Decision number: TPE-D-2114322663-54-01/F Helsinki, 20 April 2016

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

For Octadecanoic acid, 12-hydroxy-, reaction products with ethylenediamine, CAS No 100545-48-0 (EC No 309-629-8), 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 Octadecanoic acid, 12-hydroxy-, reaction products with ethylenediamine, CAS No 100545-48-0 (EC No 309-629-8, submitted by [redacted] (Registrant).

- 90-day inhalation toxicity study (OECD 413);
- Pre-natal development study (OECD 414);
- *Daphnia magna* reproduction test (OECD 211);
- Sediment-water *Lumbriculus* toxicity test using spiked sediment (OECD 225);
- Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD 222).

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 25 April 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 17 May 2013.

ECHA held a third party consultation for the testing proposals from 16 May 2014 until 30 June 2014. ECHA did not receive information from third parties.

On 17 February 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. That draft decision was based on submission number [redacted].

On 19 March 2015 ECHA received comments from the Registrant on the draft decision agreeing to ECHA's draft decision for information requests; Sub-chronic toxicity study (90-day), inhalation route; Pre-natal developmental toxicity study; Long-term toxicity testing on aquatic invertebrates: *Daphnia magna* reproduction test; Long-term toxicity to sediment organisms: Sediment-water *Lumbriculus* toxicity test using spiked sediment; Long-term toxicity on terrestrial invertebrates: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) but disagreeing to the information requests; Long-term toxicity testing on plants: Terrestrial plants, growth test 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; Effects on soil micro-organisms: Soil microorganisms: nitrogen transformation test.

On 21 April 2015 the Registrant updated his registration dossier (new submission number [redacted]).

The ECHA Secretariat considered the Registrant's comments and update dossier. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 21 January 2061 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. Sub-chronic toxicity study (90-day), inhalation route (Annex IX, Section 8.6.2.; test method: OECD 413) in rats;
2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route;
3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211);
4. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.; test method: Sediment-water Lumbriculus toxicity test using spiked sediment, OECD 225);
5. Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; 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) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

6. 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);

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

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 April 2018** 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. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

a) Examination of the testing proposal

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

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. 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 sub-chronic toxicity study (90 day) via inhalation (OECD 413).

ECHA considers that the proposed study via inhalation is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation. The proposed route has been considered as follows.

In the IUCLID file and/or CSR the registered substance is indicated to be used as a dust. Information provided on granulometry indicates that the substance includes particles of inhalable size. Consequently, inhalation exposure of humans to particles of inhalable size is likely.

Furthermore, the information provided in the IUCLID file and the CSR indicates inhalation exposure to workers, professionals and consumers. For instance, in section 9.5.2.2 of the CSR, PROC 11 results for professionals in a maximum exposure estimate of [redacted] mg/m^3.

In addition, there is potential concern for local effects on the respiratory tract following inhalation exposure:

1. the substance is of low water solubility (0.0439 mg/L) and consequently there is a potential for accumulation of the substance in the lungs; *and*
2. the inhalation dose range finding study performed in rats showed effects in the respiratory tract already at the lowest test dose while the oral study showed no effect up to the limit dose.

Therefore, ECHA regards the conditions of Annex IX, Section 8.6.2., column 2 concerning the appropriateness of the inhalation route to be met for the registered substance. The inhalation route is considered as the most appropriate route of administration for testing.

The Registrant did not specify the species to be used for testing. According to the test method OECD 413 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

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: Sub-chronic toxicity study (90-day) in rats, inhalation route (test method: OECD 413).

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

a) Examination of the testing proposal

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 according to EU OECD 414.

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 did not specify the species to be used for testing. [He did not specify the route for testing. 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)

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

a) Examination of the testing proposal

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 the registered substance for long-term toxicity testing on aquatic invertebrates *Daphnia magna* reproduction test, OECD 211 with the following justification: "*No effects being observed at the water solubility limit and at the highest loading rate tested for all of the three trophic levels (fish, aquatic invertebrates and algae) in tests of Annex VII and VIII, no aquatic PNEC were derived. Therefore, a long-term toxicity test to aquatic invertebrates was proposed to be carried out according to OECD testing guideline 211.*" 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 1.2., November 2012), 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 were no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than aquatic invertebrates (absence of toxicity in the short-term aquatic toxicity studies using water accommodated fractions).
In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, long-term fish testing may need to be conducted.

