EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114346399-37-01/F Helsinki, 25 October 2016

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

For 2,6-di-tert-butyl-p-cresol, CAS No 128-37-0 (EC No 204-881-4), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 2,6-di-tert-butyl-p-cresol, CAS No 128-37-0 (EC No 204-881-4), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex VI Section 2 and Annexes IX and X, Sections 9.2 and 9.4 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year.

This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 16 July 2014.

On 25 June 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 31 July 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 03 March 2016 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposals for amendment to the draft decision were submitted.

On 08 April 2016 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 18 April 2016 ECHA referred the draft decision to the Member State Committee.

By 10 May 2016, the Registrant did not provide any comments on the proposals for amendment. However, the Registrant provided comments on the draft decision. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was reached on 23 May 2016 in a written procedure launched on 13 May 2016.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annexes IX, X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Long-term toxicity to terrestrial invertebrates (Annex X, 9.4.4.); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222 or Enchytraeid reproduction test OECD 220;
2. Long-term toxicity testing on plants (Annex X, 9.4.6.); 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);
3. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216)
4. Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD 309) at a temperature of 12°C. ;
5. Soil simulation testing (Annex IX, 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD 307) at a temperature of 12°C.;
6. Identification of degradation products (Annex IX, 9.2.3.)using an appropriate and suitable test method, as explained in section III.4 below

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 long-term 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 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **2 May 2019** an update of the registration dossier containing the information required by this decision, including, an update of the Chemical Safety Report.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

1-3. Terrestrial toxicity, Annexes IX and X, section 9.4

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

1. Terrestrial Invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

Toxicity to terrestrial invertebrates is a standard information requirement under Annex IX, 9.4.1. and Annex X, 9.4.4. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has proposed to adapt short- and long-term toxicity testing on effects on terrestrial invertebrates using the following justification:
"In accordance with column 2 of REACH Annex IX and Annex X, a short-term and a long-term toxicity studies to invertebrates are not required since the results of the chemical safety assessment indicate that there is no need to further investigate the effects of the substance and/or degradation products on terrestrial organisms."

In his proposed adaptation the Registrant claims that there is no need to investigate the effects on terrestrial organisms further. In the technical dossier the Registrant has not described the indicators in the chemical safety assessment that would indicate that there is no need to investigate further the terrestrial toxicity of the substance and its degradation product. In the CSR he concludes that by using the equilibrium partitioning method (EPM) he has derived an RCR below 1. ECHA notes that ECHA Guidance Chapter R.7c on information requirements and chemical safety assessment (version 2.0, November 2014), sections R.7.11.5.3. and R.7.11.6 , does not recommend the screening assessment based on EPM as the intrinsic properties such as toxicity to aquatic organisms, high adsorption or high persistence indicate a high hazard potential to soil organisms.

According to section R.7.11.5.3. of the above mentioned Guidance, substances that have a log Kow/Koc >5 and EC50/LC50 < 1 mg/L for algae, daphnia or fish are considered highly adsorptive and very toxic to aquatic organisms. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (logKow = 5.2) and is very toxic to aquatic organisms (EC50/LC50 < 1 mg/L).

Taking in to account the above, ECHA considers that the column II adaptation for Annex IX, section 9.4 regarding long-term testing instead of short-term testing, is applicable to this substance. ECHA notes that long-term tests are suitable to simultaneously address the information requirements of section 9.4. of Annexes IX and X.

Based upon the available aquatic toxicity information and the physico-chemical properties of the substance and in relation to section R.7.11.6. of the above-mentioned guidance, ECHA considers that the substance would fall into soil hazard category 4. In the context of an integrated testing strategy for soil toxicity, the ECHA Guidance advocates performing long-term toxicity tests according to the information requirements of Annex X and that the lowest value obtained should be used to derive the PNEC soil.

As explained above, the information requirements are not met. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Regarding the test method, an earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates (Annex X, 9.4.4.) and at the same time to fulfil the information requirement of Annex IX, 9.4.1. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties. The Registrant is to apply the most appropriate and suitable test guideline among those listed above. However ECHA notes that when log Kow >5 and log Koc >4, as in this case, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance using one of the following test-methods: Long-term toxicity to terrestrial invertebrates (Annex X, 9.4.4.); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222; or Enchytraeid reproduction test OECD 220.

