ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114343927-39-01/F Helsinki, 27 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-butylphenol, CAS No 128-39-2 (EC No 204-884-0), 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-butylphenol, CAS No 128-39-2 (EC No 204-884-0), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Sections 9.4. of Annexes IX and X of the REACH Regulation relating to terrestrial toxicity.

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 submitted after 21 July 2016, 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 7 August 2014.

On 8 October 2014 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 14 November 2014 ECHA received comments from the Registrant on the draft decision.

The Registrant updated his registration dossier on 27 February 2015 with the submission number [redacted] and on 3 July 2015 with the submission number [redacted].

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

On 21 July 2016 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier regarding effects on terrestrial organisms

Pursuant to Articles 41(1), 41(3), 10(a)(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:

1. Long-term toxicity testing on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222, or Enchytraeid reproduction test, OECD 220, or Collembolan reproduction test in soil, OECD 232);

2. Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Terrestrial Plant Test: Seedling Emergence and Seedling Growth, OECD 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030); and

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

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above 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 requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **3 August 2017**.

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)(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.

"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.
ECHA has examined the comments of the Registrant and the dossier updates received on 27 February 2015 with the submission number [redacted] and on 3 July 2015 with the submission number [redacted]. The Registrant has provided newly calculated PNEC aquatic based on a newly submitted long-term daphnia study and a revised PNEC soil based on EPM. Furthermore the Registrant has submitted read-across assessments (using QSAR Toolbox) to fill the data gaps in the respective endpoints.

The relevance of the proposed read-across approach is addressed in section III.0.

0. Grouping of substances and read-across approach

In the updated technical dossier, the Registrant submitted read-across assessments to fill the data gaps for the information requirements issued in this decision. In all respective endpoint study records, the Registrant selected "(Q)SARs" in the IUCLID "Study result type" field, but the reference in "Data source" in RSS indicates that the approach chosen was read-across (many-to-one).

ECHA notes that the Registrant has used the QSAR Toolbox to "Predict the NOEC of the registered substance, based on read across from structural analogues, in the "phenols" category, with experimental data". ECHA considers that the Registrant sought to adapt the information requirement based on REACH Annex XI section 1.5. Grouping of substances and read-across approach.

Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances.

If a structural similarity is established, it may be possible to make predictions within the group for the target substance(s) on the basis of a demonstrable regular pattern. Alternatively, whenever there is more than one source substance in the category and no regular pattern is demonstrated for the property under consideration, the prediction may be based on a read-across from a category member with relevant information in a conservative manner (worst case). Supporting evidence is considered as an essential part of the category justification.
The Registrant attached QSAR Toolbox prediction reports in the technical dossier to support his grouping approaches. In the prediction reports, he justifies the grouping by similarity of structure: *"phenols would have similar reactivity to* [endpoint] *due to their structure".* He further supports the argument by similarity in the reactivity of phenols which is also seen in aquatic species and *"which is well documented (Ref: ECOSAR Class Definition: Phenols Class Definition Document, Online Help ECOSAR v 1.11)".*

ECHA observes that the Registrant did not clearly establish why structural similarity among the category members could constitute one element of a read-across hypothesis according to which properties of the registered substance could be predicted from the category members. Further, ECHA notes that no information on the possible structural differences among the category members is included in the prediction reports. In the Appendix 1 of the reports, ECHA observes significant structural differences among the analogue substances (e.g., regarding number of aromatic rings, length and branching of the carbon chains, as well as presence of functional groups that are not present in the target substance). The Registrant has not considered in his read-across hypothesis the impact of these considerable differences in chemical structures among the category members on the possibility to predict properties of the registered substance.

ECHA notes that the differences in structure can result in wide range of properties among the category members. Fate and physicochemical properties can highlight the differences in bioavailability and thus likely differences in the degree of toxic effects between the analogues. ECHA observes that the Registrant has not considered similarity or a regular pattern in physicochemical, toxicological and ecotoxicological properties of the substances in the categories and thus did not sufficiently support the hypothesis presented.

Furthermore, the prediction reports indicate that the predictions have been established based on values obtained from several terrestrial toxicity experiments. In principle these experiments may serve as data sources of the analogue substances. However, in the absence of robust study summaries presenting the details of the methods used, ECHA cannot verify the reliability, relevance and adequacy of the experiments on the source substances.

