EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002563-76-10/F Helsinki, 28 March 2014

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

For 2,4-di-tert-butylphenol, CAS No 96-76-4 (EC No 202-532-0), 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 2,4-di-tert-butylphenol, CAS No 96-76-4, (EC No 202-532-0) submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VII, Sections 7.14 and 8.4.1 and Annex IX, Sections 7.16, 9.2, 9.4.1, 9.4.2, 9.4.3 of the REACH Regulation.

This decision is based on the registration 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 submitted after 1 August 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(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 28 August 2012.

On 03 May 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 31 May 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision on request of *in vitro* gene mutation study in bacteria and providing further details on other requests.

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 1 August 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 11 September 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and modified Section II and Section III of the draft decision.

On 16 September 2013 ECHA referred the draft decision to the Member State Committee.

By 11 October 2013 the Registrant did not provide any comments on the proposals for amendment but only comments on the draft decision.

After discussion in the Member State Committee meeting on 4-8 November 2013, a unanimous agreement of the Member State Committee on the draft decision as amended by ECHA was reached on 5 November 2013 and ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1)(a) and (b), 41(3), 10(a)((vii), 12(1)(d), 13 and Annexes VII, IX and XI 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. Full justification for adapting testing requirement for granulometry (Annex VII, 7.14.) in accordance with the column 2 adaptation rules to support the waiving argument for this endpoint;
2. Dissociation constant (Annex IX, 7.16.; test method: OECD 112);
3. *In vitro* gene mutation study in bacteria using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. E. coli WP2 uvrA, or E. coli uvrA (pKM101), or S. typhimurium TA102 (Annex VII, 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14./OECD 471);
4. Effects on terrestrial organisms – Short-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1.; test method: Earthworm, acute toxicity tests, EU C.8./OECD 207)
   or, if long-term testing is considered appropriate, either
   Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222)
   or
   Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Enchytraeid reproduction test, OECD 220)
   or

Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Collembolan reproduction test in soil, OECD 232)
and

5. Effects on terrestrial organisms – Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216)
and
6. Effects on terrestrial organisms – Short-term toxicity to plants (Annex IX, 9.4.3. test method: Terrestrial plants, growth test, OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species)
or, if long-term testing is considered appropriate, either
Effects on terrestrial organisms – Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2; test method: Terrestrial plants, growth test, OECD 208), with at least six species tested (with as a minimum two monocotyledonous species
or
Effects on terrestrial organisms – Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2; test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030).

7. 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), as specified in Section III 7.- 9. below;
8. Soil simulation testing (Annex IX, 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307), as specified in Section III 7.- 9. below;
9. Sediment simulation testing (Annex IX, 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308), as specified in Section III 7.- 9. below;
10. Identification of degradation products (Annex IX, 9.2.3.) as specified in Section III 10. below.

ECHA notes that another registrant of the same substance has been requested to provide the information listed above in order to fulfil the relevant information requirements. Article 25 of the REACH Regulation establishes the general aim of avoidance of unnecessary testing. Furthermore, and in accordance with Article 53(1) of the REACH Regulation, the Registrant shall contact the other registrant of the same substance and make every effort to reach agreement on which registrant is to carry out the tests and to share the costs of such studies.

In addition, the Registrant is reminded of the obligation imposed by Article 11 of the REACH Regulation on all the registrants of the same substance to submit registrations for the same substance jointly.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **28 March 2016**.

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.

Pursuant to Articles 10(a) vii), 12(1)(d) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII, VIII and IX of the REACH Regulation.

1. Granulometry (Annex VII, 7.14.)

"Granulometry" is a standard information requirement as laid down in Annex VII, Section 7.14. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant waived the standard information requirement of Annex VII, section 7.14 for granulometry claiming that "*the material is marketed as a melt*". ECHA views that the waiving statement cannot be accepted since the manufactured substance is a solid and worker exposure to dust of this substance cannot be excluded under certain exposure scenario (e.g. sampling during process, cleaning of production equipment, use of substance in pilot plant and laboratories, filling of 2,4-Di-tert-Butylphenol in tank cars). Based on the available information in the registration dossier, ECHA concludes that there is thus a need for information on particle size of the substance.

