Decision number: TPE-D-2114346840-50-01/F Helsinki, 25 October 2016

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

**For 2-ethylhexyl benzoate, CAS No 5444-75-7 (EC No 226-641-8), 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 2-ethylhexyl benzoate, CAS No 5444-75-7 (EC No 226-641-8, submitted by [redacted] (Registrant).

- Long-term toxicity testing on aquatic invertebrates (EU C.20/OECD TG 211);
- Short-term toxicity on terrestrial invertebrates (OECD TG 207);
- 90-day oral toxicity study (OECD 408) in rats, oral route, including additional reproduction parameters;
- Developmental toxicity / teratogenicity study (OECD 414).

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 11 January 2016, 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 27 March 2013.

ECHA held a third party consultation for the testing proposals from 2 June 2014 until 17 July 2014. ECHA received information from third parties (see section III below).

On 4 November 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 7 December 2015 ECHA received comments from the Registrant agreeing to ECHA's draft decision on performing the long-term toxicity testing on aquatic invertebrates and long-term toxicity to terrestrial invertebrates. In addition in his comment's, the Registrant challenged the need for long-term toxicity testing on terrestrial plants and effects on soil micro-organisms.

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

On 8 September 2016 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

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

2. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408) in rats;

   This study shall be conducted for the provision of information as specified in Annex IX, Section 8.6.2 only and may not serve to cover the information requirement of Annex IX/X, Section 8.7.3. while it is at the Registrant's discretion to perform the intended additional examinations during the testing program.

3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route.

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 to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test OECD 220), while the originally proposed test for terrestrial invertebrates (test method OECD 207) is rejected pursuant to Article 40 (3) (d) of the REACH Regulation;

5. Long-term toxicity testing on plants (Annex IX, Section 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 Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030);

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

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above terrestrial studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the terrestrial PNEC.

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

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 **1 November 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 and scientific information submitted by third parties.

A. Tests required pursuant to Article 40(3)

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

"*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, EU C.20/OECD 211 with the following justification: *"No experimental data on long-term toxicity to aquatic invertebrates are available for 2-ethylhexyl benzoate (CAS 5444-75-7). In order to fulfil the data requirements as presented in Regulation (EC) No 1907/2006, Annex IX, an OECD 211 test (chronic toxicity to Daphnia magna) is proposed for 2-ethylhexyl benzoate"*. 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 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.

In such a 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.

In your comments on the draft decision you agree to *perform a "long-term toxicity test with aquatic invertebrates according to OECD 211"*

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 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.

2) Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408)

a) Examination of the testing proposal in relation to Annex IX, Section 8.6.2.

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) in rats via the oral route (EU B.26/OECD 408) to be performed with the registered substance. Based on the information provided in the technical dossier and in the chemical safety report, ECHA agrees that the oral route - which is the preferred one as indicated in ECHA Guidance on information requirements and chemical safety assessment (version 4.0, July 2015) 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 may occur, there is no concern for severe local effects following inhalation exposure. Furthermore, ECHA points out that no repeated dose toxicity study by the oral route is available. ECHA agrees that the oral route is the most appropriate route of administration for testing.

The Registrant proposed testing in rats. According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

The Registrant proposed to extend the sub-chronic toxicity study (90 day) by including additional reproductive parameters. The Registrant did not further specify the parameters. ECHA notes, that it is at the Registrant's discretion to perform the intended additional examinations during the testing program and use the results to ensure the safe use of the substance. However, the Registrant is reminded that, if a 28-day study or the 90-day study will indicate adverse effects on reproductive organs or tissues, the proposed extension of the study presently requested does not fulfil the standard information requirement in the registration dossier for reproductive toxicity set out in Annex IX, Section 8.7.3.

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 (90-day) study in rats, oral route (test method: EU B.26/OECD 408).

b) Examination of the testing proposal in relation to Annex IX/X, Section 8.7.3.

The Registrant has submitted the testing proposal for the 90-day repeated-dose study with reproductive parameters in order to cover the standard information requirement of Annex IX, 8.7.3. in addition to the requirement for Annex IX, 8.6.2 of the REACH Regulation.

According to Annex IX, Section 8.7.3., an extended one-generation reproductive toxicity study is an information requirement if adverse effects on reproductive organs or tissues have been observed in the available repeated dose toxicity studies (e.g. a 28-day or 90-day repeated dose toxicity study, OECD 421 or 422 screening studies) or if they reveal other concerns in relation with reproductive toxicity.