ECHA Secretariat notes that in his comments to the Draft Decision (DD) the Registrant has agreed that the registered substance belongs to Soil Hazard Category 4, and agreed with the information requirement in the draft decision for long-term testing to terrestrial invertebrates (OECD 222).

2. Terrestrial Plants (Annex IX, 9.4.3. and Annex X, 9.4.6.)

Toxicity to terrestrial plants is a standard information requirement under Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation. The registration dossier does not contain data for these endpoints. Instead, the Registrant has proposed to adapt short- and long-term toxicity testing on effects on terrestrial plants using the following justification:
"In accordance with column 2 of REACH Annex IX and Annex X, a short-term and a long-term toxicity studies to plants are not required since the results of the chemical safety assessment indicate that there is no need to further investigate the effects of the substance and/or degradation products on terrestrial organisms."

As explained above, the Registrant has not described the indicators in the chemical safety assessment that would indicate that there is no need to investigate further the terresrial toxicity of the substance and its degradation product. ECHA notes that ECHA Guidance Chapter R.7c on information requirements and chemical safety assessment (version 2.0, November 2014), sections R.7.11.5.3. and R.7.11.6 , does not recommend the screening assessment based on EPM as the intrinsic properties such as toxicity to aquatic organisms, high adsorption or high persistence indicate a high hazard potential to soil organisms. Furthermore ECHA consideres that based upon the available aquatic toxicity information and the physico-chemical properties of the substance and in relation to section R.7.11.6. of the above-mentioned guidance, ECHA considers that the substance would fall into soil hazard category 4. In the context of an integrated testing strategy for soil toxicity the ECHA Guidance advocates performing long-term toxicity tests according to the information requirements of Annex X and that the lowest value obtained should be used to derive the PNEC soil.

As explained above, the information requirements are not met. Consequently there is an information gap and it is necessary to provide information.

Regarding the test method, a "terrestrial plants growth test" (OECD 208), (subject to the conditions outlined below) and the "Soil Quality – Biological Methods – Chronic toxicity in higher plants test" (ISO 22030) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing on plants (Annex X, 9.4.6.) and at the same time to fulfil the information requirement of Annex IX, 9.4.3.

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

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance using one of the following test methods: long-term toxicity to plants (Annex X, 9.4.6.): 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). The Registrant is to apply the most appropriate and suitable test guideline among those listed above.

ECHA Secretariat notes that in his comments to the Draft Decision the Registrant has agreed that the registered substance belongs to Soil Hazard Category 4, and agreed with the information requirement to study long-term effects on terrestrial plants. The Registrant agrees to perform the requested long-term testing to terrestrial plants (OECD 208 or ISO 22030).

3. 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. The registration dossier does not contain data for this endpoint. Instead, the Registrant has proposed to adapt testing on effects on soil microorganisms using the following justification:
"In accordance with column 2 of REACH Annex IX, a toxicity study on soil micro-organisms is not required since the results of the chemical safety assessment indicate that there is no need to further investigate the effects of the substance and/or degradation products on terrestrial organisms."

As explained above, the Registrant has not described the indicators in the chemical safety assessment that would indicate that there is no need to investigate further the terresrial toxicity of the substance and its degradation product. ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method. Therefore the potential weight of evidence adaptation possibility outlined in the ECHA Guidance Chapter R.7c on information requirements and chemical safety assessment (version 2.0, November 2014), based on EPM and other data that is available for the substance, does not apply for the present endpoint. Furthermore ECHA consideres that based upon the available aquatic toxicity information and the physico-chemical properties of the substance and in relation to section R.7.11.6. of the above-mentioned guidance, ECHA considers that the substance would fall into soil hazard category 4. In the context of an integrated testing strategy for soil toxicity the ECHA Guidance advocates performing a study on soil microorganisms.

