EUROPEAN CHEMICALS AGENCY

Helsinki, 23 April 2018

Addressee: [redacted]

Decision number: TPE-D-2114401220-76-01/F
Substance name: [1,3-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide
EC number: 218-664-7
CAS number: 2212-81-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 02.06.2017
Registered tonnage band: 100-1000T

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

- **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12°C, including the identification of the degradation products (Annex IX, Section 9.2.3.) using the registered substance or the analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide) (CAS No 25155-25-3; EC No 246-678-3); and**
- **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, dietary exposure using the registered substance or the analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3 (EC No 246-678-3); and**

you are requested to perform as additional test:

- **Simulation testing in sediment (Annex IX, Section 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.23./OECD TG 308) at a temperature of 12°C, including the identification of the degradation products (Annex IX, Section 9.2.3.) using the registered substance or the analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3 (EC No 246-678-3).**

You 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 to the REACH

Regulation.

To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and an adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **1 February 2021**. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons for this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard Head of Unit, Evaluation E1

[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.

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposals submitted by you for the registered substance [1,3-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide, CAS No 2212-81-9 (EC No 218-664-7) (hereafter referred to as "target substance") and scientific information submitted by third parties.

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

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Simulation testing on ultimate degradation in surface water" is a standard information requirement as laid down in Annex IX, Section 9.2.1.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3 (EC No 246-678-3) in a Simulation biodegradation study in surface water (OECD TG 309 / EU C.25) with the following justification in the endpoint summary for biodegradation: *"The ready biodegradability of 1,3-bis[1-(tert-butylperoxy)-1-methylethyl]benzene was evaluated in a study performed in accordance with OECD testing guideline 301 D and GLP requirements. As no biodegradation was observed at day 28, the peroxide should not be classified as readily biodegradable."*

ECHA notes that the information currently available in the technical dossier and the Chemical Safety Assessment (CSA) is not sufficient to conclude on the biodegradation potential and consequently the persistence of the registered substance or its degradation products in water. You indicate that the registered substance is not readily biodegradable (0% in 28 days) while *"Based upon the adsorption potential of the substance of interest, sediment and water compartment exposition is likely".*

Furthermore, no valid data on degradation of the registered substance in (aerobic) water compartment is available. ECHA notes that this information indicates that the registered substance may have persistent or very persistent (P or vP) properties. Thus, it is necessary to generate additional information for this endpoint. ECHA also considers that by submitting the testing proposal you have deemed it necessary to generate further data on this endpoint.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. A Member State Competent Authority (MSCA) submitted a Proposal for Amendment (PfA) for this endpoint, on the following aspect that the amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable.

Furthermore, when reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER." ECHA agrees with the submitted MSCAs's PfA as it reflects the current approach for this endpoint.

ECHA considers that your intentions to perform this study (OECD 309)(and consider with or without the addition of SPM) at 12°C on the analogue substance, 25155-25-3 is outside the scope of the MSCA's PfA for this endpoint. In addition, ECHA considers that your intentions to perform an OECD 308 if the challenges in the OECD 309 cannot be overcome is also outside the scope of the MSCA's PfA for this endpoint. This request will be assessed in an updated registration dossier in the Dossier follow up stage.

In the testing proposal you have not specified the temperature at which the test shall be performed. 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 3.0, February 2016) 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.16-8 (version 4.0, June 2017) 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 TG 309. Therefore, the test should be performed at the temperature of 12°C.

According to Section 9.2.3 in Annex IX of the REACH Regulation identification of degradation products is a standard information requirement. You have not justified an adaptation of this requirement for aquatic compartment.

Pursuant to Annex XIII of the REACH Regulation "*the identification* [of PBT and vPvB substances] *shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products*". Therefore, the PBT/vPvB assessment should normally be carried out for each relevant transformation or degradation product. However, ECHA notes that your CSA does not contain any information on whether the degradation products could be PBT/vPvB or not. Furthermore, ECHA notes that the identification of degradation products is a standard information requirement of Section 9.2.3 of Annex IX of the REACH Regulation.

Consequently there is an information gap and it is necessary to provide information for this information requirement. The identification of degradation products should therefore be included in the requested degradation simulation test. It is also noted that the OECD TG 309 Test Guideline features the formation and identification of the degradation products.

In your comments to ECHA's draft decision according to Article 50(1) of the REACH Regulation you have proposed to conduct testing according to OECD test guidelines 303A and 302B before deciding whether the requested simulation test in surface water is necessary.