ECHA notes that there is no 28-day or 90-day repeated dose toxicity study or OECD 421 or 422 screening study available in the registration dossier, while the Registrant has proposed to perform a 90-day study with reproductive parameters. ECHA considers that therefore a test covering the standard information requirement of Annex IX, 8.7.3 is at this stage not required, because no repeated dose toxicity or reproductive toxicity screening study is currently available to evaluate if performance of an extended one-generation reproductive toxicity study is required at that tonnage level.

Once the results from the sub-chronic toxicity study are available, the Registrant should reconsider the information requirement of Annex IX, Section 8.7.3. If the sub-chronic toxicity study indicates adverse effects on reproductive organs or tissues or if it reveals other concerns in relation with reproductive toxicity a new testing proposal for this endpoint would – in accordance with the REACH Regulation – have to be submitted, unless the adaptation of this information requirement is scientifically justified and documented in accordance with one of the specific or general rules of adaptation.

c) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation.

A third party has indicated that the tonnage level of the registered substance only requires the conduct of a reproduction toxicity study if the 28-day or 90-day study indicates adverse effects on reproductive organs or tissues.

As already stated under section III.2.b above, ECHA notes that according to Annex IX, Section 8.7.3., an extended one-generation reproductive toxicity study is an information requirement if adverse effects on reproductive organs or tissues have been observed in the available repeated dose toxicity studies (e.g. a 28-day or 90-day repeated dose toxicity study, OECD 421 or 422 screening studies) or if they reveal other concerns in relation with reproductive toxicity. For the substance subject to the present decision there is no repeated dose toxicity study available in the registration dossier that could trigger a reproductive toxicity study in accordance with Annex IX, Section 8.7.3.

d) Outcome

For the above reasons the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity (90-day) study in rats, oral route (test method: EU B.26/OECD 408). It is at the Registrant's discretion to perform the intended additional examinations during the testing program. This study shall be conducted for the provision of information as specified in Annex IX, Section 8.6.2 only and may not serve to cover the information requirement of Annex IX/X, Section 8.7.3.

3) Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route.

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 B.31/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 proposed rat as the species to be used for testing. 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).

**4 - 6 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: short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), effects on soil micro-organisms (Annex IX, section 9.4.2.), and short-term toxicity testing on plants (Annex IX, section 9.4.3.). Furthermore, 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.

4) Terrestrial Invertebrates (Annex IX, 9.4.1.)

The Registrant proposed a short-term toxicity test on terrestrial invertebrates (OECD 207), with the following justification: "No experimental data evaluating the toxicity to soil macroorganisms is available for 2-ethylhexyl benzoate (CAS No. 5444-75-4).

Only negligible releases into surface waters from sewage treatment plants are expected to take place due to: a) the ready biodegradability and b) the high adsorption properties of this substance, resulting in an effective removal in sewage treatment plants. Consequently indirect exposure to soil is of no concern. If direct exposure takes place, the substance will again be rapidly degraded until ultimate biodegradation. Therefore, chronic exposure of soil organisms is unlikely. Furthermore, the substance is not toxic to aquatic organisms up to the limit of water solubility. Based on the available information, toxicity to soil macroorganisms is not expected to be of concern. Nevertheless, in order to fulfill the data requirements as presented in Regulation (EC) No 1907/2006, Annex IX, an OECD 207 test (acute toxicity to earthworm) is proposed for 2-ethylhexyl benzoate."

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. ECHA notes that, according to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (log$K_{ow}$ 6.21) and therefore meets the specific adaptation rule for long-term toxicity testing (instead of short-term) according to Annex IX, section 9.4, column 2. Therefore, considering the properties of the substance, ECHA concludes that only a long-term toxicity test on invertebrates (and not the short-term) will provide the necessary useful information.

The earthworm reproduction test (OECD 222) and Enchytraeid reproduction test (OECD 220) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

In your comments on the draft decision you state "*ECHA notes that, according to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (log Kow: 6.21) and therefore meets the specific adaptation rule for long-term toxicity testing (instead of short-term) according to Annex IX, section 9.4, column 2. Thus, the registrant agrees to perform a long-term toxicity study with terrestrial invertebrates according to OECD 222*".
In addition you also state "*The registrant will conduct a long-term aquatic invertebrate test according to OECD 211 as it was proposed in the registration dossier and agreed by ECHA. This study will be used for derivation of PNEC soil using EPM. Moreover, the registrant will perform a chronic study with terrestrial invertebrates according to OECD 222 to take into account the high adsorption potential of the substance. The PNEC soil will be derived from the new chronic study with terrestrial invertebrates using an appropriate and justified assessment factor. The subsequent risk assessment will be performed and documented within in updated CSR.....*".