In response to ECHA's draft decision of 3 May 2013, the Registrant referred to the section 7.14, column 2 adaptation rules for granulometry and provided in his comments further explanation that the material does not exist as a powder or in granular form in their supply chain. The Registrant claimed that within the entire supply chain the material is always handled under higher temperature as a melt and coming out as such from the reactor. Further, the Registrant described in detail handling of the substance in molten form within the supply chain, excluding preparation of granular or powder form out of the material.

ECHA considers that on the basis of the justification provided by the Registrant in his comments it is possible to adapt the standard information requirement for granulometry in accordance with Annex VII, section 7.13, column 2 of the REACH Regulation. For the dossier to be compliant, this justification needs to be reflected in the actual registration dossier. The Registrant is therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, required to include this justification, i.e. the description of how and in which form is the registered substance handled in the supply chain in the relevant parts of the registration dossier, including the chemical safety report (CSR).

2. Dissociation constant (Annex IX, 7.16.)

"Dissociation constant" is a standard information requirement as laid down in Annex IX, Section 7.16. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The dissociation of a substance in water is of importance in assessing its impact upon the environment and it governs the form of the substance which in turn determines its behaviour and transport. It may affect the adsorption of the substance on soils and sediments.

The Registrant waived the standard information requirement of Annex IX, section 7.16 for dissociation constant claiming that "*the substance does not contain functional groups subject to dissociation, consequently a study is not justified*". ECHA views that the waiving statement cannot be accepted since the registered substance contains a phenol group. Therefore, a partial dissociation of the neutral form of the registered substance to form a charged molecule cannot be excluded at environmentally relevant pH.

In response to ECHA's draft decision of 3 May 2013, the Registrant provided in his comments calculated pKa value from SPARC v4.6 programme, which predicts that 2,4-di-tert-butylphenol does not dissociate in the environmentally relevant pH range 5-9.

ECHA observes that in his comments, the Registrant has sought to adapt the information requirement of Annex IX, 7.16. of the REACH Regulation by means of providing results from quantitative structure-activity relationship model (QSAR). In accordance with Section 1.3. of Annex XI the conditions for this adaptation are the following:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied method is provided.

ECHA points out that the Registrant has not shown that the registered substance falls within the applicability domain of the model, that the results are adequate for the purpose of classification and labelling, and he has not provided adequate and reliable documentation of the applied method. Therefore the adaptation as provided in the Registrant's comment does not fulfill requirements of Annex XI, Section 1.3 of the REACH Regulation. Guidance on how to report (Q)SAR studies is available in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.6, Section R.6.1. (pages 9-66, Version of May 2008) and in ECHA's Practical Guide 5: How to report (Q)SARs.

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

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: Dissociation constants in water (test method: OECD 112).

3. *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.)

"*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

In the present case, ECHA notes that for the endpoint 8.4.1 of Annex VII, *in vitro* gene mutation study in bacteria, the Registrant provided in his registration dossier robust study summary for a GLP compliant *in vitro* gene mutation study in bacteria performed in 1991 according to the EU method B.13/14 with *S. typhimurium* strains TA 1535, TA 1537, TA 98, TA 100 and TA 1538.

The version of the EU Test Method B.13/14/OECD 471 in force since 1997 introduces the need for performing the test in *S. typhimurium* strain TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) having the potential to detect certain types of mutagens, such as cross-linking agents or oxidising mutagens, which may not be detected by other *S. typhimurium* strains. This means that significant changes have been made to OECD guideline 471 and that the study provided by the Registrant does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI.

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

Therefore, pursuant to Article 41(1)(a) 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: Bacterial reverse mutation test (test method:
EU B.13/14./OECD 471) using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. E. coli WP2 uvrA, or E. coli uvrA (pKM101), or S. typhimurium TA102.

4.-8. Effects on terrestrial organisms (Annex IX, 9.4.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, section 9.4.1.), effects on soil micro-organisms (Annex IX, section 9.4.2.), and short-term toxicity to plants (Annex IX, section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, section 9.4 specifies that these studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. It also provides that in the absence of toxicity data for soil organisms, the equilibrium portioning method (EPM) may be applied to assess the hazard to soil organisms. It further

provides 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.

