ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 8 January 2018

Addressee [redacted]

Decision number: CCH-D-2114384248-40-01/F
Substance name: BIS(2,2,6,6-TETRAMETHYL-4-PIPERIDYL) SEBACATE
EC number: 258-207-9
CAS number: 52829-07-9a
Registration number: [redacted]
Submission number: [redacted]
Submission date: 29 May 2015
Registered tonnage band: 1000+T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. / OECD TG 471) with the registered substance;**

2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance;**

3. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species (rabbit or rat), oral route with the registered substance;**

4. **Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance specified as follows:**

   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce some toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**
   - **Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;**
   - **Cohorts 2A and 2B (Developmental neurotoxicity);**

5. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

6. **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 with the registered substance;

7. **Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD TG 307) at a temperature of 12 °C with the registered substance;**

8. **Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24./OECD TG 308) at a temperature of 12 °C with the registered substance;**

9. **Long-term toxicity testing to sediment organisms (Annex X, Section 9.5.1.; test method: using one or more of the following test methods: Sediment-water Chironomid toxicity using spiked sediment (OECD TG 218) or Sediment-water Lumbriculus toxicity test using spiked sediment (OECD TG 225) or Sediment-Water Chironomid Life-Cycle Toxicity Test using Spiked Sediment (OECD TG 233) with the with the registered substance.**

10. **Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD TG 222, or Enchytraeid reproduction test, OECD TG 220, with the registered substance;**

11. **Long-term toxicity testing on plants (Annex X, Section 9.4.6.,; test method: Terrestrial plants, growth test, OECD TG 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) with the registered substance;**

12. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) and carbon transformation test, EU C.22/OECD TG 217) with the registered substance.**

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 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 and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **15 July 2021**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. 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, shall 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 Ofelia Bercaru, Head of Unit, Evaluation E3

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

An "*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.

In the technical dossier you have provided a study record for a non-guideline, non-GLP Ames test from the year 1976. However, this study does not provide the information required by Annex VII, Section 8.4.1., for the following reasons: (i) no positive controls for TA98, TA100 and TA1537 with metabolic activation, (ii) no strain with an AT basepair at the primary reversion site is tested, (iii) no independent repeat test performed, and (iv) initial bacterial concentration not indicated. Assessment of these parameters and the related information are required according to the OECD TG 471 for the study to be considered adequate. ECHA considers that due to these shortcomings, the provided study is not considered valid and reliable.

As explained above, the information provided 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.

In the comments to the draft decision you have explained your intention to apply a read-across and grouping approach to fulfil the information requirements for the endpoint *in vitro* gene mutation in bacteria, with the data from the source substance Tinuvin 292 (EC 915-687-0). You have provided a read-across justification document [redacted]

ECHA understands that your read-across approach is based on structural similarities and similar toxicological profiles of the substances.

Regarding genotoxicity ECHA notes the source substance did not induce mutations in the *in vitro* gene mutation study in bacteria (OECD 471). The target substance was negative in mammalian cell gene mutation assay (OECD 476; no studies with the source substance) and in the *in vitro* mammalian chromosome aberration test (OECD 473). The source substance was positive in *in vitro* mammalian chromosome aberration test (OECD 473) but negative in the *in vivo* micronucleus test (OECD 474). In addition, the structural differences between source and target substances do not indicate a difference in genotoxic potential. Thus it can be concluded that the target and source substances (as parent substances) are not likely to be genotoxic. With regard to possible hydrolysis products, ECHA further notes that based on the data provided in the read-across justification document, HTMP (hydrolysis product of the target substance), HPMP (hydrolysis product of the source substance) and sebacic acid (common hydrolysis product of both substances) are negative in the *in vitro* gene mutation study in bacteria (OECD 471).

ECHA considers that this information, although based on a limited data set, further supports the non-genotoxicity of the target and source substances.

Based on the information presented in your comments on the draft decision the proposed prediction for the outcome of the *in vitro* gene mutation study in bacteria Ames test provided in your comments on the draft decision meets the requirements of Annex XI, Section 1.5.

While ECHA acknowledges that with this information (i.e. read-across justification document and robust study summaries of the source study and supporting studies) the read-across adaptation may be considered as acceptable, ECHA notes that this information needs to be included in the technical dossier in the formats requested by the REACH Regulation. While for the purpose of this decision making, ECHA does not take into account any dossier updates after the notification of this draft decision under Article 50(1) of the REACH Regulation, ECHA notes that dossier updates and any adaptations therein will be evaluated by ECHA at the follow up stage. Therefore, the request to submit information addressing the information requirement as specified below remains in the decision.

ECHA considers that the bacterial reverse mutation test (test method EU B.13/14. / OECD TG 471) is appropriate to address the standard information requirement of Annex VII, Section 8.4.1. of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 471).

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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.

You have sought to adapt this information requirement according to Annex IX, Section 8.7.2., column 2. You provided the following justification for the adaptation:

"Study scientifically unjustified: A developmental toxicity study is considered unjustified based on the available information. In repeat-dose toxicity studies up to 90 days in rats and dogs, no indication of the substance causing effects on the reproductive organs were seen. Furthermore, a 1-Generation study did not affect the development of the offspring, that can be interpreted as organogenesis is not disturbed at any stage.

This is in line with the assessment of the toxicokinetic behaviour suggesting the substance is not extensively absorbed and undergoes a rapid metabolism and elimination, without any

potential for accumulation in the exposed organism. It is concluded that exposure to the substance is not hazardous for reproduction in any species including humans. This argumentation is in accordance with column 2 of REACH Annex IX for criteria to avoid animal testing".