ECHA notes according to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach. Then, the Registrant can consider that an accurate allocation of an appropriate soil hazard category according to table R7.11-2, of the abovementioned guidance, is possible. Consequently, it may be possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4.

Also, in additon concerning species selection, you state in your comments on the draft decision "*In addition no acute toxic effects were observed in the reported aquatic studies. According to ECHA Guidance on information requirements and chemical safety assessment R.7c section R.7.11.5.3, page 135/136, one single short-term test on a suitable species would be adequate to meet the requirements of Annex IX, where there is no toxicity in the standard acute toxicity tests and the substance is highly adsorptive (log Kow > 5; ECHA, 2014b). In the absence of a clear indication of selective toxicity, an invertebrate (earthworm or collembolan) test is preferred, as outlined in ECHA guidance section R.7.11.5.3, page 136 (ECHA, 2014b). Therefore, based on the reasons stated above carrying out the long-term toxicity test on terrestrial invertebrates is adequate for the assessment of terrestrial toxicity. The OECD 222 study is one of the best established methods for testing of chemicals in the terrestrial environment. Earthworms cover all three possible routes of uptake in the soil (uptake via surface contact, ingestion of soil particles as well as via pore water). For strongly binding substances like 2-ethylhexyl benzoate preference should be given to test systems and test organisms that cover the exposure via ingestion or strong soil particle contact (ECHA, 2014b). Thus, earthworms are the most suitable test species since they would be highly exposed to toxicants in soil and hence are sensitive to the potential adverse effects of the substance".*

ECHA considers both the earthworm reproduction test (OECD 222) and Enchytraeid reproduction test (OECD 220) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA acknowledges your indicated species selection and your reasoning to undertake testing on the earthworm reproduction testing, initially. However, both OECD guidlelines are still provided as options in the draft decision.

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: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222, or Enchytraeid reproduction test (OECD 220), while the short-term toxicity test on terrestrial invertebrates (OECD 207) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

5) Terrestrial Plants (Annex IX, 9.4.3.)

The test required by ECHA under subsection 4 above 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 "Only negligible releases into surface waters from sewage treatment plants are expected to take place due to: a) the ready biodegradability and b) the high adsorption properties of this substance, resulting in an effective removal in sewage treatment plants. Consequently indirect exposure to soil is of no concern. If direct exposure takes place, the substance will again be rapidly degraded until ultimate biodegradation. Therefore, chronic exposure of soil organisms is unlikely. Furthermore, the substance is not toxic to aquatic organisms up to the limit of water solubility. Based on the available information, toxicity to terrestrial plants is not expected to be of concern." The Registrant proposed adaptation to standard information requirement based on negligible indirect exposure and direct exposure based on rapid degradation. However, the Registrant has reported wide dispersive professional and consumer uses for the substance and therefore adaptation based on negligible direct and indirect exposure of soil compartment is not possible.

According to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach.

However, ECHA notes that the Registrant has proposed to test the long-term toxicity to aquatic invertebrates (section III. A.1 of the present Decision) and that the results of this proposed test may lead to a revision of the currently derived PNECaquatic. Therefore, ECHA considers that accurate allocation of an appropriate soil hazard category according to table R7.11-2, of the abovementioned guidance, is not possible at this time. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4. Since a screening assessment for terrestrial organisms is not possible, testing for effects on all terrestrial organisms indicated in section 9.4 of Annex IX is considered necessary.

Based on the substance properties as discussed under subsection 4 above, ECHA considers that the substance has a high potential to adsorb to soil ($logK_{ow}$ 6.21). According to Annex IX, section 9.4, column 2, high absorbance potential or persistence of the substance requires adaptation to long-term toxicity testing instead of short-term. No argument has been provided in the dossier as to why, despite the substance's potential to adsorb, long-term testing is not appropriate. Therefore ECHA concludes that only a long-term toxicity test on plants (and not the short-term) will provide the necessary useful information. 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 assessment factor (AF) if information on an 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.

