Decision number: TPE-D-2114310498-49-01/F Helsinki, 19 November 2015

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For bis(piperidinothiocarbonyl) hexasulphide, CAS No 971-15-3 (EC No 213-537-2), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for bis(piperidinothiocarbonyl) hexasulphide, CAS No 971-15-3 (EC No 213-537-2), submitted by [redacted] (Registrant).

- OECD Guideline 211 (*Daphnia magna* Reproduction Test);
- OECD Guideline 225 (Sediment-Water *Lumbriculus* Toxicity Test Using Spiked Sediment);
- OECD Guideline 222 (Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*));
- OECD Guideline 414 (Prenatal Developmental Toxicity Study) in rat via the oral route.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 8 July 2015, i.e. 30 calendar days after the end of the commenting period.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

ECHA received the registration dossier containing the above-mentioned testing proposals for further examination pursuant to Article 40(1) on 29 April 2013.

ECHA held two third party consultations:
- for the testing proposal for Prenatal Developmental Toxicity Study from 29 April 2014 until 13 June 2014 and did not receive information from third parties;
- for long-term toxicity testing on fish from 16 February 2015 until 2 April 2015 and received information from third party (see section III below).

On 30 April 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 8 June 2015 ECHA received comments from the Registrant on the draft decision.

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

On 3 September 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: Prenatal Development Toxicity Study, EU B.31/OECD 414) in rats or rabbits, oral route;
2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211);
3. Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222).

The Registrant shall carry out the following additional tests pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

4. Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2; test method: Terrestrial plants, growth test, OECD 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030);
5. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216);
6. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).

while the originally proposed test for a Long-term toxicity to sediment organisms (test method: Sediment-water *Lumbriculus* toxicity test using spiked sediment, OECD 225) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Note for consideration by the Registrant:

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

conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **27 November 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

A. Tests required pursuant to Article 40(3)

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has submitted a testing proposal for a pre-natal developmental toxicity study in rats according to OECD 414 to be performed with the registered substance with the following justification: *"No study is available to evaluate the toxicity of DPTH on the foetal development. A test plan (OECD 414) is proposed on rats."*

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

The Registrant proposed testing in rats. He proposed testing by the oral route. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit 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 rat or the rabbit as a first species to be used.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD 414).

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

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"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. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has submitted a testing proposal for testing for long-term toxicity testing on aquatic invertebrates *Daphnia magna* reproduction test, OECD 211 with the following justification: "*In accordance with column 2 of REACH Annex VII, the long-term aquatic toxicity study on Daphnia (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble. As the solubility of the substance was determined to be < 100 µg/L, no short-term toxicity testing on invertebrates is proposed for aquatic compartments. Therefore, it is proposed to perform a long-term aquatic toxicity study on Daphnia according to the OECD 211 guideline.*"

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. There is no information on the short-term toxicity of the substance to aquatic invertebrates and fish available in the registration dossier. Thus, there were no indications in the dossier that the fish would be substantially more or less sensitive than aquatic invertebrates.

Thus, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

Notes for consideration by the Registrant

Due to the low solubility of the substance in water OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances should be consulted by the Registrant for choosing the design of the requested long-term ecotoxicity test and for calculation and expression of the result of this test.

3., 4. and 5. Effects on terrestrial organisms (Annex IX, Section 9.4.)

Pursuant to Article 40(3)(a) and (c) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test and to carry out additional tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

The Registrant must address the standard information requirements set out in Annex IX, section 9.4., for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), and short-term toxicity testing on plants (Annex IX, section 9.4.3.). Column 2 of section 9.4 of Annex IX 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.
The information on the endpoint 'effects on terrestrial organisms' is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

a) Terrestrial Invertebrates (Annex IX, Section 9.4.1. and Column 2 of Annex IX, Section 9.4.)