For all the reasons listed above, ECHA considers that the proposed grouping and read-across approaches do not allow a reliable prediction of the properties of the registered substance for the endpoints under consideration. As a consequence, ECHA is of the opinion that the information, as currently provided, cannot be regarded as relevant and reliable.

ECHA rejects the read-across proposed by the Registrant, as it does not provide appropriate evidence to fulfil the information requirements included in the draft decision.

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.
Originally the registration dossier did not contain data for these endpoints. Instead, the Registrant proposed to adapt short- and long-term toxicity testing on effects on terrestrial invertebrates using the following justifications:

"Column 2 of the Corrigendum to Regulation (EC) No 1907/2006, Annex X, states, "Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. The choice of the appropriate test(s) depends on the outcome of the chemical safety assessment.
These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely."
The Koc for sediment is 4.493E+03 L/kg and the BCF worm is 380 L/kg wwt. No direct exposure to soil is expected and the exposure and risk assessment, conducted using EUSES V 2.1.1 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."

In his proposed adaptation the Registrant claims that there is no direct exposure to soil. ECHA points out that according to column 2 of sections 9.4 of Annexes IX and X, studies do not need to be conducted only when direct **and indirect** exposure of the soil compartment is unlikely. ECHA also considers that such uses are reported in the technical dossier for which soil exposure cannot be excluded, e.g. Environmental Release Category (ERC) 8d.

In his proposed adaptation the Registrant further argues that based on the Equilibrium Partitioning Method (EPM) all Risk Characterisation Ratios (RCR) for the terrestrial environment are all less than 1. The Registrant seems to consider that with the EPM alone all five standard information requirements for effects on terrestrial organisms could be waived. However, the provision does not state that the EPM alone is sufficient to justify the adaptation of the standard information requirements. The second subparagraph of that Column 2 provision needs to be read in its entirety. Its aim is to establish whether there is a possibility to waive some of the standard information requirements stemming from Column 1 of Annex IX, 9.4. In order for an adaptation of the Column 1 provisions to be justified, the Registrant would have to demonstrate by means of the Chemical Safety Report (CSR) that the conditions of an adaptation possibility in Column 2 or Annex XI are fulfilled. In establishing this, in some cases, registrants may use the EPM. Upon such a basis, registrants can thus, depending on the case, establish whether some taxonomic group(s) could be waived.

In this context registrants have to take into account the other relevant provisions in Column 2 of Annex IX. The last sub-paragraph of that provision states that when a substance has a high potential to adsorb to soil or is highly persistent, even for registrations at a tonnage level between 100 up to 1000 tonnes long-term testing shall be considered instead of short-term testing. For registrations at a tonnage level of 1000 tonnes long-term testing is a standard information requirement.

In this specific case, ECHA notes that the Registrant has not justified an adaptation pursuant to Column 2 or Annex XI. A statement that the EPM leads to an RCR below 1 does not fulfil the conditions of any adaptation rule in REACH.

In the Registrant's comment and update, in order to address ECHA's concerns that the EPM is not sufficient to justify the adaptation of the standard information requirements, the Registrant conducted a read across assessment to fulfil this information requirement, using structural analogues in the 'phenols' category with experimental data, utilizing the OECD QSAR Toolbox.

The registrant is using a read-across prediction to fill the data gap and combine these with the results of EPM assessment to conclude that the risk for soil organisms is sufficiently controlled without further testing.

As ECHA does not accept the proposed read-across approach based on the reasons provided in section III.0., the read-across approach predicted by QSAR Toolbox cannot fulfil the Annex X requirements nor to be used for PNECsoil calculations. In addition, according to the Guidance document R.7 C, EPM is not suitable to derive PNECsoil for Soil Hazard Category 4 substances. Therefore, RCRs calculated based on EPM-derived PNECsoil are not sufficient to show that the risk for soil organisms is sufficiently controlled without further testing.

Therefore, ECHA notes that the Registrant has not demonstrated that available data would lead to the conclusion that the substance is or is not toxic to soil organisms (Annex XI, 1.2.).

