EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114346398-39-01/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, EC No 204-881-4 (CAS No 128-37-0), 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, EC No 204-881-4 (CAS No 128-37-0), 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 12 February 2015.

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 24 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, proposal for amendment to the draft decision were submitted.

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

The ECHA Secretariat reviewed the proposal 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 proposal for amendment.

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 related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.)
2. Description of the analytical methods (Annex VI, Section 2.3.7.)

B. 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 and 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:

3. 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;
4. 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);
5. 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. ;
6. 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.;

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.

C. 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 related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.)

"High-pressure liquid chromatogram, gas chromatogram" is an information requirement as laid down in Annex VI, Section 2.3.6. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The chromatogram for the substance quantification is missing.

The Registrant shall provide a chromatogram and the results thereof for the substance quantification. The analytical results are necessary to confirm the compositional profile for the registered substance, as reported in IUCLID section 1.2.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct chromatographic data as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

ECHA Secretariat notes that in his comments to the draft decision the Registrant indicates that he is prepared to update the requested information on High-pressure liquid chromatogram, gas chromatogram: High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.). The Registrant is reminded that this decision does not take into account any updates submitted after 25 June 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

2. Description of the analytical methods (Annex VI, Section 2.3.7.)

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The description of the analytical method used for the substance quantification is not included.

The Registrant shall provide the description of the analytical method used for the substance quantification. For a chromatographic technique the following minimum information is requested: details on the sample/standard preparation, column specification, the identity of carrier gas/eluent and detector type.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct description of the methods used to identify and quantify the registered substance as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

ECHA Secretariat notes that in his comments to the draft decision the Registrant indicates that he is prepared to update the requested information on High-pressure liquid chromatogram, gas chromatogram: Description of the analytical methods (Annex VI, Section 2.3.7.). The Registrant is reminded that this decision does not take into account any updates submitted after 25 June 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

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

Pursuant to Articles 10(a)(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, VIII, IX, and X of the REACH Regulation.

3-4. Effects on terrestrial organisms (Annex IX, 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.

3. 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:

"*BHT is not supposed to be directly applied to soil. Furthermore, the test substance is rapidly degradable in soil simulation tests and hence, in case of indirect exposure of soil, BHT is expected to rapidly degrade. Therefore soil is not expected to be a compartment of concern. The risk to terrestrial arthropods is negligible. Hence this endpoint can be waived.*" In his proposed adaptation the Registrant claims that exposure to soil is unlikely. However, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which soil exposure cannot be excluded, e.g. Environmental Release Category (ERC) 8a and 8d, and also that the exposure estimations provided by the Registrant in the Chemical Safety Report (CSR) indicate that there is exposure to soil in a number of developed exposure scenarios. ECHA therefore considers that the Registrant has not demonstrated that soil exposure is unlikely.

The Registrant furthermore argues, that the substance is rapidly degradable and therefore soil is not expected to be a compartement of concern. ECHA notes that this is not a valid justification to waive the standard information requirements stemming from Column 1 of Annexes IX/X, Section 9.4. Furthermore ECHA notes that in a case described by the Registrant he needs to investigate the faith of the degradation products in soil.

ECHA further notes that the Registrant uses the Equilibrium Partitioning Method (EPM) to assess the hazard to soil organisms.

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 have a log Kow/Koc >5 are considered highly adsorptive. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (logKow = 5.1). Therefore ECHA considers that the Column 2 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 Guidance does not recommend the screening assessment based on EPM as the intrinsic properties indicate a high hazard potential to soil organisms. It 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.

Consequently there is an information gap and it is necessary to provide information for short- and long-term toxicity on terrestrial invertebrates.