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: 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

Once results of the proposed test on long-term toxicity to aquatic invertebrates 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 aquatic organisms, the Registrant 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 the Registrant comes to the conclusion that no further investigation of effects on aquatic organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

Due to the low solubility of the substance in water and the fact that the substance is a UVCB substance and might contain residual amines, the 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 tests and for calculation and expression of the result of this test.

b) Outcome

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

4. Long-term toxicity testing on sediment organisms

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the 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. Nevertheless, according to Article 12(1) of and Annex VI to the REACH Regulation, its Annexes VI to XI stipulate minimum information requirements, and for each registration the precise information requirements will differ under consideration of the Annexes as a whole and the overall requirements of registration, evaluation and duty of care.

The Registrant has submitted a testing proposal for testing the registered substance 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 – 1000 tonnes per year, the Registrant has indicated a need to generate this information with the following justification: *"No effects being observed at the water solubility limit and at the highest loading rate tested for all of the three trophic levels (fish, aquatic invertebrates and algae) in tests of Annex VII and VIII, no aquatic PNEC were derived. Thus no PNEC for sediment can be derived according to the Equilibrium Partitioning Method. Therefore, a long-term toxicity test to sediment invertebrate (Lumbriculus) was proposed to be carried out according to OECD testing guideline 225."*

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b, (Section R.7.8.10) sediment assessment may be needed even at tonnages below 1000 t/y for substances that are highly hydrophobic (Log Kow >5).

Considering that, according to Article 12(1) of the REACH Regulation, the information required in the Annexes are minimum information requirements, ECHA therefore agrees that long-term sediment testing is indicated for the registered substance with a high potential to adsorb to sediment.

ECHA considers that the proposed study is appropriate to further investigate long-term toxicity to sediment organisms.

b) Outcome

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

5-7. Effects on terrestrial organisms

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.

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

The Registrant proposed a long-term toxicity test on terrestrial invertebrates (OECD 222), with the following justification: "*In accordance with column 2 of REACH Annex IX in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. As the substance was not shown to be non-persistent, the Log Kow > 5 and there is no indication that the substance is very toxic (EC/LC50 <1 mg/L for algae, daphnia or fish), the substance belongs according to REACH Guidance R.7C Table R.7.11-2 to soil hazard category 3.*
Therefore, a long-term toxicity test (reproduction) with soil macro-invertebrate (earthworm, OECD testing guideline 222) was proposed to be carried out.".

According to 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), 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 (logK_{ow} 11.3-18.6) and is likely to be very persistent which is default setting for not readily biodegradable substances, when value of the half-life in soil is not available 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.

Outcome

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.

6) Terrestrial plants (Annex IX, 9.4.3.) Long-term toxicity testing on plants (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 as follows: "*In accordance with column 2 of REACH Annex IX in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. As the substance was not shown to be non-persistent, the Log Kow > 5 and there is no indication that the substance is very toxic (EC/LC50 <1 mg/L for algae, daphnia or fish), the substance belongs according to REACH Guidance R.7C Table R.7.11-2 to soil hazard category 3.*
Therefore, a long-term toxicity test (reproduction) with soil macro-invertebrate (earthworm, OECD testing guideline 222) was proposed to be carried out. Therefore, no test to assess the toxicity on terrestrial plants was 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. Furthermore, the correct soil hazard class cannot be determined at this stage, due to a lack of observed effects in the short-term aquatic studies.

In the comments to the draft decision, the Registrant argued that the substance should be assigned a soil hazard category 3 on the basis of absence of toxicity to fish, aquatic invertebrates and algae in short term studies performed with the registered substance. ECHA considers that given the substance properties (very high logKow, low water solubility, limited biodegradability) short-term aquatic studies are not sufficient to conclude on the toxicity of the registered substance.