4. Short-term or long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1.)

The Registrant has waived testing on terrestrial invertebrates using the following justification:

"Column 2 of the Corrigendum to Regulation (EC) No 1907/2006, Annex IX, states, ¿These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment. In particular for substances that have a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term.¿

The Koc for sediment based upon read-across to 2,6-di-tert-butylphenol, is 4.493E+03 L/kg and the BCF worm is 758 L/kg wwt. No direct exposure to soil is expected and the exposure and risk assessment, conducted using ECETOC TRA based upon the equilibrium partitioning method, do not indicate any cause for concern with regard to the environment. The RCRs for the terrestrial environment were all less than 1.

Based upon the above rationale no further testing is recommended."

Regarding exposure of the soil compartment, ECHA notes that, according to the evidence presented within the Registration dossier, this exposure is likely. The use pattern of the registered substance as a fuel additive suggests that direct or indirect exposure of soil is likely and in Section 3.7.3 of the registration dossier it is indicated that there is a generic exposure potential for soil. In the Chemical Safety Assessment, the PNECsoil is derived using the equilibrium partitioning method (EPM). The Registrant does not present any risk characterisation ratios for the soil compartment but states *"In order to make the terrestrial assessment safe, sludge from a WWTP or STP must not be spread on agricultural land if the level of 2,4-DTBP in the effluent entering the WWTP or STP is > 0.00247 mg/L."*

In his comments to ECHA's draft decision of 3 May 2013, the Registrant states that there is negligible exposure of soil following the use of the registered substance. ECHA, however, refers to the argumentation above in this section and points out that direct soil exposure following fuel handling and use is well-documented and, based on the use of the registered substance as a fuel additive, direct releases to soil should be expected. ECHA concludes that the adaptation for waiving based on column 2 of Annex IX, section 9.4 relating to unlikely exposure of the soil compartment cannot be accepted since there is clearly a potential for exposure of soil.

Concerning the use of EPM to assess the hazard to soil organisms, Table R.7.11-2 in Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008) indicates that for substances meeting the criteria for Hazard Category 4, *"Screening assessment based on EPM not recommended, intrinsic properties indicate a high hazard potential to soil organisms."* Thus, according to the REACH guidance the PNECsoil should be based on measured soil toxicity data instead of the equilibrium partitioning method (EPM).

In the present case, the Registrant currently uses the EPM to conduct the risk assessment for the soil compartment. Using this approach, the Registrant recommends risk management measures to control the risks to soil arising from indirect emissions to soil via a sewage treatment plant. This is documented in Section A of the Chemical Safety Report where it is stated "*In order to make the terrestrial assessment safe, sludge from a WWTP or STP must not be spread on agricultural land if the level of 2,4-DTBP in the effluent entering the WWTP or STP is > 0.00247 mg/L.*" In order to derive the appropriate risk management measures for soil, a PNEC soil should be obtained based on measured toxicity to soil-dwelling organisms.

ECHA further observes that Section 2.2 of the Chemical Safety Report refers to professional wide dispersive outdoor use of the registered substance as a fuel additive in closed systems. Consumer use of fuel additives is also included. This could potentially lead to direct emission of the registered substance to soil which would not be controlled by the risk management measures proposed for a sewage treatment plant. In order to assess the potential risks to soil by direct emissions, measured toxicity data on soil-dwelling organisms is needed. The use of the EPM approach is not suitable for the registered substance based on its intrinsic properties.

Regarding the persistency and hazards of the substance, ECHA notes that, according to the evidence presented within the registration dossier, the registered substance possesses intrinsic properties indicating a high hazard potential to soil organisms. The registered substance is not readily biodegradable (0% biodegradation in 28 days) and is considered by the Registrant to meet the criteria for persistent/very persistent. This was also the conclusion reached by the TC NES Subgroup on Identification of PBT and vPvB substances. The measured LogKow is 4.8 at 23 °C, which is close to the threshold of 5.0 indicating a high adsorption potential for soil (see ECHA *Guidance on information requirements and chemical safety assessment* (May 2008) Section R.7.11.5.3 page 121).

The registered substance is very toxic to aquatic organisms based on its toxicity to algae (72h EC50 0.37 mg/l (measured concentration) with Desmodesmus subspicatus), and is classified by the Registrant as hazardous to the aquatic environment, Aquatic Chronic 1 and Aquatic Acute 1.

