity study and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the expansion must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

3. Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4.)

"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.

You have sought to adapt the standard information requirements of Annexes IX and X, section 9.4. using the following justification:

"In accordance with section 1 of REACH Annex XI, testing on soil toxicity does not appear scientifically necessary. The already available studies on aquatic organisms) indicate that neither in acute tests in 3 trophic levels nor in chronic tests in daphnia and algae any effects have been observed up to the limit of the water solubility of 0.6 mg/l. In the absence of soil toxicity data, REACH guidance document R7b recommends to use EPM (equilibrium partitioning method). However, as no toxicity was found in aquatic organisms, EPM cannot be used to generate definitive toxicity data for sediment. For this reason a PNEC soil could not be derived. Soil dwelling organisms which are fed by the water phase including pore water are considered to be possibly affected by the substance in a similar way as aquatic organisms. Thus, also no toxicity to this kind of sediment organism is expected. On the other hand, organisms fed by organic matter may be affected as the substance has a strong affinity to adsorb to soil particles (logKoc = 3.35 or higher).
In this case, toxicity would only be expected when uptake of the soil particles including adsorbed substance would lead to a significant resorption from the gut system. However due to the strong adsorption resorption is considered to be unlikely. Furthermore, traces of

substance if resorbed, would be excreted rather rapidly and not be accumulated in the organisms as shown by the low bioconcentration factor of <22."
ECHA notes that the technical dossier includes a professional use of the registered substance as an *"additive for herbicide formulations"*, ERC 8d. Therefore, intentional release to environment is expected and direct exposure to soil is likely.

Moreover, you do not provide any scientific justification explaining why the extrapolation from the aquatic vertebrate BCF to terrestrial invertebrate BCF is a valid prediction, nor provide any scientific justification in the technical dossier on the adsorption-resorption dynamics of the registered substance in the gut system of sediment/soil dwelling organisms.

Thus, your justification for adaptation of the information requirement does not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptation 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 requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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 Equilibrium Partitioning Method (EPM) approach.

You have considered that it is unfeasible, with the currently available information, to derive a PNEC for aquatic organisms. 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 ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance is likely to be very persistent (default setting for substances that are not readily biodegradable). 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.
ECHA notes that long-term tests are suitable to simultaneously address the information requirements of section 9.4. of Annexes IX and X.

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.

In your comments to the draft decision, you agreed to perform the requested test.

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), or Collembolan reproduction test in soil (test method: OECD TG 232).

4. Long-term toxicity to plants (Annex X, Section 9.4.6)

"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.

You have sought to adapt the standard information requirements of Annexes IX and X, sections 9.4.3 and 9.4.6. using the following justification: *"In accordance with section 1 of REACH Annex XI, testing on soil toxicity does not appear scientifically necessary. The already available studies on aquatic organisms) indicate that neither in acute tests in 3 trophic levels nor in chronic tests in daphnia and algae any effects have been observed up to the limit of the water solubility of 0.6 mg/l. In the absence of soil toxicity data, REACH guidance document R7b recommends to use EPM (equilibrium partitioning method).*

However, as no toxicity was found in aquatic organisms, EPM cannot be used to generate definitive toxicity data for sediment. For this reason a PNEC soil could not be derived. Soil dwelling organisms which are fed by the water phase including pore water are considered to be possibly affected by the substance in a similar way as aquatic organisms. Thus, also no toxicity to this kind of sediment organism is expected. On the other hand, organisms fed by organic matter may be affected as the substance has a strong affinity to adsorb to soil particles (logKoc = 3.35 or higher). In this case, toxicity would only be expected when uptake of the soil particles including adsorbed substance would lead to a significant resorption from the gut system. However due to the strong adsorption resorption is considered to be unlikely. Furthermore, traces of substance if resorbed, would be excreted rather rapidly and not be accumulated in the organisms as shown by the low bioconcentration factor of <22."

ECHA notes that the technical dossier includes a professional use of the registered substance as an *"additive for herbicide formulations"*, ERC 8d. Therefore, intentional release to environment is expected and direct exposure to soil is likely.

Moreover, you have sought to justify the adaptation of this endpoint standard information requirement, terrestrial plant toxicity, with soil/sediment organism physiology and sorption dynamics (e.g." *a significant resorption from the gut system", "organisms fed by organic matter"),* while you have not provided any scientific justification on the validity of this extrapolation and prediction from observation in fish to plants.

Thus, justification for adaptation of the information requirement does not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptation cannot be accepted.

As established within point (6) 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. 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 TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

In your comments to the draft decision, you agreed to perform the requested test.

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).

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

"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.

You have waived the standard information requirements of Annex IX, section 9.4.2. using the following justification: *"In accordance with section 1 of REACH Annex XI, testing on soil toxicity does not appear scientifically necessary. The already available studies on aquatic organisms) indicate that neither in acute tests in 3 trophic levels nor in chronic tests in daphnia and algae any effects have been observed up to the limit of the water solubility of 0.6 mg/l. In the absence of soil toxicity data, REACH guidance document R7b recommends to use EPM (equilibrium partitioning method).*

However, as no toxicity was found in aquatic organisms, EPM cannot be used to generate definitive toxicity data for sediment. For this reason a PNEC soil could not be derived. Soil dwelling organisms which are fed by the water phase including pore water are considered to be possibly affected by the substance in a similar way as aquatic organisms. Thus, also no toxicity to this kind of sediment organism is expected. On the other hand, organisms fed by organic matter may be affected as the substance has a strong affinity to adsorb to soil particles (logKoc = 3.35 or higher). In this case, toxicity would only be expected when uptake of the soil particles including adsorbed substance would lead to a significant resorption from the gut system. However due to the strong adsorption resorption is considered to be unlikely. Furthermore, traces of substance if resorbed, would be excreted rather rapidly and not be accumulated in the organisms as shown by the low bioconcentration factor of <22."

ECHA notes that the technical dossier includes a professional use of the registered substance as an "*additive for herbicide formulations"*, ERC 8d. Therefore, intentional release to environment is expected and direct exposure to soil is likely.

Moreover, you have sought to justify the adaptation of this endpoint standard information, effects on soil microorganisms, with soil/sediment organism physiology and sorption dynamics (e.g." *a significant resorption from the gut system", "organisms fed by organic matter"),* while you have not provided any scientific justification on the validity of this extrapolation and prediction from fish to microorganisms.

Thus, your justification for adaptation of the information requirements does not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptation 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 requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA notes that the tests requested under points (6 and 7) above are not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R.7C, Section R.7.11.3.1., p115, the nitrogen transformation test is considered sufficient for most non-agrochemicals. However, as the substance has known agrochemical uses, ECHA considers that both the nitrogen and carbon transformation tests should be performed simultaneously.

In your comments to the draft decision, you agreed to perform the requested test.

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), and Soil microorganisms: carbon transformation test (test method: EU C.22./OECD TG 217).

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 11 October 2016.

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

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

ECHA took into account your comments and amended the requests. Based on your comments the degradation related requests were removed from the decision and will be addressed in a new compliance check.

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

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-58 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

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

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