ECHA notes that OECD TG 303A cannot be used for the determination of environmental half-lives and is not designed for the identification of degradation products. This test guideline is thus is not suitable to fulfil the standard information requirements as laid down in Annex IX, Section 9.2.1.2. and 9.2.3. of the REACH Regulation. If you plan to conduct testing according to this test guideline for the purpose of exposure assessment refinement, you will need to submit a separate testing proposal as it is beyond the scope of the present one. Such a test is indeed regarded as 'further biotic degradation testing' according to the second column of Annex X, Section 9.2.1. of the REACH Regulation.

ECHA further considers that results of the modified OECD TG 302B test can be used to assess the inherent biodegradability of the registered substance, but not to determine its environmental half-life as this test is performed under conditions that are not environmentally realistic, with very high concentrations of the test substance and of the inoculum, and because first-order kinetics cannot be assumed. Thus, this test cannot fulfil in itself the standard information requirements as laid down in Annex IX, Section 9.2.1.2. and 9.2.3. of the REACH Regulation.

Still, ECHA acknowledges that, under certain conditions, you could consider these tests in a weight of evidence approach (OECD 303A) or as screening information (OECD 302B) for the P assessment as explained in ECHA Guidance, chapters R.11. and R.7.9.

With regard to the substance to be tested, ECHA notes that you have proposed to conduct the tests with an analogue substance.

ECHA notes that the proposed analogue substance (i.e. the 'source substance': [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3, EC No 246-678-3) is a multi-constituent substance made of [redacted], whereas the registered substance (i.e. the 'target substance': CAS: 2212-81-9) is a mono-constituent which consists mainly of the [redacted]. ECHA further notes that the source substance contains more impurities ([redacted]) compared to the target substance ([redacted]).The target substance does not contain impurities that are not present in the source substance as well, and the impurities contained in the target substances are in proportions that are always lower or equivalent to those in the source substance.

For the purpose of the PBT/vPvB assessment, Annex XIII of the REACH Regulation requires that "*the identification* [of PBT and vPvB substances] *shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products*". Section R.11.4.1. of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) further specifies that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*".

Therefore ECHA considers that the persistence shall be assessed for each constituents, impurities and additives present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable. When investigating the potential persistence of the registered substance, you shall thus assess the persistence of every constituent in concentrations at or above 0.1% (w/w).

This can be achieved by performing a simulation test either with the registered substance itself or with the proposed analogue substance, since the analogue substance includes all the main constituents and impurities of the registered substance. However, ECHA also notes

that the analogue substance is expected to be more difficult to test as it contains more constituents/impurities than the registered substance. Therefore, ECHA would consider a simulation test performed with the proposed analogue substance to be acceptable to fulfil the requirement of Annex IX, Section 9.2.1.2. of the REACH Regulation, but recommends that you perform the test with the registered substance as it is deemed to be technically easier.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision or the analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3 (EC No 246-678-3): Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25/OECD TG 309) at a temperature of 12°C, including the identification of the degradation products (Annex IX, Section 9.2.3.).

2. Bioaccumulation in aquatic species, preferably fish (Annex IX, Section 9.3.2.)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3 (EC No 246-678-3) for a bioaccumulation in aquatic species (Annex IX, Section 9.3.2. of the REACH Regulation); with the test method: "*Fish dietary bioconcentration test: No international test guideline exists, but an abbreviated method has been developed by Parkerton et al. (2001) (also see Anon., 2004a), based on the dietary accumulation studies of Fisk et al. (1998).*" and with the following justification in the endpoint summary for bioaccumulation: "*According to claimed uses of [1,3-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide aquatic compartment exposure is likely. At the moment no data is available for characterizing [1,3-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide long-term effects on organisms inhabiting aquatic compartment. No substance specific data on metabolism and kinetics are available.*
Based on physical-chemical characteristics, particularly low water solubility (<0.62 mg/l), octanol-water partition coefficient (experimental log Kow is > 5.5, calculated log Kow:7.3) and low vapour pressure (0.001 Pa at 25°C), no or only limited absorption by the dermal and inhalation routes is expected, which is further supported by the acute dermal toxicity study results. Moreover the substance is not a skin irritant; therefore no increase of skin absorption is expected.
Based on the high logKow and the very low water solubility, the substance can be regarded as a lipophilic substance. Such a lipophilic compound may be taken up by micellular solubilisation by oral route exposure.
As a consequence, a fish dietary bioconcentration test would be the most relevant test to propose."