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 the Registrant has in his comments agreed that the registered substance belongs to Soil Hazard Category 4, and agreed with the information requirement in the draft decision, indicating "*Based on the results of the aquatic ecotoxicological studies, aquatic invertebrates are the most sensitive aquatic organisms. Thus, investigating the effects on earthworm reproduction according to OECD 222 is justified.*"

4. 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:

"*BHT is not supposed to be directly applied to soil. Furthermore, the test substance is rapidly degradable in soil simulation tests and hence, in case of indirect exposure of soil, BHT is expected to rapidly degrade. Therefore soil is not expected to be a compartment of concern. The risk to terrestrial plants is negligible. Hence this endpoint can be waived.*"

As explained above, this information does not meet the requirements for an adaptation according to column 2 of Annexes IX/X, Section 9.4. 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 the Registrant has in his comments agreed that the registered substance belongs to Soil Hazard Category 4, and agreed with the information requirement in the draft decision, indicating "*The Guidance document also requests to study long-term effects on terrestrial plants. The Registrant agrees to perform a chronic plant test as well either according to OECD 208 with at least six species or according to ISO 22030.*"

5-6. Simulation testing in surface water and soil (Annex IX, 9.2.1.2; ; 9.2.1.3.)

5. 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 an adaptation from the Annex IX, 9.2.1.2 requirement:
"*As the substance is rapidly degradable under simulated environmental conditions as proven by tests with 14C labelled BHT, no further tests on biodegradation in surface water or sediment are performed. This endpoint can be waived. Rapid dissipation can be assumed in case that 2,6-di-tert-butyl-p-cresol unintentionally reaches the sediment compartment".*

In the technical dossier the Registrant has provided the following information on the ready biodegradability of the registered substance; 4.5 % degradation in 28 days with deviations from the Test Guideline OECD 301C (50 mg/L inoculum concentration) and 5.2 % in primary degradation in 35 days, and residual of 10.8 % BHT in solution, half-life of 3 -7 days in similar to OECD 301C TG with radio labelled BHT, 14CH3- and 14C-phenyl-BHT (Inui et al., 1979). Taking into account the above, the Registrant concluded the registered substance likely to be a readily (bio) degradable substance.

In his comments on the Draft Decision (DD) the Registrant agrees that without the addition of a solubilizer the registered substance is poorly degradable, whereas under enchanced conditions ultimate degradation reached 39 %. According to the Registrant this would indicate inherent degradability. In his comments the Registrant also agrees that based on the currently available information, no definitive conclusion on persistence of the registered substance may be made. The Registrant proposes a tiered testing strategy. This is discussed in detail under the section **Conclusion on the simulation tests 5-6.**
ECHA considers that the information provided in the registration dossier is not sufficient to conclude rapid degradation of the parent or the relevant transformation and/or degradation products under simulated environmental condition. The pass level for ready biodegradability, which is 60 % of the theoretical oxygen demand within 28 days in OECD 301C, has not been met. Furthermore ECHA notes that the simulation test should be performed by using indigenous environmental media to provide information on biodegradation under environmentally relevant conditions. The registrant has provided two studies on modified ready biodegradability test with activated sludge as an inoculum. Activated sludge inoculum is not considered as adequate test media to predict degradation in the environment. ECHA concludes that the Registrant has not provided adequate evidence on rapid degradation in surface water. Therefore, 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.

6. 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 equivalent or similar to OECD 304A Inherent biodegradability in soil on the degradation of the registered substance 2,6 -di-tert-butyl-p-cresol (BHT) (Mikami et al., 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.

Under nonsterilized conditions 63-82% of BHT was decomposed (about 1-2% mineralized to CO2) after one day. After 24 days of incubation 77-92% was decomposed (21-29% mineralized to CO2). Under sterilized conditions 25 -35% of BHT was decomposed after 24 hours. After 24 days of incubation 27-41% was decomposed. In both cases mineralization was negligible (< 2%). After 24 days 50-61% remained unchanged. Under sterilized and nonsterilized conditions BHT-OOH, BHT-OH, BHT-CH2OH, BHT-CHO, BHT-COOH were identified as degradation products of BHT. As overall result the Registrant reported a half-life (DT50) of BHT in soil to be less than 24 hours at a temperature of 25 °C.