The Registrant proposed a long-term toxicity test on terrestrial invertebrates (OECD Guideline 222 (Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*))), with the following justification: "*As the water solubility of dipentamethylene thiurame hexasulphide was determined to be < 100 µg/L, short-term toxicity tests on aquatic organisms have not been performed (except an algae study), and thus, no PNECfreshwater was derived. As a consequence, EPM method cannot apply and thus a toxicity test on soil organism is required in order to derive PNECsoil. Due to its high potential to adsorb to soil, a long-term toxicity test on macroorganisms is proposed.*"

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 has a high potential to adsorb to soil, as recognised by the Registrant in the justification of the proposed test, and is likely to be very persistent (default setting for not readily biodegradable substances when half-life in soil is missing), and therefore ECHA agrees that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX). The proposed test is suitable to address the information requirement of Annex IX, section 9.4.1.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222.

b) Terrestrial plants (Annex IX, Section 9.4.3. and Column 2 of Annex IX, Section 9.4.)

The proposed test that ECHA has accepted above can only address the information requirement of Annex IX, section 9.4.1. It is not sufficient by itself to address the standard information requirement of Annex IX, section 9.4.3. ECHA notes that the registration dossier does not contain data for this endpoint.

The Registrant proposed to adapt this standard information requirement by ommiting the testing with the following justification: "*In order to derive PNECsoil, a long-term toxicity test on macroorganisms is proposed. If RCR shows a risk, further terrestrial toxicity test will be proposed.*"

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. Consequently there is an information gap and it is necessary to provide information for the standard information requirement of Annex IX, Section 9.4.3.

ECHA considers based on the substance properties as discussed under subsection (a) above, that the substance has a high potential for adsorption and persistence. High adsorption potential and persistence of the substance indicates the need for long-term testing to be performed (Column 2 of Section 9.4. of Annex IX). At this tonnage level, according to column 2 the registrant shall consider long-term testing. No argument has been provided as to why long-term testing is not appropriate. Furthermore, ECHA *Guidance on information requirements and chemical safety assessment* Chapter R10, section R.10.6.2., (version May 2008) allows the potential application of a lower AF if information on additional long-term terrestrial toxicity test of two trophic levels were available. In contrast, the Guidance does not allow for a lower AF to be applied if information on a short-term study were to become available in addition to the long-term invertebrate study, which ECHA accepted under subsection (a) above. Therefore ECHA concludes that considering the properties of the substance only a long-term toxicity test on plants (and not the short-term) will provide the necessary useful information.

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. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out one of the following additional studies using the registered substance subject to the present decision: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

c) Effects on soil microorganisms (Annex IX, Section 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation. ECHA notes that the registration dossier does not contain data for this endpoint and that the proposed test that ECHA accepted under subsection (3.1)) above is not sufficient to address this standard information requirement.

The Registrant proposed to adapt this standard information requirement by ommiting the testibng with the following justification: "*In order to derive PNECsoil, a long-term toxicity test on macroorganisms is proposed. If RCR shows a risk, further terrestrial toxicity test will be proposed.*"

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, Sections 9.4.1. and 9.4.3. does not apply for the present endpoint.

Consequently there is an information gap and it is necessary to provide information for the standard information requirement of Annex IX, Section 9.4.3. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test (test method: EU C.21 or OECD 216).

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

d) Notes for consideration by the Registrant

ECHA notes that the Registrant has also proposed a toxicity test on aquatic invertebrates and the results of this test and of the long-term fish toxicity testing may subsequently allow the derivation of PNECwater. If the results of the these toxicity tests on aquatic invertebrates and fish allow the subsequent derivation of a PNECwater, the Registrant may consider the ITS as recommended in section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), and determine the need for further testing on terrestrial organisms. If he includes a justified proposal for adaptation of Annex IX, 9.4.3. in the registration dossier he will not be required to perform the toxicity test on plants.

In his comments according to Article 50(1) the Registrant explained that the substance "*falls therefore within the scheme as belonging to "Hazard category 3", which states that long-term toxicity testing has to be performed on both earthworm and soil microorganisms*" and indicated that if after completion of these two tests with earthworms and microorganisms CSA will indicate that there is some risk for the soil compartment, he will perform long-term toxicity testing with soil plants. ECHA considers that the Registrant's comment, in principle, confirms the note given in the paragraph cited above.