In his comments to the DD the Registrant has disagreed to perform the OECD 216 study on soil microorganisms due to available WoE on low toxicity to aquatic microorganisms. To substantiate the low-toxicity WoE on soil microorganisms, the Registrant has discussed the following studies in his comments; Yoshioka et al. 1985; Tetrahymena pyriformis (growth inhibition test, 1.7 mg/L. In addition, in the comments the Registrant has provided the following additional WoE to argue low-toxicity to soil microorganisms; activated sludge respiration inhibition (OECD 209), Pseudomonas putida (cell multiplication inhibition test and Robra test, EC50 500 mg/L), P. fluorescens (growth inhibition test, EC0 > 50 mg/L), Tetrahymena pyriformis (growth inhibition, 3.6 mg/L) and Vibrio fischeri.

As stated in the draft decision, "This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation" and only one study of the above is available in the technical dossier with submission number [redacted]. Therefore, at this stage of the process ECHA is not in the position to verify whether the information referred to above is included in the latest technical dossier. Consequently, there is still a data gap for soil microorganisms ((Annex IX, Section 9.4.2). The Registrant may consider adapting the testing requested 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.

As it is already explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for toxicity for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R.7C, Section R.7.11.3.1., p123, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

4-5. Simulation testing in surface water, and soil (Annex IX, 9.2.1.2; 9.2.1.3.)

4. Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2)

"Simulation testing on ultimate degradation in surface water" is a standard information requirement as laid down in Annex IX, 9.2.1.2 of the REACH Regulation. Column 2 of Section 9.2.1.2 of Annex IX further indicates that the study needs to be conducted if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products and that the choice of the appropriate test(s), which may include simulation degradation tests in appropriate media, depends of the results of the CSA. Column 2 indicates that the study does not need to be conducted if the substance is highly insoluble in water or if the substance is readily biodegradable.

Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the present dossier, ECHA notes that the information on this endpoint is not available. The technical dossier does not either contain acceptable adaptation for this standard information requirement in accordance with Column 2 of Section 9.2.1.2 of Annex IX or Annex XI to the REACH Regulation for this standard information requirement.

The technical dossier contains the following justification for adaptation of the standard information requirement under Annex IX, 9.2.1.2: *"In accordance with column 2 of REACH Annex IX, the study does not need to be conducted since the chemical safety assessment indicates that there is no need to investigate further the degradation of the substance and its degradation products".*

The justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.2.1.2 or the general adaptation rules of Annex XI. The Registrant has not described the indicators in the chemical safety assessment that would indicate that there is no need to investigate further the degradation of the substance and its degradation product.

Based on the following information provided in the technical dossier the registered substance is not readily biodegradable in the meaning of Column 2 of Section 9.2.1.2. of Annex IX. In the technical dossier the Registrant has provided the following Weight of Evidence (WoE) on the ready biodegradability of the registered substance with low water solubility of 0.6 mg/L; slow primary degradation (4.7 % 14CO2 of 14C-CH3-BHT) and volatilisation of BHT (23.1 %) after 28 days of incubation (Inui et al., 1979), 4.5 % degradation in 28 days (Test Guideline OECD 301C) and a QSAR estimation (BIOWIN v4.10) concluding not readily biodegradable. Taking into account the above, the Registrant concluded that under test conditions no biodegradation was observed. Furthermore, the Registant has provided a list of the five major metabolites identified BHT-OOH, BHT-OH, BHT-CH2OH, BHT-CHO and BHT-COOH.

In the Chemical Safety Report the Registrant concludes that; *There are no appropriate half-life data available for drawing conclusions as to the P / vP properties of the assessed substance.* However, in the CSA and hazard / risk / persistency assessment the Registant has considered the registered substance to be persistent. Furthermore, ECHA notes that fate of the identified degradation products has not been reflected in the dossier.

Based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which exposure cannot be excluded e.g. Environmental Release Category (ERC) 8a, and also that the exposure estimations provided by the Registrant in the Chemical Safety Report (CSR) indicate that there may be exposure to surface water. ECHA therefore considers that the Registrant has not demonstrated that exposure is unlikely. Furthermore the registered substance is classified as Aquatic Chronic 1 very toxic to aquatic life with long lasting effects.

