Helsinki, 4 December 2019

Addressee: [redacted]

Decision number: CCH-D-2114493147-42-01/F
Substance name: Reaction mass of [[(2-hydroxyethyl)imino]dimethylene]bisphosphonic acid, sodium salt and 4-(Phosphonomethyl)-2-hydroxy-2-oxo-1,4,2-oxazaphosphorinane, sodium salt
List number: 939-513-8
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 01/02/2017
Registered tonnage band: 100-1000

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. **Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: OECD 421/422) in rats, oral route with the registered substance;**

2. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats with the registered substance;**

3. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance;**

4. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD TG 201) with the registered substance;**

5. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**

6. **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (OECD TG 222) or Enchytraeid reproduction test (OECD TG 220), using the registered substance;**

7. **Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3. column 2; test method: Terrestrial plant test: seedling emergence and seedling 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) using**

the registered substance;

8. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) using the registered substance.**

You are required to submit the requested information in an updated registration dossier by ***13 December 2021*** except for the information requested for a Sub-chronic toxicity study (90-day) which shall be submitted in an updated registration dossier by ***11 December 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 and 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, has to 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 Wim De Coen, Head of Unit, Hazard Assessment.

[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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Before entering to the information requests, ECHA provides a clarification on the test substance and on previous testing proposals.

You have referred to testing proposal made for the following endpoints: *sub-chronic toxicity study (90 day), pre-natal developmental toxicity, long term toxicity on aquatic invertebrates, toxicity to soil macroorganisms except arthropods, and toxicity to terrestrial plant.* These testing proposals were submitted in the registration dossier of the former lead registrant. The former lead registrant was the addressee of the testing proposal draft decision received from ECHA on 15 March 2016 (Communication number TPE-D-2114321161-69-01/D). However, ECHA notes that after the testing proposal examination was started, the previous lead registrant ceased the manufacture of the substance. Therefore this led to the termination of the testing proposal examination by ECHA and this was communciated to the former lead registrant with a communication (Communication number: TPE-C-2114340496-47-01/F). Therefore, your attempt to adapt the information requirements by referring to an ongoing the testing proposal examination is rejected.

Concerning the test substance used in the reproduction/developmental toxicity screening test (OECD TG 422), ECHA notes that the test substance is [[(2-hydroxyethyl)imino]dimethylene] bisphosphonic acid, sodium salt, CAS 22036-78-8, EC 244-743-0 which is a *constituent* of the registered substance, Reaction mass of [[(2-hydroxyethyl)imino]dimethylene]bisphosphonic acid, sodium salt and 4-(phosphonomethyl)-2-hydroxy-2-oxo-1,4,2-oxazaphosphorinane, sodium salt, EC No. 939-513-8. However, the registered substance has other constituents in addition to the one used for this test, and therefore the respective information requirement cannot be met with this study. In your comments to the draft decision, you outline that there is a mistake in the test material identifiers for this study summary. You indicated that you will clarify the test material identifier in the next update, to ensure the test material identity is fully clear.

1. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

"Screening for reproductive/developmental toxicity" (test method OECD TG 421 or 422) is a standard information requirement as laid down in Annex VIII, Section 8.7.1. of the REACH Regulation if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from *in vitro* methods that the substance may be a developmental toxicant. No such evidence is presented in the dossier. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have provided a study record(s) for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422) with [[(2-hydroxyethyl)imino]dimethylene] bisphosphonic acid, sodium salt, CAS 22036-78-8, EC 244-743-0, which is a *constituent* of the registered substance as indicated in your CSR.

While you have not explicitly claimed an adaptation, you have provided information that ECHA interpretes as an attempt to adapt the information requirement according to Annex XI,

Section 1.5.

However, you have not justified how data on one constituent of the registered substance would allow a read-across for the whole of the registered substance. Therefore, your dossier is lacking a basis for predicting relevant human health properties of the registered substance from data for the source substances.

In the absence of this information, ECHA cannot verify that the properties of the registered substance can be predicted from the data on the source substance.

Hence, you have not established that relevant properties of the registered substance can be predicted from data on the analogue substance. Since your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5., it is rejected and it is necessary to perform testing on the registered substance.