With regards to the PBT screening assessment, you indicate that the registered substance is

not readily biodegradable (0% in 28 days) and no further valid data on degradation of the registered substance is available. ECHA notes that this information indicates that the registered substance may have persistent or very persistent (P or vP) properties. Furthermore, the value used in the dossier for the log Kow of the registered substance is an estimated value of 7.3, as the experimental procedure only indicates a partition coefficient of >5.5.

Both are indicative of the substance potentially meeting the B- or vB-criterion in the PBT assessment (BCF>2000 and >5000 respectively). ECHA also considers that by submitting the testing proposal you have deemed it necessary to generate further data on this endpoint.

You have also indicated that: *"in vitro methods have the potential to provide important data on bioaccumulation assessments, and although many require sacrifice of live animals, all may contribute to a reduction in (or refinement of) animal testing. (..)So, before carrying a complete fish dietary bioconcentration tests, we propose to use one of these alternative methods in order to comment on the metabolic capacities of fish concerning the substance of interest. Hepatocytes test might be the most appropriate proposal, testing would be done on the structurally analogous [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide".*

ECHA observes that *in vitro* data on fish metabolism is not appropriate to fulfil standard REACH information requirement, though results of such studies can support the bioaccumulation assessment and can be considered as part of a potential weight of evidence approach.

In addition to the testing proposal, you have submitted a study for an *in vitro* fish liver S9 metabolism study on the analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3 (EC No 246-678-3). ECHA observes that in this study both the extrapolation from *in vitro* to the overall *in vivo* metabolism rate constant and the determination of the *in vitro* metabolism rate constant are too uncertain to draw firm conclusion about the bioaccumulation potential of the analogue substance.

ECHA observes that OECD 305 test guideline includes a test for both aqueous and dietary (OECD TG 305-III: Dietary Exposure Bioaccumulation Fish Test) exposure. As the dietary exposure method does not directly provide a BCF that can be compared to the bioaccumulation criteria, the aqueous exposure shall be used whenever feasible. However, taking into account low water solubility (0.04 mg/L) and high octanol-water partition coefficient (experimental log Kow is > 5.5, calculated log Kow: 7.3) of the registered substance, ECHA considers that fish bioaccumulation testing via dietary route is appropriate in this case.

ECHA requested your considerations for alternative methods to fulfil the information requirement for bioaccumulation in aquatic species. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

In your comments to ECHA's draft decision according to Article 50(1) of the REACH Regulation you have proposed to assess first the potential persistence of the substance before deciding whether a bioaccumulation test is needed. You have agreed to investigate further the bioaccumulation potential of the substance if it is shown to be persistent.

However, you have proposed to conduct a bioaccumulation test according to OECD test guideline 315 (Bioaccumulation in Sediment-dwelling Benthic Oligochaetes), whereas you will perform the requested OECD 305 test only if the results of the OECD 315 test on oligochaetes does not rule out a high bioaccumulation potential for the substance. ECHA notes that the information derived from the OECD 315 test can be used to fulfil REACH Annex IX 9.3.2. standard information requirements. However, if the P/vP assessment indicates that further information for the definitive conclusion on B/vB properties needs to be generated, according to the ECHA *Guidance on information requirements and chemical safety assessment (PBT/vP/vB assessment), Chapter R.11.4.1.2.*, the preferred test methods for investigating bioaccumulation is 1) OECD 305 - I aqueous exposure, 2) then OECD 305-III dietary exposure if aquatic exposure is not technically feasible (as considered for this case), 3) and if, for some reason, the other tests were not technically feasible, or if exposure from sediment were expected to be more relevant than from the water column, only then OECD 315 would be the preferred option.

ECHA also notes that the existing *in vitro* fish liver S9 assay with the analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3 (EC No 246-678-3) can be included as one piece of evidence in a potential weight of evidence approach, but would not be appropriate in itself to fulfil the standard information requirement of Annex IX, Section 9.3.2. of REACH (see ECHA Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017), chapter R.11.4.1.2.10).

With regard to the substance to be tested, ECHA notes that you have proposed to conduct the tests with an analogue substance.