In his comments to the draft decision the Registrant has stated that taking into account the deficiencies of available degradation studies and the physical-chemical properties of the substance further investigation should be done before proceeding with higher tiered test as simulation test. The Registrant proposes a tiered testing strategy. This is discussed in detail under the section **Conclusion on the simulation tests 4-5.**

Taking into account the above, ECHA considers that the information provided on degradation of the substance in the registration dossier is not sufficient to demonstrate absence of the need for further information on the degradation of the registered substance and the relevant transformation and/or degradation products in surface water.Based on the above, the adaptation cannot be accepted and there is an information gap in the registration dossier.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

5. Soil simulation testing (Annex IX, 9.2.1.3.)

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, 9.2.1.3 of the REACH Regulation. Column 2 of Section 9.2.1.2 of Annex IX further indicates that the study needs to be conducted if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products and that the choice of the appropriate test(s), which may include simulation degradation tests in appropriate media, depends of the results of the CSA. Column 2 indicates that the study does not need to be conducted if the substance is readily biodegradable or if direct and in direct exposure of soil is unlikely.

Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the present dossier the Registrant provides a non-guideline study on the degradation of the 14C-2,6-di-tert-butyl-4-methyl phenol (Mikami, Gomi and Miyamoto, 1979). The 24 day test was performed with tree soils in the dark at test temperature of 25 °C. The Registrant reported that the registered substance, BHT was relatively unstable in the three soils tested. In the non sterilized soils 77-92 % of the substance was decomposed and 21-29 % mineralized after 24 days of incubation. Under sterilized conditions 27-41 % was decomposed after 24 days and mineralization was negligible (2 %). Under non-sterilized conditions the amount of total volatile 14C was 26 to 42 % (21 to 29 %14CO2).Under sterilized conditions the amount of volatile 14C was 43 to 56 % after 24 days (2 %14CO2). The Registrant concluded that BHT was altered to non volatile products mainly by biological processes. In soil more than 10 degradation products were found and BHT-OOH and BHT-OH were identified as major transformation products. In addition, the Registrant concludes that BHT, as well as its degradation products, is quite biodegradable and hardly persists in the soil environment.

ECHA notes that the test temperature used in the provided study is not comparable to recommend Test Guideline to study the degradation in soil OECD 307 where the constant test temperature of 20 ±2 °C or lower temperature of e.g. 10 ±2 °C is recommended. Furthermore, ECHA notes that the information on transformation rates (half-lives) of the parent substance and its degradation products and the indicated attachment of the description of biotransformation pathways is missing. Temperature correction of degradation half-lives from already available study results to 12 °C is recommended. In the absence of equations/models reflecting temperature dependence of biodegradation, the Arrhenius equation as provided in the Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment (Version 2.0 November 2014) under the section on "Temperature dependence of hydrolysis". The performed study is not fully comparable to the recommended Test Guideline OECD 307 in regards of test duration, test temperature, and reporting of the test results e.g. results on microbial activity, repeatability and sensitivity of the analytic methods used, rates of recovery, mass balance during and after the study. In addition, ECHA notes that direct and indirect exposure of the soil compartment is likely based on the substance properties and use patterns. The registered substance has low water solubility of 0.6 mg/L, partition coefficient of log Kow 5.2 and adsorption coefficient of Log Koc 4.362, indicating adsorptive properties and specified uses include uses e.g. as fuels, fuel additives, greases, lubricants and lubricant additives.

In his comments to the draft decision the Registrant proposes a tiered testing strategy before conducting the simulation tests. This is discussed in detail under the section Conclusion on the simulation tests 4-5.

Therefore, ECHA considers that information in the registration dossier provided on degradation is not sufficient to conclude on the degradation of the registered substance and the relevant transformation and/or degradation products in soil.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements of Annex IX, 9.2.1.3. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Conclusion on the simulation tests 4-5.

In his comments to the draft decision the Registrant has proposed a testing strategy to assess the degradation of the registered substance. The Registrant now proposes to conduct an additional inherent biodegradation study (OECD 302) to assess whether the requested simulation tests are finally needed. The Registrant further indicated that, if simulation testing is necessary, the requested simulation tests should be conducted in a tiered approach starting from the most relevant compartment. In his comments the Registrant has provided results from a Level III Fugacity Model (EPI Suite v4.11). Based on the model the registered substance is expected to mainly distribute into the soil compartment (83%). Therefore the Registrant proposes that if a simulation test is to be conducted the priority compartment would be soil.