In your comments to the draft decision, you outline that there is a mistake in the test material identifiers for this study summary such that it is indicated that the test material contained only the linear form. However, the study report makes clear that the test material was the equilibrium mixture of both forms and as such it demonsates the case that this data requirement is already met by existing reliable data. You indicated that you will clarify the test material identifier in the next update, to ensure the test material identity is fully clear. ECHA will assess the provided information after the adopted decision's deadline.

According to the test methods OECD TG [421/422], the test is designed for use with rats. On the basis of this default assumption ECHA considers testing should be performed with 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) Chapter R.7a, Section 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:
- Reproductive/developmental toxicity screening test (test method: OECD TG 421) *or* Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD TG 422) in rats by the oral route.

You should also carefully consider the order of testing of the requested screening (OECD TG 421/422) and the developmental toxicity studies (OECD TG 414) to ensure that unnecessary animal testing is avoided, paying particular attention to the endpoint specific Guidance (https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf) Section R.7.6.2.3.2., pages 484 to 485 of version 6.0 – July 2017."

2. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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 provided a study record for a "combined repeated dose

toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422) with [[(2-hydroxyethyl)imino]dimethylene] bisphosphonic acid, sodium salt, CAS 22036-78-8, EC 244-743-0. However, as stated in Section 1 of this decision, your adaptation according to Annex XI, Section 1.5. is rejected, as you have not provided sufficient justification and documentation to substantiate your read-across hypothesis.

Furthermore, the submitted study pursuant to OECD TG 422 does not provide the information required by Annex IX, Section 8.6.2., because the exposure duration is less than 90 days and the number of animals examined per dose group for histopathology and clinical chemistry is significantly lower than in the 90 day sub-chronic toxicity study (OECD TG 408).

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 has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 5.0, December 2016) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely, the exposure concentrations reported in the chemical safety report for the inhalation route are low (typically less than [redacted]) compared to the toxicity profile of the substance. Hence, the test shall be performed by the oral route using the test method OECD TG 408.

In your comments to the draft decision, you have agreed to perform the test on the sodium salt of HEBMP, as required in the draft decision. The result of this test will be read across to the acid form of HEBMP.

According to the test method OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

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: Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats with the registered substance

3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

A "pre-natal developmental toxicity study" (test method OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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 provided a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422) with [[(2-hydroxyethyl)imino]dimethylene] bisphosphonic acid, sodium salt, CAS 22036-78-8, EC 244-743-0. However, as stated in Section 1 of this decision, your adaptation according to Annex XI, Section 1.5. is rejected.

Moreover, this study does not provide the information required by Annex IX, Section 8.7.2.

because it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations. Therefore, your adaptation of the information requirement is 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.

In your comments to the draft decision, you have agreed to perform the test on the sodium salt of HEBMP, as required in the draft decision. The result of this test will be read across to the acid form of HEBMP.

According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first 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) Chapter R.7a, Section 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: OECD TG 414) in a first species (rat or rabbit) by the oral route.

4. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same 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.

Column 2 of Annex VII, Section 9.1.2 specifies that the study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.

You have sought to adapt this information requirement according to Annex XI, Section 2. You provided the following justification for the adaptation: "*In accordance with Section 2 of REACH Annex XI, the study does not need to be conducted because an assessment of the toxicity to aquatic algae and cyanobacteria is technically not possible. HEBMP and its salts have the capacity to form complexes with essential trace nutrients present in the test media, rendering them unavailable for uptake. Conversely, algal growth may also be stimulated by the presence of supplementary phosphorus released by the photolytic degradation of phosphonic acids.*" In addition you included a justification for the adaptation in the CSR.

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI; Section 2 because the OECD 201 test guideline and OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6/REV1 (e.g. Annex 4) specifically describe toxicity mitigation testing for chelant chemicals. ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 2.0, November 2014) also explains in Table R.7.8-3 how chelating agents can potentially be tested. An approach using increased nutrient metal concentrations was for instance used in the EU risk assessment for edetic acid (European Union risk assessment report, edetic acid (EDTA), EUR 21314 EN; http://echa.europa.eu/documents/10162/65615721-ab6d-4f28-b48f-73cf9d8cc529).

In addition, ECHA further notes that the justification for the adaptation indicated in the CSR outlines scientific claims which cannot be verified based on the reference list provided. ECHA notes that only one of the references mentioned can be located , [redacted] 2010 ([redacted] but it is not publicly available.