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 half-life for the parent substance has been provided at 25 °C. 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" is recommended to be used in temperature correction. In addition, the Registrant has not reported the half-lives for the identified degradation products BHT-OOH, BHT-OH, BHT-CH2OH, BHT-CHO, BHT-COOH. ECHA concludes that the performed study is not fully comparable to the Test Guideline OECD 307 recommended in the ECHA Guidance on information requirements and chemical safety assessment (Chapter R7b, R.7.9.4) 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. Furthermore, ECHA notes that direct and indirect exposure of the soil compartment is likely based on the substance properties and use patterns as describe in section III B. 3 above. The registered substance has low water solubility of 0.76 mg/L, and partition coefficient of log Kow 5.1 indicating adsorptive properties.

In his comments the Registrant has provided results from a Level III Fugacity Model for the registered substance (EPI Suite v4.11). According to the Registrant, based on its intrinsic properties and the level III fugacity 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 the soil environment. 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 study he may consider whether further simulation studies are needed or whether it is possible to adapt the other standard information requirements. The Registrant would need to provide scientific reasoning for any adaptation. The acceptability of an adaptation would be evaluated by ECHA at the follow-up stage.

Therefore, ECHA considers that the 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. Therefore, the provided information is not sufficient to fulfil the standard information requirement in Annex IX 9.2.1.4

Conclusion on the simulation tests 5-6.

ECHA notes that in their comments to the DD the Registrant has further discussed the currently available information on the degradation of the registered substance. The Registrant acknowledges that based on current information it is not possible to conclude on the persistence of the substance. Therefore, the Regisrant proposes a testing strategy to fulfil the information requirements for Annex IX sections 9.2.1.2, 9.2.1.4, 9.2.1.3 and 9.2.3. The Registrant proposes to start the assessment with an inherent biodegradability study. The Registrant points out that lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series would provide sufficient information to confirm persistency, whereas mineralisation of ≥ 70% (DOC removal or O2 uptake) could be considered as evidence of substance being not P and not vP. The Registrant proposes to use this approach to determine whether the registered substance is persistent or not persistent. In case of negative results the Registrant proposes to perform simulation test in the most relevant compartment. ECHA notes that this approach is aligned with the approach given ECHA Guidance R.11. 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 studies 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.

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.

In their comments to the DD the Registrant has provided information on the detected transformation products in consice manner. In the technical dossier this information was reported in several sections. However, information on the fate of the transformation products is not fully considered. The fate of the transformation products shall be considered and determined in the simulation study(ies) conducted.

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.

Note for consideration by 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.

In his comments on the draft decision, the Registrant has noted that as already demonstrated in the existing technical dossier and CSR, the parent substance is neither PBT nor vPvB as the B/vB criterion and T criterion are not fulfilled. As the parent substance is neither B nor T, the Registrant considered a more in-depth evaluation on the degree of persistence questionable. ECHA notes that PBT assessment shall also consider the PBT/vPvB properties of the relevant transformation and/or degradation products. ECHA notes further that the justification provided in the technical dossier to adapt the information requirements for Simulation testing, does not at the moment meet the criteria for Column 2 of Section 9.2.1.4 of Annex IX or general adaptation rules of Annex XI. It fails to meet this criteria as the Registrant has not described the indicators in the chemical safety assessment which would indicate that there is no need to further investigate the degradation of the substance and its degradation product(s).

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. 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.

7. Deadline to submit the requested information in this decision

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also contained a requst for a sediment simulation study, identification of degradation product(s) and soil micro-organisms study. In his comments the Registrant requested to extend the timeline for conducting the studies from 30 months to 36 months. However, as the above stated studies are now not addressed in the present draft decision, ECHA considers that a reasonable time period for providing the required information and the possibility to follow the indicated tiered testing approach raised in the Registrant's comments on the draft decision and addresseed in the draft decision, in the form of an updated IUCLID dossier is still 30 months. The deadline of the decision was therefore not modified.

IV. Adequate identification of the composition of the tested material

In carrying out the studies required by the present decision it is important to ensure that the particular sample of substance tested 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.

Furthermore, 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.