ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114348396-41-01/F Helsinki, 23 November 2016

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

For bis(2-propylheptyl) phthalate, CAS No 53306-54-0 (EC No 258-469-4), 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 bis(2-propylheptyl) phthalate, CAS No 53306-54-0 (EC No 258-469-4), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement[s] of Annex VI/VII/IX/X, Sections 3.5., 8.4.1., 8.7.2., 9.1.5., 9.4.2., 9.4.4., 9.4.6., 9.1.5., 9.5.1., and 9.1.6.1. of the REACH Regulation.

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 21 July 2016, 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.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2018.

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 5 December 2013.

On 19 August 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 24 September 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision for requests for *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.), Pre-natal developmental toxicity study (Annex X, 8.7.2.), Long-term toxicity to sediment organisms (Annex X, 9.5.1.), Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.), Long-term toxicity testing on plants (Annex X, 9.4.6) and Effects on soil micro-organisms (Annex IX, 9.4.2.)

The Registrant updated his registration on 23 September 2014 with the submission number [redacted], and again on 11 January 2016 with submission number [redacted].

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

On 21 July 2016 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.

Subsequently, proposal(s) for amendment to the draft decision were submitted.

On 26 August 2016 ECHA notified the Registrant of the proposal(s) for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal(s) for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal(s) for amendment received and amended the draft decision.

On 5 September 2016 ECHA referred the draft decision to the Member State Committee.

By 26 September 2016, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 25–27 October 2016, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 26 October 2016.

ECHA took the decision pursuant to Article 51(6) 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)(vi) and/or (vii), 12(1) e), 13 and Annexes VII, 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. *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. /OECD 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102, as specified in section III.A.3 below.;

2. Pre-natal developmental toxicity study (Annex X, 8.7.2.; test method: EU B.31./OECD 414) in rabbits, oral route;

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD 210);

4. Long-term toxicity to sediment organisms (Annex X, 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218 or test method: Sediment-water Lumbriculus toxicity test using spiked sediment, OECD 225);

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

6. Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Terrestrial plants, growth test, OECD 208 with at least six species - two monocotyledonous and four dicotyledonous - tested or test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants – ISO 220300);

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

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **30 January 2019**. [The timeline has been set to allow for sequential testing as appropriate.]

Notes for consideration by the Registrant

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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

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III. Statement of reasons

Pursuant to Article 41(3), 10(a)(iii), (vi) and/or (vii) and Annexs VI to X, Section 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)(vi) and/or (vii), 12(1e) 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 to X of the REACH Regulation.

1. *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.)

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. 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.

According to paragraph 13 of the current OECD 471 test guideline (updated 1997) at least five strains of bacteria should be used. These should include four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by E.coli WP2 strains or *S. typhimurium* TA102 which have an AT base pair at the primary reversion site.

The Registrant has provided a test from the year 1995 according OECD 471 and GLP with an assigned reliability score of 2. The test used four different strains of *S. typhimurium* TA [1535, TA 1537, TA 98 and TA 100]. However, since the test was conducted, significant changes have been made to OECD guideline 471 and this means that the study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2. of the REACH Regulation.

ECHA concludes that a test using *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 has not been submitted by the Registrant and that the test using one of these is required to conclude on *in vitro* gene mutation in bacteria.

In his comments on the draft Decision, the Registrant agreed to carry out an OECD 471 study as requested.

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: Bacterial reverse mutation test (test method: EU B.13/14. / OECD 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

2. Pre-natal developmental toxicity study (Annex X, 8.7.2.)

Pre-natal developmental toxicity studies 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 available for a pre-natal developmental toxicity study in a second species.

As explained above, the information available 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 testing a rodent species and ECHA therefore considers that the test in a second species should be carried out in a non-rodent species. According to the test method EU B.31/OECD 414, the rabbit is the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rabbit as a second species to be used.

In his comments on the draft Decision, the Registrant agreed to carry out an OECD 414 study as requested.

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: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rabbits by the oral route.

3. Long-term toxicity testing on fish (Annex IX, 9.1.6.1.)

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant sought to waive the standard information requirements of Annex IX, Section 9.1.6 using the following justification: '*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic 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, to Regulation (EC) No 1272/2008 or is assessed to be a PBT or vPvB. The hazard assessment of DPHP reveals neither a need to classify the substance as dangerous for the environment, nor is it a PBT or vPvB substance. Therefore, and for reasons of animal welfare, a long-term toxicity study in fish is not provided*'.