The Registrant provided comments on the draft decision of 3 May 2013 indicating that the registered substance does not have Log Kow > 5, it is not ionisable at an environmentally relevant pH and does not have a high potential for binding to soil. The Registrant indicates that the Koc, based upon read-across to 2,6-di-tert-butylphenol (2,6-DTBP), is 4.493E+03 L/kg in sediment and the "BCF worm" is 758 L/kg wwt. The Registrant accepted that the registered substance meets the criteria for soil Hazard Category 4 according to REACH Guidance R.7C, Table R.7.11-2.

ECHA states that meeting the Hazard Category 4 criteria is not solely based on the Log Kow, Log Koc or bioaccumulation potential of the substance but is based on i) the persistence of the substance in soil (not readily biodegradable, 0% biodegradation in 28 days and considered by the Registrant to meet the criteria for P/vP) and ii) its high toxicity to aquatic organisms (72h EC50 0.37 mg/l (measured concentration) with *Desmodesmus subspicatus*).

The above justification for waiving provided by the Registrant does not meet the criteria of Column 2 of Annex IX , section 9.4, or the general adaptation rules of Annex XI. ECHA considers that the substance is likely to be very persistent and therefore the Registrant shall consider long-term toxicity testing for this endpoint.

As for test methods, the 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. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties. If long-term testing is not considered appropriate, the Earthworm, acute toxicity test (test method: EU C.8./OECD 207) is considered as appropriate for the fulfilment of the information requirements for short-term toxicity testing to terrestrial invertebrates.

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:

Earthworm, acute toxicity test (test method: EU C.8./OECD 207)

Or, if long-term testing is considered appropriate, either

Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222)
or
Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Enchytraeid reproduction test, OECD 220) or
Effects on terrestrial organisms – Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Collembolan reproduction test in soil, OECD 232).

5. Effects on soil micro-organisms (Annex IX, 9.4.2.)

The Registrant has waived testing on effects on soil microorganisms using the identical justification as presented above under '4. Short-term or long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1.)'.

Regarding exposure of the soil compartment, ECHA refers to the arguments presented in the section 4 above and concludes that the adaptation for waiving based on column 2 of Annex IX, section 9.4 relating to unlikely exposure of the soil compartment cannot be accepted since there is clearly a potential for exposure of the soil compartment.

Concerning the use of EPM, 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. does not apply for the present endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), Chapter R.7C, R.7.11.3.1. p112, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

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:

Soil microorganisms: nitrogen transformation test (test method : EU C.21./OECD 216).

6. Short-term or long-term toxicity to terrestrial plants (Annex IX, 9.4.3.)

The Registrant has waived testing on effects to terrestrial plants using the identical justification as presented above under '4. Short-term or long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1.)'.

Regarding exposure of the soil compartment, ECHA refers to the arguments presented in the section 4 above and concludes that the adaptation for waiving based on column 2 of Annex IX, section 9.4 relating to unlikely exposure of the soil compartment cannot be accepted since there is clearly a potential for exposure of the soil compartment.

Concerning the use of EPM, ECHA refers to the arguments presented in the section 4 above and concludes that 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.

Regarding the persistency and hazards of the substance, ECHA refers to the arguments presented in the section 4 above and concludes, in line with column 2 of Annex IX, Section 9.4., that the substance is likely to be very persistent and therefore the Registrant shall consider long-term toxicity testing for this endpoint.

Regarding test methods, 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 short-term toxicity testing, ECHA considers three species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with one monocotyledonous species and two dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 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:

Terrestrial plants, growth test (test method: OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species).

Or, if long-term testing is considered appropriate, either

Terrestrial plants, growth test (test method: 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 (test method: ISO

22030).

7.- 9. Simulation testing in surface water, soil and sediment (Annex IX, 9.2.1.2.; 9.2.1.3.; 9.2.1.4.)

7. 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 does not need to be conducted if the substance is highly insoluble in water or if the substance is readily biodegradable. The registrant may also seek to adapt the information requirement pursuant to the general adaptation rules of Annex XI, including exposure based adaptation governed by Section 3 of that Annex. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant waives the requirement for sediment simulation testing with the following justification:
"*Column 2 of the Corrigendum to Regulation (EC) No 1907/2006, Annex IX, states, ¿Further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil).*

No direct exposure to surface water is expected and the exposure and risk assessment, conducted using EUSES V 2.1.1 based upon the total tonnage for 2,4-DTBP, do not indicate any cause for concern with regard to the aquatic environment. The RCRs for the aquatic environment were all <1.

Based upon the above rationale no further testing is recommended."