ECHA secretariat notes that the proposed testing strategy proposed by the Registrant follows the principles of the guidance provided in the ECHA Guidance document R.11 (November 2014) for PBT assessment. ECHA does not object to the undertaking of screening study(ies) in order to judge whether ultimate conclusion on the persistence can be made or whether further information is needed. Nevertheless, the results from such study(ies) would not, by themselves, fulfil the information requirement of Annex IX section 9.2.1.2 or 9.2.1.3, but may provide the basis for adaptation of the standard information requirements provided by the REACH Regulation.

As outlined under the section Note for consideration of the Registrant, ECHA considers that the Registrant may wish to start the testing in a specific compartment. Based on the outcome of the performed study, he may consider whether further simulation studies are needed or whether it is possible to adapt the other standard information requirements. The Registrant may consider adapting the testing requested in the decision 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. Compliance of the information in the updated dossier will be assessed in the follow up stage.

Regarding the test method, Article 13(3) of the REACH Regulation states that "Where tests on substances are required to generate information on intrinsic properties of substances, they shall be concluded in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission of the Agency as being appropriate".

In the present case, depending on the substance profile, the Registrant may conclude on degradability, by applying the most appropriate and suitable Test Guideline among those listed in the ECHA Guidance on information requirements and chemical safety assessment, Volume 5 Chapter R7b (November 2014) and in the paragraph below. The test guidelines include the description of their respective applicability domains. OECD 309 Guideline is applicable to simulate the biodegradation of organic chemicals under environmentally realistic conditions in surface water, OECD 308 is applicable to simulate the biodegradation of organic chemicals in sediment compartment and OECD 307 is applicable to simulate the biodegradation of organic substances in soil.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 2.0, November 2014) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD 307, OECD 308 and OECD 309. Therefore, the test should be performed at the temperature of 12°C.

Therefore, pursuant to Article 41(1)(a) and (b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD 309).

and

Aerobic and anaerobic transformation in soil simulation biodegradation study (EU C.23./OECD 307) at a temperature of 12°C.

6. Identification of degradation products (Annex IX, 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the study does not need to be conducted if the substance is readily biodegradable.

The Registant has provided information on degradability of the substance and conluded the registered substance to be not readily biodegradable as described above in subsection 4. In addition, a list of identified five major metabolites BHT-OOH, BHT-OH, BHT-CH2OH, BHT-CHO and BHT-COOH has been provided.

ECHA notes that the the Registant has not provided adequate information on the identification, stability, behaviour, and quantity of the degradation products relative to the parent compond and that there is no adaptation provided by the Registrant to cover this end point.

Regarding appropriate and suitable test method, the methods will have to be substance specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition degradation half-life, log Kow and potential toxicity of the metabolite may be investigated.

ECHA secretariat notes that in his comments to the draft decision the Registrant has agreed to provide more information on the degradation product(s).

Therefore, pursuant to Article 41(1)(a) and (b) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Identification of the degradation products using an appropriate and suitable test method, as explained above in this section.

Before conducting the above test the Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.2, November 2012), Chapter ECHA Guidance on information requirements and chemical safety assessment Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

Note to the Registrant

Before conducting any of the requested tests the Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.2, November 2012), Chapter R7b, Sections R.7.9.4 and R.7.9.6 and Chapter R.11.1.3 on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

Based on the above, the Registrant is advised to consult the REACH guidance on information requirements chemical safety assessment in Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment taking into account the potential degradation products of the registered substance, and to update the CSR accordingly.

Moreover, Pursuant to Annex I, section 4.1., the Registrant shall consider the information relevant for screening for P, B and T properties of the parent substance and the degradation products to decide whether further information needs to be generated for the PBT and vPvB assessment. Where only degradation of the parent substance is monitored, this does not address all concerns and further assessment of the degradation products may be required in order to complete the PBT/vPvB assessment. If testing in accordance with Annex IX or X of the REACH Regulation is deemed necessary, the Registrant is required to submit a testing proposal.

IV. Adequate identification of the composition of the tested material

Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation, E3.

[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.