However, the justification for waiving does not meet the criteria of the specific adaptation rule of Column 2 of Annex IX, section 9.1. ECHA considers that the information currently available in the technical dossier for short-term and long-term toxicity to fish is not sufficient to conclude on the toxicity potential of the registered substance to fish.
In the technical dossier, the Registrant has addressed the endpoint for short-term toxicity to fish with data from an Acute Toxicity Test (OECD 203). However, ECHA notes that the test concentrations used in the study were above the water solubility limit of the substance (<0.1 ug/l). Furthermore, at all test concentrations, the test substance was observed as insoluble oily liquid on the water surface. Also the measured concentrations vary from [redacted] to [redacted]% of the nominal concentrations. Finally, ECHA notes that even in the negative control 2.5 mg bis(2-propylheptyl) phthalate/L was measured after 96 hours. Together with the observation of an oily layer, this makes any conclusion on the actual dissolved concentrations that the fish might have been exposed to, highly uncertain.

Moreover, it results already from Annex VIII, Section 9.1.3, Column 2, that a long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble. The substance is poorly water soluble and has a log Kow of around 10.7, and the duration of a short-term toxicity test is in any case very likely too short for the substance to reach an equilibrium in the fish. ECHA notes in this context that the long-term toxicity to fish tests are suitable to simultaneously address the information requirements of section 9.1.3 of Annex VIII and section 9.1.6 of Annex IX.

Therefore, the adaptation cannot be accepted and thus it is necessary to generate additional data for this endpoint.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers the FELS toxicity test according to OECD TG 210 to be the most suitable as it is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215). Moreover, the FELS toxicity test covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), *Chapter R7b, Figure R.7.8-4).*

A Member State Competent Authority proposed to amend the decision to include a request for a Fish sexual Development Test (OECD 234) on the basis that the existing short-term toxicity to fish study (OECD 203) was invalid and the column 2 adaptation of annex VIII section 9.1.3 regarding 'Long-term toxicity testing on fish for poorly water soluble substances', was applicable. Furthermore, the Member State Competent Authority considered that there were indications for possible estrogenic as well as thyroid mode of actions of the registered substance. More specifically, the Member State Competent Authority noted that histopathological findings in the pituitary and thyroid glands were observed in studies with rats, which indicated a thyroid mode of action, and the sex ratio was affected in reproduction studies with rats, which could indicate an estrogenic mode of action. In addition, the Member State Competent Authority considered that the registered substance has similar structural and physical chemical properties to DEHP (CAS 117-81-7), which is identified as an SVHC and is on the candidate list as an Endocrine Disruptor for the environment. Consequently, the Member State Competent Authority considered that the indications for possible endocrine disruption warranted a test that covered the potential endocrine effects on aquatic organisms.

The Registrant, in his comments to the proposal for amendment, disagreed with the Member State Competent Authority. The Registrant considered that the available relevant testing data on the registered substance provides no indication of estrogenic activity and the observed thyroid effects is a secondary mode of action that is not relevant to humans, as rodents are more sensitive to thyroid effects. In addition, the Registrant also disagreed that the registered substance has similar structural and physico-chemical properties to DEHP, and instead considers that the registered substance is more similar to DIDP (CAS 68515-49-1 / 26761-40-0). Furthermore, the Registrant considers that the existing short-term study is valid and therefore disagreed with the proposal to perform a long-term toxicity test on fish. However, the Registrant agreed to change the klimisch score of the existing short-term study from 1 to 2. The Registrant also considered that a long-term toxicity test on fish is not necessary on the grounds of animal welfare and the technical challenges involved.

ECHA agrees with the Registrant that the available data does not seem to indicate oestrogenicity or antiandrogenicity. However, ECHA considers that the observed thyroid effects raise a concern that sensitive life stages of different animal species may be affected. Since the available data does not indicate any specific sex hormone related mode of action, ECHA does not consider that a request for the Fish Sexual Development Test (OECD TG 234) is appropriate to address the concern, because the identified concern, thyroid toxicity, is not addressed with the test.

ECHA agrees with the Member State Competent Authority that the existing short-term toxicity test on fish is invalid for the reasons previously outlined. Furthermore, ECHA notes that if technical difficulties prevent testing from being completed, the Registrant should provide information on why the requested test was not technically possible within the Registration dossier.

With regards to the structural similarity of the registered substance to both DEHP and DIDP, ECHA considers that the available information does not indicate that the registered substance is more similar to DIDP than to DEHP. Based on the shape of the molecule, the registered substance appears more similar to DEHP, and the molecular size (which may affect the bioavailability of the molecule) of the registered substance falls between DEHP and DIHP. Overall, ECHA does not consider it possible to reliably conclude that the registered substance is more similar to DIDP than to DEHP in terms of structure and effects.

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: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for consideration by the Registrant

Due to the low solubility of the substance in water the Registrant should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

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

"Long-term toxicity testing 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.

The Registrant has waived testing on sediment organisms using the following justification: '*The test substance produces neither acute nor chronic toxicity in freshwater aquatic organisms (fish, invertebrates, and an alga) within the range of water solubility. Furthermore, the substance is readily biodegradable. Based on this information, there is no indication that sediment organisms may be more sensitive towards the effects of the test substance than the other test species are. It can therefore be assumed with sufficient confidence, that a study with sediment organisms would not provide any additional information improving risk assessment significantly*'.