ECHA notes that the proposed analogue substance (i.e. the 'source substance': [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3, EC No 246-678-3) is a multi-constituent substance made of [redacted], whereas the registered substance (i.e. the 'target substance': CAS: 2212-81-9) is a mono-constituent which consists mainly of the [redacted]. ECHA further notes that the source substance contains more impurities ([redacted]) compared to the target substance ([redacted]). The target substance does not contain impurities that are not present in the source substance as well, and the impurities contained in the target substances are in proportions that are always lower or equivalent to those in the source substance.

For the purpose of the PBT/vPvB assessment, Annex XIII of the REACH Regulation requires that "*the identification* [of PBT and vPvB substances] *shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products*". Section R.11.4.1. of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) further specifies that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*".

Therefore ECHA considers that bioaccumulation shall be assessed for each constituents, impurities and additives present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable. When investigating the bioaccumulation potential of the registered substance, you shall thus assess the bioaccumulation of every constituent in concentrations at or above 0.1% (w/w).

This can be achieved by performing a bioaccumulation test either with the registered substance itself or with the proposed analogue substance, since the analogue substance includes all the main constituents and impurities of the registered substance. However, ECHA also notes that the analogue substance is expected to be more difficult to test as it contains more constituents/impurities than the registered substance. Therefore, ECHA would consider a bioaccumulation test performed with the proposed analogue substance to be acceptable to fulfil the requirement of Annex IX, Section 9.3.2. of the REACH Regulation, but recommends that you perform the test with the registered substance as it is deemed to be technically easier.

No Member State Competent Authority (MSCA) submitted a Proposal for Amendment (PfA) for this endpoint. ECHA considers that it is your intention to perform this study (OECD 305)(via the aqueous exposure) on the analogue substance, 25155-25-3, as outlined in the substance evaluation decision, following the outcome of the P. ECHA considers your intention is outside the scope of this decision making stage as no MSCA's PfA was submitted for this endpoint. This request will be assessed in an updated registration dossier in the Dossier follow up stage.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision or the analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3 (EC No 246-678-3):
Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, dietary exposure route using the registered substance.

Notes for your consideration

Before conducting the above test, you are advised to consult the ECHA *Guidance on the information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.11.4 and Figure R.11-4 on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. In particular, you are advised to first conclude on whether the registered substance is not persistent (P) and not very persistent (vP) or whether it may fulfil Annex XIII of the REACH Regulation criteria of being P or vP and to consult the PBT assessment for Weight-of-Evidence determination and the integrated testing strategy for bioaccumulation assessment, in particular concerning relevant constituents, impurities, additives and degradation/ transformation products. Also, you need to carefully consider the potential formation of stable degradation products with PBT/vPvB properties. You should revise the PBT assessment when information on bioaccumulation is available.

In addition, you are advised to consult the ECHA Guidance on information the information requirements and chemical safety assessment, Chapters R.4, 5, 6, R.7b and R.7c. If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, you are referred to the advice provided in ECHA's Practical Guide on "How to use alternatives to animal testing to fulfil your information requirements" (chapters 3.3, 4.2 and 4.4).

Due to the low solubility of the substance in water and high octanol-water partition coefficient, you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b*, Table R.7.8-3 (version 4.0, June 2017) summarising aquatic toxicity testing of difficult substances) for choosing the design of the requested test and calculation and expression of the results of

the test.

3. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out additional tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI. ECHA considers that proposed test on Simulation testing on ultimate degradation in surface water is not sufficient by itself to address the standard information requirements of Annex IX, Section 9.2.1.

"Sediment simulation testing" is a standard information requirement for substances with a high potential for adsorption to sediment as laid down in Annex IX, Section 9.2.1.4. of the REACH Regulation. In the technical dossier you specify that registered substance has a high potential for adsorption, while water and sediment exposure is likely.

ECHA notes that the information currently available in the technical dossier and the Chemical Safety Assessment (CSA) is not sufficient to conclude on the biodegradation potential and consequently the persistence of the registered substance or its degradation products in sediment. You indicate that the registered substance is not readily biodegradable (0% in 28 days) while "*Based upon the adsorption potential of the substance of interest, sediment and water compartment exposition is likely*". Furthermore, no valid data on degradation of the registered substance in aquatic sediment compartment is available. ECHA notes that this information indicates that the registered substance may have persistent or very persistent (P or vP) properties. Thus, it is necessary to generate additional information for this endpoint. As the substance has a high potential for adsorption to sediment, sediment simulation testing is a standard information requirement for the substance. The information on this endpoint is however not available for the registered substance. Consequently there is an information gap and it is necessary to provide information for this endpoint.