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 and testing shall be conducted, as a minimum with two monocotyledonous species and four dicotyledonous species. The Registrant should consider if testing on additional species is required to cover the information requirement.

ECHA notes, in summary, in your detailed comments on the draft decision the following:

- You agree to perform a chronic toxicity test with terrestrial invertebrates and a chronic study with aquatic invertebrates according to OECD 211 will be performed in order to derive a PNECaquatic and apply the EPM to calculate a PNECsoil screen (if effects are visible within the new OECD 211 study) to update.

- You agree to revise the Chemical Safety Assessment for the terrestrial compartment on the outcome of the long term aquatic invertebrate study as it is accepted that effect concentrations from chronic studies are generally lower compared to acute studies and/or screening calculations like EPM based on aquatic data (ECB, 2003). Therefore, it is considered appropriate that the result from one chronic test applying adequate assessment factors is more reliable, robust and sensitive for a derivation of the PNECsoil compared to the assessment using the PNECsoil derived by EPM.

- You agree to critically evaluate both the PNEC and PEC values as soon as the result of the chronic study with terrestrial invertebrates is available. It will be further demonstrated that the PEC/PNECsoil is < 1, i.e. no indication of risk from the confirmatory long-term soil toxicity testing with terrestrial invertebrates. In conclusion no additional study with terrestrial plants is considered necessary at this time. If the revised Chemical Safety Assessment indicates a risk for terrestrial organisms further testing with terrestrial organisms might become relevant and will be proposed to the agency accordingly. However, the proposed integrated testing strategy is justified and in accordance with Regulation (EC) No 1907/2006.

- In addition no acute toxic effects were observed in the reported aquatic studies. According to ECHA Guidance on information requirements and chemical safety assessment R.7c section R.7.11.5.3, page 135/136, one single short-term test on a suitable species would be adequate to meet the requirements of Annex IX, where there is no toxicity in the standard acute toxicity tests and the substance is highly adsorptive (log Kow > 5; ECHA, 2014b). In the absence of a clear indication of selective toxicity, an invertebrate (earthworm or collembolan) test is preferred, as outlined in ECHA guidance section R.7.11.5.3, page 136 (ECHA, 2014b). Therefore, based on the reasons stated above carrying out the long-term toxicity test on terrestrial invertebrates is adequate for the assessment of terrestrial toxicity. The OECD 222 study is one of the best established methods for testing of chemicals in the terrestrial environment. Earthworms cover all three possible routes of uptake in the soil (uptake via surface contact, ingestion of soil particles as well as via pore water). For strongly binding substances like 2-ethylhexyl benzoate preference should be given to test systems and test organisms that cover the exposure via ingestion or strong soil particle contact (ECHA, 2014b). Thus, earthworms are the most suitable test species since they would be highly exposed to toxicants in soil and hence are sensitive to the potential adverse effects of the substance. Testing with terrestrial plants only covers one route of exposure (see Table R.7.11-1; ECHA, 2014b). The main exposure route of terrestrial plants to toxicants in soil is the root uptake of pore water. Since 2-ethylhexyl benzoate is characterised by a very low water solubility (0.4 mg/L at 20 °C, pH: 6.8-7.6; EU Method A.6, column elution method) the uptake via soil pore water is negligible and already covered with the chronic study with terrestrial invertebrates.

ECHA acknowledges your agreement to perform the Long-term toxicity testing on aquatic invertebrates OECD 211. Also, you preferred Earthworm reproduction testing using the OECD 222, and also in accordance to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, to use this PNEC in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach, considering an accurate allocation of an appropriate soil hazard category according to table R7.11-2, of the abovementioned guidance, is possible, to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4.

In the current dossier or in the provided comments on the draft decision, there is no available long term aquatic testing or long term terrestrial invertebrate testing. Thus, currently, it is not possible to allocate the substance to a soil hazard category and to adapt some of the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4. Since a screening assessment for terrestrial organisms is not possible, testing for effects on all terrestrial organisms indicated in section 9.4 of Annex IX is considered necessary, this includes Terrestrial plants, section 9.4.3.

As indicated in the notes for consideration by the Registrant stated below in the draft decision, ECHA notes that if the results of the proposed test on long-term toxicity to 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 2.0, November 2014), and determine the need for further testing on terrestrial organisms.

Also, following the completion of the preferred Earthworm reproduction testing using the OECD 222, you may adapt the terrestrial plant 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. Any adaptation will be evaluated by ECHA at the follow-up stage. However, if it is not possible to adapt the terrestrial plant testing requested, the testing request will need to be fulfilled as per this decision.