However, ECHA considers that, based on information provided in the registration dossier, the registered substance is not readily biodegradable within the meaning of Column 2 of Section 9.2.1.2 of Annex IX. There is an inherent biodegradation test (OECD 302C) available in the registration dossier conducted with 100 mg/l dw sewage sludge and 30 mg/l registered substance. There was 0% degradation in 28 days. A further study, BOD Test for insoluble Substances, was conducted with 34.5 mg/l test material and showed 2% biodegradation in 28 days. The sludge concentration is not reported. The Registrant concludes that the substance "*cannot be considered as biodegradable.*" In their PBT assessment, the Registrant concludes "*whilst 2,4-DTBP may oxidize in aquatic solutions and may undergo photodegradation, based upon the above data 2,4-di-tert-butylphenol should be considered to meet the Persistent, P/vP criteria."*

In addition, ECHA considers that the substance cannot be considered as highly insoluble within the meaning of Column 2 of Section 9.2.1.2 of Annex IX. The measured water solubility is reported as 33 mg/l in the registration dossier based on a study of reliability 1. Furthermore, direct and indirect exposure of the aquatic compartment is likely based on the use pattern as a fuel additive with consumer uses.

Regarding exposure based adaptation governed by Section 3 of Annex XI, ECHA refers to the Registrant's above justification relating to 'no direct exposure'. ECHA considers that the Registrant has not, contrary to Section 3 of Annex XI to the REACH Regulation, provided any adequate justification and documentation showing that there is no or insignificant exposure to water, sediment or soil. ECHA notes that the CSR predicts exposure of freshwater, freshwater sediments, marine water and marine sediments. As explained in Section III 4. above, direct soil exposure following fuel handling and use is well-documented and, based on the use of the registered substance as a fuel additive, direct releases to soil should be expected.

For the above reasons, 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. Therefore, the adaptation cannot be accepted and there is an information gap in the registration dossier.

As for the test method, ECHA considers that the test method "Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/OECD 309" is suitable and appropriate.

8. Sediment simulation testing (Annex IX, 9.2.1.4.)

"Sediment simulation testing" is a standard information requirement according to column 1, Section 9.2.1.4 of Annex IX of the REACH Regulation. Column 2 of Section 9.2.1.4 of Annex IX further states that the study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of sediment is unlikely. The registrant may also seek to adapt the information requirement pursuant to the general adaptation rules of Annex XI. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant waives the requirement for sediment simulation testing using the same justification as for surface water simulation testing above. As discussed above, the Registrant concludes that the substance "*cannot be considered as biodegradable.*" In addition, direct and indirect exposure of sediment is likely based on the use pattern as a fuel additive with consumer uses and the measured Log Kow of 4.8 at 23 °C indicates a potential to adsorb to soil and sediment.

Regarding exposure based adaptation governed by Section 3 of Annex XI, ECHA considers that the Registrant has not provided any adequate justification and documentation showing that there is no or insignificant exposure to water, sediment or soil. ECHA notes that the CSR predicts exposure of freshwater, freshwater sediments, marine water and marine sediments. As explained in Section III 4. above, direct soil exposure following fuel handling and use is well-documented and, based on the use of the registered substance as a fuel additive, direct releases to soil should be expected. 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 since the substance is not readily biodegradable and direct and indirect exposure of sediment is likely and since there is no valid adaptation in line with Annex XI presented for this endpoint in the dossier. Therefore, the adaptation cannot be accepted and there is an information gap in the registration dossier.

As for the test method, ECHA considers that the test method "Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308" is suitable and appropriate.

9. 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 9.2.1.3 of Annex IX further indicates that the study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of soil is unlikely. The registrant may also seek to adapt the information requirement pursuant to the general adaptation rules of Annex XI, including exposure based adaptation governed by Section 3 of that Annex. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant waives the requirement for soil simulation testing with the following justification:
"Column 2 of the Corrigendum to Regulation (EC) No 1907/2006, Annex IX, states, ¿Further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil).¿

2,4-di-tert-butylphenol does not have a high potential for binding to soil. The Koc, based upon read-across to 2,6-DTBP, is 4.493E+03 L/kg in sediment and the BCF worm is 758 L/kg wwt.

No direct exposure to soil is expected and the exposure and risk assessment, conducted using EUSES V 2.1.1, does not indicate any cause for concern with regard to the environment. The RCRs for the terrestrial environment were less than 1.