In fact, based on the information in the technical dossier on aquatic toxicity and on environmental fate, and in relation to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., November 2012), ECHA considers that there are indications that the substance is very toxic to aquatic organisms and for high persistence of the substance in soil. More specifically, ECHA notices that the substance is classified as very toxic to aquatic life and that the Registrant in the CSR concludes that the substance should be considered to meet the criteria as Persistent/ very Persistent. Therefore, as the standard information requirements for long-term testing have not been adapted in a justified manner, long-term soil toxicity testing is required.

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. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.1., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 41(1) 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 reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD 222), or Enchytraeid reproduction test (test method: OECD 220), or Collembolan reproduction test in soil (test method: OECD 232).

2. Toxicity testing on 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.
Originally the registration dossier dids not contain data for these endpoints. Instead, the Registrant proposed to adapt short- and long-term toxicity testing on effects on terrestrial plants using the following justifications:

"Column 2 of the Corrigendum to Regulation (EC) No 1907/2006, Annex X, states, "Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. The choice of the appropriate test(s) depends on the outcome of the chemical safety assessment.
These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely."
The Koc for sediment is 4.493E+03 L/kg and the BCF worm is 380 L/kg wwt. No direct exposure to soil is expected and the exposure and risk assessment, conducted using EUSES V 2.1.1 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."

In Registrant's comment and update, in order to address ECHA's concerns that the EPM is not sufficient to justify the adaptation of the standard information requirements the Registrant conducted a read across assessment to fulfil this information requirement, using structural analogues in the 'phenols' category with experimental data, utilizing the OECD QSAR Toolbox.

The registrant is using a read-across prediction to fill the data gap and combine these with the results of EPM assessment to conclude that the risk for soil organisms is sufficiently controlled without further testing.

As ECHA does not accept the proposed read-across approach based on the reasons provided in section III.0., the read-across approach predicted by the QSAR Toolbox predictions cannot fulfil the Annex X requirements nor to be used for PNECsoil calculations. In addition, according to the Guidance document R.7 C, EPM is not suitable to derive PNECsoil for Soil Hazard Category 4 substances. Therefore, RCRs calculated based on EPM-derived PNECsoil are not sufficient to show that the risk for soil organisms is sufficiently controlled without further testing.

Therefore, the information available on these endpoints 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 short- and long-term toxicity on terrestrial plants.

Both the Terrestrial plants, growth test (OECD 208, in the configuration as explained below) and the Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) are considered capable of generating information appropriate for the fulfilment of the information requirement for long-term toxicity testing on plants. Each of these tests is suitable to also address the information requirement of Annex IX, section 9.4.3., as specified above. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

OECD guideline 208 (Terrestrial Plant Test: Seedling Emergence and Seedling Growth) 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(1) 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 Plant Test: Seedling Emergence and Seedling Growth (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).

3. Soil micro-organisms (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.

Originally the registration dossier did not contain data for this endpoint. Instead, the Registrant proposed to adapt testing on effects on soil microorganisms 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 is 4.493E+03 L/kg and the BCF worm is 380 L/kg wwt. No direct exposure to soil is expected and the exposure and risk assessment, conducted using EUSES V 2.1.1 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."

In Registrant's comment and update, in order to address ECHA's concerns that the EPM is not sufficient to justify the adaptation of the standard information requirements the Registrant conducted a read across assessment to fulfil this information requirement, using structural analogues in the 'phenols' category with experimental data, utilizing the OECD QSAR Toolbox.

The Registrant is using a read-across prediction to fill the data gap and combine these with the results of EPM assessment to conclude that the risk for soil organisms is sufficiently controlled without further testing.

As ECHA does not accept the proposed read-across approach based on the reasons provided in section III.0., the read-across approach predicted by the QSAR Toolbox predictions cannot fulfil the Annex X requirements nor to be used for PNECsoil calculations. In addition, according to the Guidance document R.7 C, EPM is not suitable to derive PNECsoil for Soil Hazard Category 4 substances. Therefore, RCRs calculated based on EPM-derived PNECsoil are not sufficient to show that the risk for soil organisms is sufficiently controlled without further testing.

Therefore 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 1.1, November 2012), Chapter R.7C, Section R.7.11.3.1., p115, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1) 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).

Notes for consideration by the Registrant:

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 Guidance (based on EPM and other data that is available for the substance) does not apply for the present endpoint.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and 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 . The 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 Leena Ylä-Mononen Director of Evaluation

[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.