6. Fish, early-life stage (FELS) toxicity test (Annex IX, Section 9.1.6.1.)

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation.

"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. Besides, it is noted that Annex VIII Section 9.1.3. Column 2 of the REACH Regulation states that long term aquatic toxicity on fish shall be considered if the substance is poorly water soluble. ECHA notes that the water solubility of the registered substance is low (10.48 µg/L at 20°C). ECHA understands that the substance is poorly water soluble.

ECHA observes that long-term toxicity study with fish is waived noting that "*it is proposed to perform a long-term aquatic toxicity study on aquatic invertebrates according to the OECD 211 guideline in order to confirm lack of toxicity up to the water solubility limit*". ECHA notes that according to the *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b the Chemical Safety Assessment (CSA) is to be based on all available toxicity information, and that the information used for the derivation of the predicted no effect concentration (PNEC) for water should at least cover species of three trophic levels: algae/aquatic plants, invertebrates (*Daphnia* preferred), and fish. Furthermore, it is specified that if there is compelling evidence to suggest that the fish value is likely to be at least a factor of about 10 less sensitive than aquatic invertebrates or algae there are no further requirements for fish testing. However, as noted in the section III.2. above there is no indication in the dossier that the fish would be substantially (i.e. by at least a factor of 10) more or less sensitive than aquatic invertebrates or algae. Furthermore, ECHA notes that due to the low solubilty of the registered substance the short-term toxicity testing with fish would not be relevant and conclusive. Therefore, ECHA considers that it is necessary to provide information on long-term toxicity with fish and, consequently, there is an information gap for the long-term toxicity testing on fish (Annex IX, section 9.1.6. of the REACH Regulation).

In his comments according Article 50(1) the Registrant explained, referring to above cited ECHA *Guidance*, Chapter R7b, that "*long-term fish testing [is] not necessary, if PEC/PNEC <1 based on the Daphnia long-term result and AF 50*". Therefore, the Registrant concluded that if after completion of long-term toxicity test with *Daphnia* "*the Chemical Safety Assessment indicates that there is some risk for the aquatic compartment by applying an assessment factor (AF) of 50 (RCR > 1) – or if no PNECwater can be derived – then a long-term toxicity testing on fish shall be proposed to ECHA in a further test plan*".

ECHA notes that there is no information either on short-term fish toxicity or on long-term fish toxicity available in the dossier, which are both standard information requirements and the information needs to be present in the registration dossier, unless a specific adaptation according to column 2 or general adaptation according to Annex XI applies. However, as noted above, for the CSA information on pelagic toxicity should at least cover species of three trophic levels (including fish). Thus, CSA is not possible without information on toxicity of the substance to fish and consequently this information shall be provided in the registration dossier.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6., ECHA considers that the FELS toxicity test according to OECD 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b, Figure R.7.8-4). The test method OECD 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 2.0, November 2014). For these reasons, ECHA considers the FELS toxicity test using the test method OECD 210 as appropriate and suitable.

ECHA received third party information concerning the long-term fish toxicity testing during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

The third party has indicated that "*with respect to physicochemical properties (water solubility 10.48 µg/L, predicted log Pow 4.43) the substance was classified as non-B/non-vB by the registrant. The chemical safety assessment taking into account mitigating factors as insolubility in water and also the outcome of the proposed long-term toxicity assay in aquatic invertebrates may deserve as a basis to decide if long-term toxicity testing in fish can be waived.*" As noted above, ECHA concludes that there is an information gap for the long-term toxicity testing on fish and information on the toxicity of the substance to fish is necessary to enable derivation of PNEC for water compartment.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the additional study using the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).

Notes for consideration by the Registrant

Due to the low solubility of the substance in water OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances should be consulted by the Registrant for choosing the design of the requested long-term ecotoxicity test and for calculation and expression of the result of this test.