Based upon the above rationale no further testing is recommended."

As discussed above, the Registrant concludes that the substance "*cannot be considered as biodegradable*." In addition, direct and indirect exposure of soil is likely based on the use pattern as a fuel additive with consumer uses and the measured Log Kow of 4.8 at 23 °C indicates a potential to adsorb to soil and sediment.

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 9.2.1.3, since the substance is not readily biodegradable and direct and indirect exposure of soil is likely.

Regarding exposure based adaptation governed by Section 3 of Annex XI, ECHA considers that the Registrant has not provided any adequate justification and documentation showing that there is no or insignificant exposure to water, sediment or soil. ECHA notes that the CSR predicts exposure of freshwater, freshwater sediments, marine water and marine sediments. As explained in Section III 4. above, direct soil exposure following fuel handling and use is well-documented and, based on the use of the registered substance as a fuel additive, direct releases to soil should be expected.

Therefore, the adaptation cannot be accepted and there is an information gap in the registration dossier. As for the test method, ECHA considers that the test method "Aerobic and anaerobic transformation in soil, EU C.23/OECD 307" is suitable and appropriate.

Conclusion on the simulation tests (points 7.-9. above)

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:

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);

and

Soil simulation testing (Annex IX, 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307);

and

Sediment simulation testing (Annex IX, 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308).

Before conducting any of the tests mentioned above 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 three simulation tests. 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. The Registrant retains the right to include fully justified adaptations for simulation testing.

10. 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 registrant may also seek to adapt the information requirement pursuant to the general adaptation rules of Annex XI.

The Registrant provides the following justification for waiving this study:

"Biotic Degradation
Two studies were conducted (modified MITI(II) test and a BOD test for insoluble substances) to assess the aquatic metabolism of 2,4-DTBP in primary sludge from a sewage treatment plant, intended to be representative of a 2,4-DTBP use site. At weekly sampling intervals over a 28 day perios, aliquots of the sludge were analysed to determine the rate of biodegradation of 2,4-DTBP. Results from these studies determined that 2,4-DTBP does not degrade under these conditions and therefore there will be no degradation products to be identified.
Abiotic Degradation
2,4-di-tert-butylphenol is an alkyl-substituted phenol derivative and has no functional groups that can be hydrolyzed, i.e. ester, amide or any substituents on the alkyl-groups or the aromatic ring that could be substituted by OH- ions under the condition of the guideline test on hydrolysis as function of pH (OECD 111, EU method C7). Therefore, from the

structure of the substance it can be deduced that it does not undergo abiotic degradation through hydrolysis. There will therefore be no degradation products to be identified.

Overall no degradation products were produced via biotic or abiotic degradation."

As discussed above, the Registrant concludes that the substance "cannot be considered as biodegradable" Therefore, the adaptation of Column 2 of Section 9.2.3. of Annex IX cannot be applied. The Registrant has not either presented any valid adaptation within the meaning of Annex XI in his dossier.

ECHA further points out that in their PBT assessment, the Registrant concludes "*whilst 2,4-DTBP may oxidize in aquatic solutions and may undergo photodegradation, based upon the above data 2,4-di-tert-butylphenol should be considered to meet the Persistent, P/vP criteria.*" However, the Registrant has not considered the PBT/vPvB properties of relevant transformation and/or degradation products in their PBT assessment. According to the revised Annex XIII to the REACH Regulation, which registrants must comply with by 19 March 2013, "The identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products." (the fifth introductory paragraph of Annex XIII).

Therefore, there is a data gap for this endpoint. ECHA also considers that there are potential oxidation and photodegradation products of the registered substance which have not been identified.

Regarding an 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.

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), 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.

In accordance with Annex I, Section 4 of the REACH Regulation, the Registrant should revise the PBT assessment when results of the tests 7-10 detailed above are available. The Registrant is also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.1, November 2012), Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

Deadline for submitting the information required under Section II

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 9 months from the date of adoption of the decision. In follow-up to the proposals for amendment additional tests were included amongst the tests requested by the decision. ECHA considered that 9 months may not suffice to conduct the additional testing. ECHA considers an additional 15 months are adequate for sequential testing as outlined above. Therefore the timeline was extended to 24 months. The decision was amended accordingly.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

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

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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://echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

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