According to ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), Chapter R10 (Section R.10.3.1 including Table R.10-4), in order to derive PNECaquatic, it is neccesary to provide at least one short-term L(E)C50 from each of the three trophic levels: Primary producers (plants), represented by algae; plant eating animals, represented by invertebrates (e.g. Daphnia) and predators, represented by fish.
You have submitted information on short-term toxicity of two trophic levels, therefore there is a need to provide information on the third trophic level, thus, aquatic plants.

Therefore, your adaptation of the information requirement is 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.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

In your comments to the draft decision,you agree that an adaptation to the test design, specifically the test medium, is necessary to test your type of substance, due to the commonly affecting phosphonate complexing agents. The adaptation you suggest is considered by you to be more conservative than that of the OECD guidance 23 recommendations.

Considering the registered substance, ECHA sees this as a reasonable option, but reminds you that if adapations to the standard guidelines are performed, a detailed justification of the performed adaptations needs to be included in the endpoint study record.

In addition, you mention that you will evaluate two existing studies for the inclusion in the registration data set before planning any new study. ECHA will assess the provided information after the adopted decision's deadline.

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: Algae growth inhibition test (EU C.3./OECD TG 201).

Notes for your consideration

Due to the chelating property of the substance you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6/REV1 (July 2018) and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), 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).

Once results of the test on growth inhibition study on aquatic plants is available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. According to ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on the results of the growth inhibition study on aquatic plants and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term aquatic invertebrate testing may need to be conducted. However, if a risk is indicated, the long-term aquatic invertebrate study needs to be conducted.

5. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

As stated above, your attempt to adapt this information requirement by referring to an ongoing the testing proposal examination is rejected.

In addition, the CSR states that there is a testing proposal, for the OECD TG 211 :" *There is evidence from short-term aquatic data set of limited toxicity to invertebrates. A long-term study may be useful to refine the PNEC and hazard assessment. The test could be conducted on whole substance of known composition, representative of the supplied substance, or on a purified sample of the cyclic constituent and this would be explored as part of test planning. The acid or a sodium salt form at appropriate pH could be used in testing and the results read across to the registration substance. Planned study period: After approval by ECHA"*

ECHA considers that the OECD TG 211 is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation. ECHA considers further that testing for aquatic ecotoxicity with the (whole) registered substance is more appropriate than the other alternatives proposed. Because of the inherent properties of the acid solution, you would need to adjust the solution to environmental pH, which would resemble a regular solution with a salt form. Therefore, ECHA requires you to use the registered substance for testing the long term toxicity to aquatic invertebrates.

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.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

In your comments to the draft decision, you agree that there is a data gap, and that you will perform the test if required by the re-evaluated PNEC and risk characterisation outcomes.

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: *Daphnia magna* reproduction test (test method: EU C.20./OECD TG 211).

Notes for your consideration

Once results of the test on growth inhibition study on aquatic plants and if deemed necessary, also the long-term toxicity to aquatic invertebrates test are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, you shall submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If you come to the conclusion that no further investigation of effects on aquatic organisms is required, you shall update your technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

Due to the chelating property of the substance you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6/REV1 (July 2018) and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), 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).

In addition, regarding the use of the Water Accommodated Fraction (WAF) approach, please note that the WAF approach is problematic when used with a test substance containing several constituents, as in the case of the registered substance. In such cases the toxicity cannot be allocated to specific constituents directly and interpretation of the results in the risk assessment requires careful consideration taking into account differences in fate of the constituents in the environment. When constituents of varying solubility are present there can be partitioning effects which limit dissolution in the water. These effects should be minimised and appropriate loadings selected accordingly to allow an appropriate determination of the toxicity of the different constituents. In that respect, it is critical that a robust chemical analysis is carried out to identify those constituents present in the water to which the test organisms are exposed. Additionally, chemical analysis to demonstrate attainment of equilibrium in WAF preparation and stability during the conduct of the test is required. Methods capable of identifying gross changes in the composition of WAFs with time are required. Methods such as ultra-violet spectroscopy or total peak area have been used successfully for this purpose. The method used to prepare the WAF should be fully described in the test report and evidence of its compositional stability over time should be provided.

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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"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.