While there is no testing proposal addressing the data gap in your dossier, you have submitted an anaerobic sediment study according to a US EPA guideline on the analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3 (EC No 246-678-3). However, ECHA notes that this test cannot be regarded as a simulation study since the test conditions were not reflecting environmental conditions. Consequently, results of this test cannot be used to fulfill the information requirement of Annex IX, Section 9.2.1.4. of the REACH Regulation.

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 4.0, June 2017) 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.16-8 (version 3.0 February 2016) 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 TG 308. Therefore, the test should be performed at the temperature of 12°C.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound or incorporated into the biomass. When reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

According to Section 9.2.3 in Annex IX of the REACH Regulation identification of degradation products is a standard information requirement. In the technical dossier you have attempted to adapt this requirement for anaerobic sediments: *"Tert-butanol, the main expected breakdown product, was detected in water and sediment layers at all time point (except day 0) but below a quantifiable level until day 90: it represented an average of 61.5% of the test substance applied dose."* ECHA observes that this explanation is not sufficient to fulfil the standard information requirement for the identification of degradation products. The concentration of tert-butanol, the expected monitored product, was monitored. However, other breakdown products are not identified. Thus, this adaptation cannot be accepted. As elaborated in Section 2 of this decision PBT assessment shall take into account properties of all relevant constituents and transformation products. ECHA notes that your CSA does not contain any information on whether the degradation products could be PBT/vPvB or not. Consequently there is an information gap and it is necessary to provide information for this information requirement. The identification of degradation products should therefore be included in the requested degradation simulation test. It is also noted that the OECD TG 308 Test Guideline features the formation and identification of the degradation products.

In your comments to ECHA's draft decision according to Article 50(1) of the REACH Regulation you indicate the intention to conduct testing according to OECD test guidelines 303A and 302B. As explained in section 2 of the present decision, neither a OECD 303A test nor a OECD 302B would fulfill as such the information requirement of Annex IX, Section 9.2.1.4. and 9.2.3. of the REACH Regulation. However, under certain conditions, you could consider these tests in a weight of evidence approach (OECD 303A) or as screening information (OECD 302B) for the P assessment as explained in ECHA Guidance, chapters R.11. and R.7.9.

With regard to the substance to be tested, ECHA notes that you have proposed to conduct the tests with a analogue substance (i.e. the 'source substance': [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3, EC No 246-678-3).

No Member State Competent Authority (MSCA) submitted a Proposal for Amendment (PfA) for this endpoint. ECHA considers that it is your intention to perform this study (OECD 308) on the analogue substance, 25155-25-3, if the challenges in the OECD 309 cannot be overcome. ECHA considers your intention is outside the scope of this decision making stage as no MSCA's PfA was submitted for this endpoint. This request will be assessed in an updated registration dossier in the Dossier follow up stage. Please see request 1.above for further details.

As explained above, in section 2 of the present decision, you can perform the requested simulation test either with the registered substance or with the proposed analogue substance, since the analogue substance includes all the main constituents and impurities of the registered substance. However, ECHA recommends that you perform the test with the registered substance as it is deemed to be technically easier.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the following additional study using the registered substance subject to the present decision or the analogue substance [1,3(or1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (Meta/para-bisperoxide), CAS no. 25155-25-3 (EC No 246-678-3): Aerobic and anaerobic transformation in aquatic sediment systems (test method: EU C.24/OECD TG 308) at a temperature of 12°C, including the identification of the degradation products (Annex IX, Section 9.2.3.).

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above in Sections 2-3 are available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), 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.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 13 June 2016.

ECHA held a third party consultation for the testing proposals from 20 October 2016 until 5 December 2016. ECHA did not receive information from third parties.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

You were notified that the draft decision does not take into account any updates after **15 March 2017**. You updated your registration with submission number [redacted] on **14 March 2017**. However, due to technical reasons this submission failed. You made a second update on **6 June 2017** with submission number [redacted]. Given the exceptional circumstances, ECHA has taken into account the latter update when processing this decision, resulting in the removal of the testing proposal for a pre-natal developmental toxicicity study in a second species (Annex X, Section 8.7.2) and amending the decision with regard to: simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.), bioaccumulation in aquatic species (Annex IX, Section 9.3.2.), and simulation testing in sediment (Annex IX, Section 9.2.1.4.).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposals for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendments.

ECHA referred the draft decision to the Member State Committee.
Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-58 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. In carrying out the tests 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 or imported. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.