ECHA notes that the substance has a high potential to absorb to soil (Log Koc >5.63) and poor water solubility (<0.0001 mg/l) therefore exposure to sediment can be anticipated. Furthermore, section R.7.8.12.2., Chapter R.7b of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012) states that '*For substances that are highly insoluble and for which no effects are observed in aquatic studies, the application of the equilibrium partitioning method is not possible. In this case, at least one sediment test has to be performed*'.

Therefore, ECHA considers that the justification provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex X, section 9.5.1, or the general adaptation rules of Annex XI REACH. Therefore, the adaptations cannot be accepted. Consequently, the information currently available in the technical dossier is not considered as sufficient to conclude on the long-term toxicity potential of the registered substance to sediment organisms and thus it is necessary to generate additional data for this endpoint.

Section R.7.8.12.2., of the abovementioned guidance states that '*If there are no long-term sediment tests available, a test with preferably either Lumbriculus variegatus or Chironomus spec. using spiked sediment should be performed*'.

In his comments on the draft Decision, the Registrant agreed to carry out an OECD 218 study as requested.

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: Sediment-water Chironomid toxicity using spiked sediment (test method OECD 218) or Sediment-water Lumbriculus toxicity test using spiked sediment (test method OECD 225).

5. – 7. Effects on terrestrial organisms (Annex IX and X, 9.4)

"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.

The Registrant has waived the standard information requirements of Annex IX and X, section 9.4. using the following justification: *'The test substance produces neither acute nor chronic toxicity in freshwater aquatic organisms (fish, invertebrates, and alga) within the range of water solubility. Furthermore, the substance is readily biodegradable. Based on this information, there is no indication that terrestrial organisms may be more sensitive towards the effects of the test substance than the other species are. It can therefore be assumed with sufficient confidence, that studies with terrestrial organisms would not provide any additional information improving risk assessment significantly'*.

ECHA notes that the substance has a high potential to absorb to soil (Log Koc >5.63) and poor water solubility (<0.0001 mg/l) therefore exposure to soil can be anticipated. Furthermore, section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1, November 2012) states that *'where the water solubility is <1 mg/l, the absence of acute toxicity can be discounted as reliable indicator for potential effects on soil organisms due to the low exposures in the test'*. A chronic study for aquatic invertebrates is available.

Therefore, ECHA concludes that the justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX or X, Section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptations cannot be accepted. Consequently there is an information gap and it is necessary to provide information for this endpoint.

a) Terrestrial invertebrates (Column 2 of Annex IX, Section 9.4. and Annex X, Section 9.4.4.)

The registrant has 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 Equilibrium Partitioning Method (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 and Annex X is considered necessary. However, ECHA notes that the results from an existing valid toxicity test on aquatic invertebrates may be used to derive a PNECaquatic.

According to section R.7.11.5.3., of the abovementioned guidance, substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil ($logK_{oc}$ >5.63). 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 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. 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 his comments on the draft Decision, the Registrant agreed to carry out an OECD 222 study as requested.

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) Terrestrial plants (Column 2 of Annex IX, Section 9.4. and Annex X, Section 9.4.6)

As established within subsection (a) 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 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 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

In his comments on the draft Decision, the Registrant agreed to carry out an OECD 208 study as requested.

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 plants, growth test (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).

If the results of the existing toxicity test on aquatic invertebrates, or the requested long-term toxicity test on fish, allow the subsequent derivation of a PNECwater, the Registrant 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 the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the information requirements of section 9.4. of Annexes IX and X, of the REACH Regulation.

c) Effects on soil micro-organisms (Annex IX, Section 9.4.2.)
As explained above, 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 this endpoint.

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 his comments on the draft Decision, the Registrant agreed to carry out an OECD 216 study as requested.

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).

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.

B. Deadline for submission of the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 18 months from the date of adoption of the decision. In his comments on the draft decision of 24 September 2014, the Registrant requested an extension of the timeline to 26 months. He sought to justify this request for extra time for performance of the OECD 305 radiolabelling & extra preparation of the OECD 414 regarding palatability and range finder studies. As ECHA removed the OECD 305 study request and the standard OECD 414 performance of the study and updating IUCLID is 12 months, we considered 18 months sufficient. Therefore, ECHA did not modify the deadline of the decision, at that stage. In his further comments on the draft decision submitted during the Registrant's commenting period on the submitted proposals of amendment, the Registrant requested an extension of the timeline to 26 months. He sought to justify this request by indicating laboratory capacity issues. ECHA requested the Registrant to substantiate his claim. The Registrant submitted evidence to justify his claim for an extension. Therefore, ECHA has granted the request and set the deadline to 26 months.

IV. Adequate identification of the composition of the tested material

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants 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 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.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2.

[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.