7. Long-term toxicity testing on sediment organisms (Annex X, Section 9.5.1.)

Pursuant to Article 40(3)(d) of the REACH Regulation, ECHA may reject a proposed test.

"Long-term toxicity to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. of the REACH Regulation.

The Registrant has submitted a testing proposal for testing for long-term toxicity testing on sediment organisms Sediment-water *Lumbriculus* toxicity test using spiked sediment, OECD 225. Although the current registration dossier concerns a substance manufactured in quantities of 100 to 1000 tonnes per year, the Registrant has indicated a need to generate this information with the following justification: *"As the water solubility of dipentamethylene thiurame hexasulphide was determined to be < 100 µg/L, short-term toxicity tests on aquatic organisms have not been performed (except an algae study), and thus, no PNECfreshwater was derived. As a consequence, EPM method cannot apply and thus a toxicity test on sediment organism is required in order to derive PNECsediment."*

According to the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b, (Section R.7.8.10) a sediment assessment may be needed even at tonnages below 1000 t/y for substances that are highly hydrophobic (Log Pow >5). ECHA notes that the Registrant disregarded (claimed as not reliable) results of an experimental study performed according to OECD Guideline 117 (Partition Coefficient (n-octanol / water), HPLC Method). However, ECHA notes that according to the OECD Guideline 117 *"It is up to the user to select the appropriate reference substances. The reference substances should normally have log Pow values which encompass the log Pow of the test substance, i.e. at least one reference substance should have a Pow above that of the test substance, and another a Pow below that of the test substance. Extrapolation should only be used in exceptional cases. It is preferable that these reference substances should be structurally related to the test substance. [...] If data on the partition coefficients of structurally related substances are not available, a more general calibration, established with other reference substances, may be used."* Therefore, ECHA notes that the use of a structurally related reference substance for calibration is not mandatory. Therefore, ECHA considers that the results of the study performed according to OECD Guideline 117 (i.e. Log Pow of 6.2 at 20 °C), if the principles of the Guideline are otherwise followed, should be reliable and acceptable for the chemical safety assessment.

Bearing in mind that, as indicated in the Registrant's justification of the testing proposal submitted, there is a need for information on long-term sediment toxicity for the predicted no effect concentration (PNEC) for sediment determination and considering that, according to Article 12(1) of the REACH Regulation, the information required in the Annexes are minimum information requirements, ECHA agrees that long-term sediment testing is indicated for the registered substance with a high potential to adsorb to sediment.

However, in his comments according to Article 50(1) the Registrant explained that *"the aquatic toxicity testing on Daphnia may allow deriving PNECwater that will be used for PNECsediment estimation and risk assessment"* and *"if after completion of the aquatic pelagic studies, the Chemical Safety Assessment indicates that there is some risk for the sediment compartment by applying the equilibrium partitioning method (RCR>1), then a long-term toxicity testing on sediment organism shall be proposed to ECHA in a further test plan."*
ECHA observes that in the comment provided the Registrant refers to the application of integrated testing strategy for the sediment toxicity endpoint, which overrules the Registrant's earlier argument provided to justify submitted testing proposal. Therefore, ECHA considers that there appears to be no longer a trigger for the Annex X, 9.5.1. study which is not tailored for the real information needs at this tonnage level.

Therefore, pursuant to Article 40(3)(d) of the REACH Regulation, the suggested study for a Long-term toxicity to sediment organisms (test method: Sediment-water *Lumbriculus* toxicity test using spiked sediment, OECD 225) is rejected as not tailored to real information needs for the registered substance subject to the present decision.

Notes for consideration by the Registrant

Once results of the requested tests on long-term toxicity to aquatic organisms are available, the Registrant 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 sediment organisms, the Registrant shall submit a testing proposal for a long-term toxicity test on sediment organisms.

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed tests, 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 of the same substance to agree to the tests proposed (as applicable to their tonnage level) 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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the 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.

Authorised1 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.