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).

6) 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 test required by ECHA under subsection 4 above is not sufficient to address the standard information requirement of Annex IX, section 9.4.2. 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 your comments on the draft decision, you state "*The registrant does not see the need to further test the effects on soil microorganisms. Reliable data including a biodegradation study and an activated sludge respiration inhibition study provide enough evidence that the substance is of low toxicity to microorganisms. One reliable biodegradation study according to OECD 301B with 2-ethylhexyl benzoate (CAS No. 5444-75-7) is available indicating no inhibition of degradation of the test substance. The test substance was degraded to 76.5% (CO2 evolution) after 28 d fulfilling the 10-day window using non-adapted domestic activated sludge as inoculum. Thus, the test substance is readily biodegradable according to the OECD criteria.*

*The ECHA Guidance on information requirements and chemical safety assessment R.7b section R.7.8.16.1, page 158 states that once a compound degrades well in a ready biodegradability test, this concentration can be used as a NOEC value (ECHA, 2014a). Since this is the case for 2-ethylhexyl benzoate the NOEC can be derived to be ≥ 10 mg C/L.*

*An additional study with activated sludge microorganisms according to OECD 209 confirms the absence of effects to microorganisms. In this study three concentrations up to 100 mg/L were tested and the respiration rate of activated sludge of a predominantly domestic sewage was measured. No effects were recorded after 3 h resulting in an EC50 (3 h) of > 100 mg/L. According to ECHA Guidance on information requirements and chemical safety assessment R.7c section R.7.11.5.3, page 136 a test on soil microbial activity will only be additionally necessary for a valid PNEC derivation if inhibition of sewage sludge microbial activity occurred (ECHA, 2014b). This is clearly not the case.*
*Based on the arguments discussed, the registrant does not consider a study according to OECD 216 as relevant for the refinement of the Chemical Safety Assessment with regard to terrestrial toxicity".*

In his comments to the draft decision, the Registrant has disagreed to perform the OECD 216 study on soil microorganisms due to available weight of evidence (WoE) showing low toxicity to aquatic microorganisms. To substantiate the low-toxicity WoE on soil microorganisms, the Registrant has raised the following studies in his comments. These are available in the current dossier on the registered substance; activated sludge respiration inhibition (OECD 209) and B*iodegradation study according to OECD 301B*.

Based on the above information and the submitted studies in the technical dossier, ECHA agrees that you have provided some evidence in a WoE approach according to the general rules in Annex XI of the REACH Regulation and indicated that the level of toxicity to microorganisms appears to be below the water solubility limit. However, ECHA considers that only one line of evidence is indicated as activated sludge media is used in both activated sludge respiration inhibition (OECD 209) and B*iodegradation study according to OECD 301B*. For an acceptable WoE ECHA considers that further lines of evidence would be required. ECHA notes the Registrant could use in addition another line of separate evidence using results from a study conducted using another media.

ECHA notes further that in his comments the Registrant has indicated that according to ECHA Guidance on information requirements and chemical safety assessment R.7c section R.7.11.5.3, page 136 a test on soil microbial activity will only be additionally necessary for a valid PNEC derivation if inhibition of sewage sludge microbial activity occurred (ECHA, 2014b). ECHA notes on p. 136 of REACH Guidance R. 7. C the following is indicated above the part referred to by the Registrant: "*In circumstances where less than a full soil toxicity data-set is available, both the available soil data and the EPM modified aquatic toxicity data should be used in deriving the PNEC$_{soil}$.*" The Guidance then states that "*Where inhibition of sewage sludge microbial activity has been observed in Annex VIII testing, a test on soil microbial activity will additionally be necessary for a valid PNEC to be derived.*" ECHA notes that in this section of the Guidance, the use of the EPM and the need for soil microorganisms study are linked together. However, as also indicated in the draf decision sent to the Registrant ECHA considers 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. Therefore ECHA considers that it is not possible to waive the standard information requirement for soil microorganisms by using the EPM as part of the adaptation, as already indicated to the Registrant in the note for consideration at the end of this section.

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

If the results of the proposed test on long-term toxicity to aquatic invertebrates also proposed by the Registrant 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.

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.

In addition, it is important to ensure that the particular sample of the 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[1] by Hannu Braunschweiler, Head of Unit, Evaluation E1

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.