Therefore the soil hazard class of the registered substance cannot yet be determined and ECHA considers consequently Table 7.11-2 (section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment*, version 2.0, November 2014) cannot be used to adapt the standard information requirements.

Furthermore, the Registrant claimed that the registered substance, being a highly insoluble powder, would not be bioavailable through (pore) water to plants and microorganisms, that ingestion would be deemed to be the major pathway of exposure, and consequently only earthworms should be tested. ECHA notes that, although the registered substance indeed has a very high logKow and a low water solubility, and ingestion might be the most relevant exposure route, the substance has been shown to degrade to some extent. The degradation products of the registered substance are likely to have a higher water solubility and lower logKow. The registrant has not provided evidence that such biodegradation products cannot exert effects mainly through (pore) water. ECHA also notes that no further information on the biodegradation products is available in the registration dossier. Therefore, ECHA maintains that all three terrestrial trophic levels should be tested, under the conditions explained below for point 7 of the Effects on terrestrial organisms under "notes for consideration by the Registrant".

By proposing a long-term toxicity test (accepted by ECHA under subsection (5) above), ECHA considers that the Registrant has concluded on the need for long-term toxicity testing to be performed instead of short-term, on the basis that the substance meets the column 2 adaptation criteria of Annex IX, section 9.4. On this basis, ECHA considers that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX). Moreover, section R.10.6.2., Chapter R10 of the abovementioned Guidance 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 (b) above.

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.

Outcome

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).

7) Effects on soil microorganisms (Annex IX, 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 (5) above is 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 (test method: EU C.21 or OECD 216).

In the comments to the draft decision, the Registrant argued that the OECD 301 study has shown that the substance is not bioavailable. ECHA, on the contrary, concludes that the OECD 301 study clearly shows that the substance was bioavailable under the conditions tested as degradation ([redacted]% after 28 days, [redacted]% after 60 days) has been observed. The observed degradation occurred in conditions that should enhance bioavailability (addition of Tween 85 and silicone oil), and no information is available in the registration dossier on the bioavailability of the substance without such additions.

Additionally, the registrant claims that toxicity data on (aquatic) micro-organisms from the registered substance and similar substances can be used to prove a lack of toxicity to soil micro-organisms. To this purpose, the Registrant has provided in the comments to the draft decision, and as attachment to the IUCLID dossier, a table containing data for the toxicity to microorganisms of other highly insoluble UVCBs based on 12-HAS chemistry which in the Registrant's opinion would confirm that these substances are not toxic to microorganisms.

ECHA notes that in the registration dossier there is no hypothesis and justification establishing a basis whereby eco-toxicological properties of the registered substance may be predicted from data for the analogue substances provided by the Registrant in the table. In the absence of any justification supporting the proposed grouping/read-across approach, ECHA considers that the Registrant has failed to provide an adequate and reliable documentation of the applied method as required by Annex XI, Section 1.5 of the REACH Regulation. Therefore, ECHA is not in a position to conclude on the proposed read-across approach which could allow establishing that relevant properties of the registered substance can be predicted from those of the analogue substances. The proposed read-across has therefore to be rejected as not acceptable.

Finally, the registrant claims that in analogy with Annex VIII, 9.1.4, column 2, high water insolubility can be used as an adaptation for the endpoint of Annex IX, 9.4.2, effects on micro-organisms. ECHA concludes that:

- Annex IX, 9.4.2 does not contain an adaptation possibility based on water solubility
- Microbial communities in water and soil cannot easily be compared: micro-organisms in soil have different strategies and the occurrence in biofilms does not preclude exposure or toxicity from (highly) hydrophobic substances.
- As explained above, it is clear from the OECD 301 experiment that the current substance can be available to microbial communities, at least when measures are taken to increase bioavailability.

Outcome

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).

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 may subsequently allow the derivation of PNECwater. If the results of the proposed toxicity test on aquatic invertebrates 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 1.1, November 2012), 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.

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 9.4.3. does not apply for the present endpoint.

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 has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

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.

Authorised by Ofelia Bercaru, Head of Unit, Evaluation E3