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), 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, Reaction mass of [[(2-hydroxyethyl)imino]bis(methylene)]bisphosphonic acid and Phosphonic acid, P-[(tetrahydro-2-hydroxy-2-oxido-4H-1,4,2-oxazaphosphorin-4-yl)methyl]-
and its salts has a high potential to adsorb to soil (logKod = 1500 L/kg for linear constituent (22 °C) and logKod = 110 L/kg for cyclic constituent (22 °C)) and it is considered very persistent which is default setting for not readily biodegradable substances when a value of half life in soil is not available. Moreover, in the CSR under Section 4.1.3, you state: "*Adsorption data indicate that irreversible binding to substrate is expected to be the dominant process for removal of HEBMP from soil and sediment. HEBMP and its salts are therefore very unlikely to be persistent in the environment long-term*". Therefore ECHA considers that the column II adaptation, third indent of Annex IX, section 9.4 regarding long-term testing instead of short-term testing, is applicable to this registered substance.

According to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), for substances with high potential to adsorb in soil, where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, and there is no indication of the substance to be very toxic to aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach.

Currently there is not enough adequate 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 second indent 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.

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 e.g. the substance shows high adsorption

potential, as in this case, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

In your comments to the draft decision, you agree to perform the 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).

Notes for your consideration

As the OECD Testing Guidances 220 and 222 requires, the pH should be measured and reported at the beginning and the end of both the range finding test and the definitive test, in control and all treated soils. ECHA considers that for this specific case you should consider the dissociation properties and report dominant species in the pH of the test material.

ECHA notes that the results from the toxicity test(s) on aquatic invertebrates and algae requested under subsection (points 4 and 5) of the present Decision may allow the subsequent derivation of a PNECwater. Consequently, 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 3.0, June 2017), and determine the need for further testing on terrestrial organisms.

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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"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.

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), 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, Reaction mass of [[(2-hydroxyethyl)imino]bis(methylene)]bisphosphonic acid and Phosphonic acid, P-[(tetrahydro-2-hydroxy-2-oxido-4H-1,4,2-oxazaphosphorin-4-yl)methyl]- and its salts has a high potential to adsorb to soil ($logK_{od}$ = 1500 L/kg for linear constituent (22 °C) and logKod = 110 L/kg for cyclic constituent (22 °C)) and it is considered very persistent which is default setting for not readily biodegradable substances when value of half life in soil is not available. Moreover, in the CSR under Section 4.1.3, you state: "*Adsorption data indicate that irreversible binding to substrate is expected to be the dominant process for removal of HEBMP from soil and*

sediment. HEBMP and its salts are therefore very unlikely to be persistent in the environment long-term". Therefore ECHA considers that the column II adaptation for third indent of Annex IX, section 9.4 regarding long-term testing instead of short-term testing, is applicable to this substance.

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 second indent 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 to the draft decision,you agree that there is a data gap, and that you will perform the test if required by the re-evaluated PNEC and risk characterisation outcomes.

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).

Notes for your consideration

ECHA notes that the results from the toxicity test(s) on aquatic invertebrates and algae requested under subsection (points 4 and 5) of the present Decision may allow the subsequent derivation of a PNECwater. Consequently, 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.

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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"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 the information requirement for "effects on soil micro-organisms". You provided the following justification for the adaptation: *"In accordance with Column 2 of REACH Annex IX, the short-term toxicity test with terrestrial microorganisms (required in Section 9.4.2 of REACH Annex IX) does not need to be conducted as the chemical safety assessment according to Annex I indicates that this is not necessary. In addition, reliable evidence already exists that HEBMP-xNa does not cause inhibition (in the form of total respiration, heterotropic respiration, or nitrification), in aquatic microorganisms (activated sludge) at concentrations up to 1000 mg/l (800 mg/l as active acid equivalent)."*

ECHA notes that Column 2 of Annex IX Section 9.4. does not include the mentioned adaptation. Moreover, the microbial communities present in the activated sludge of a predominantly domestic sewage is deemed to be different from the microbial communities present in an aerobic surface field soil, and thus, the effects of the registered substance on these can also differ. Besides, according to the evidence presented within the registration dossier, exposure of the soil compartment is likely.

Therefore, your adaptation of the information requirement is rejected. 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 section R.7.11.3.1. of the above-mentioned guidance, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

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

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 24 July 2018.

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

In your comments you agreed to the draft decision. 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 adopted the decision under Article 51(3) of REACH.

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 requests in this decision, or to otherwise fulfil the information requirements 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 tests 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 tests 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 tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.