ECHA notes that Annex IX, Section 8.7., column 2 specifies that reproductive toxicity studies do not need to be conducted if "*the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure*". ECHA notes that all three criteria need to be met in order to omit the conduct of a reproductive toxicity study.

ECHA notes that based on the toxicokinetic assessment provided by you, the substance "*is expected to be well absorbed from the gastrointestinal tract*". Absorption is further supported by effects observed in the sub-chronic toxicity studies. In addition, based on the data provided in the CSR, human exposure occurs.

ECHA further notes that while you refer to Column 2 of Annex IX, your adaptation could also be interpreted as an attempt to adapt the information requirement according to Annex XI, section 1.2., by using a weight of evidence approach. Indeed, you have based your adaptation on lack of effects on the reproductive organs in the (sub)-chronic studies and lack of developmental effects in the one-generation study. ECHA notes that an absence of adverse effects on reproductive organs does not provide information on developmental toxicity and that the one-generation toxicity study does not provide the information required by Annex IX, Section 8.7.2. because it does not include key investigations of a pre-natal developmental toxicity study such as examinations of foetuses for skeletal and visceral malformations and variations. ECHA therefore concludes that the data provided does not provide sufficient information to conclude on the developmental toxicity of the registered substance.

ECHA concludes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 8.7, column 2 and Annex XI, section 1.2.

Therefore, your adaptation of the information requirement is rejected.

As explained above, the information provided 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.
According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

In your comments to the draft decision you agree to perform the test with the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a first species (rat or rabbit) by the oral route.

3. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

You have sought to adapt this information requirement according to Annex X, Section 8.7., column 2. You provided the same justification as the one you provided for adapting the information requirement in Annex IX section 8.7.2.

ECHA notes that you have adapted this information requirement for the same reasons as you did for the pre-natal developmental toxicity, first species. For the same reasons as set out in Appendix 1, section 2 above, your adaptation of the information requirement is rejected.

As explained above, the information provided 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.

According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with rabbits or rats as a second species, depending on the species tested in the first pre-natal developmental toxicity study.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, OJuly 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

In the comments to the draft decision you state that a decision on the pre-natal developmental toxicity study in a second species will be taken based on the results of the first pre-natal developmental toxicity study and taking into account the adaptation possibilities in Annex X, Section 8.7. or Annex XI. ECHA considers that a pre-natal developmental toxicity study in a second species is required unless the specific rules for adaptation in Annex X, Section 8.7. or Annex XI are met. It is a standard information requirement that cannot be waived based on a future pre-natal developmental toxicity test on a first species.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species (rabbit or rat) by the oral route.

Notes for your consideration

You are reminded that before performing a pre-natal developmental toxicity study in a second species you must consider the specific adaptation possibilities of Annex X, Section 8.7.2., column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

4. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

The basic test design of an extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Further detailed guidance on study design and triggers is provided in the ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 6.0, July 2017).

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

a) The information requirement

ECHA understands that you have sought to adapt this information requirement using a weight of evidence approach according to Annex XI, Section 1.2 based on information obtained in a "one-generation reproduction toxicity study" (test method: OECD TG 415) conducted with the registered substance and on further arguments that you presented as follows: *"REACH allows the assessment of the reproductive toxicity of a given chemical with the help of findings from studies with repeated administration. This is in line with the idea that the information requirements under REACH are regarded as the evaluation of endpoints which does not necessarily require data from specific studies.*

Because of a high correlation, histopathology data and organ weights from repeated dose studies may be used to assess male fertility (Mangelsdorf, 2003). These parameters, taken from 90 day studies, were in fact shown to be more sensitive than fertility parameters that were measured during multi-generation studies. It could also be shown that exposure for 4 weeks suffices for an assessment of male fertility, although 90 day studies have been regarded as superior in the past because they cover a complete cycle of spermatogenesis (Mangelsdorf, 2003). If such a 28 day study shows neither relevantly elevated testis or ovary weights nor histopathological alterations in those organs, the weight of the evidence is that effects on reproduction are also not expected (BAuA Forschungsbericht Fb 984, 2003). A comparison of more than one hundred 90 day studies with two-generation studies that used the same test substance additionally showed that the NOAELs differed by less than the variation limit of studies, i.e. a factor of two (Janer, 2007). Therefore, the information gained from a two-generation study can be regarded as minimal if a 90 day study will be performed."

ECHA has assessed the weight of each of these lines of information and the conclusions of this assessment are reported below.

The one-generation reproductive toxicity study conducted with the registered substance in accordance with the OECD test guideline 415 does provide information on the reproductive toxicity of the registered substance on aspects such as mating and fertility indices, litter size and development of the offspring up to the weaning. However, this study does not provide the information required by Annex X, Section 8.7.3. because it does not investigate all the key aspects/elements and cover the exposure duration and life stages of an extended one-generation reproductive toxicity study (OECD TG 443). The main missing key aspects/elements are premating exposure duration for ten weeks also for females to cover the folliculogenesis, information on estrous cyclicity and sperm parameters, thyroid hormone measurements, and an extensive postnatal evaluation of the F1 generation. Furthermore, in this case the criteria of Annex X, Section 8.7.3., column 2 are met for inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and information for those properties is not provided in this one-generation reproductive toxicity study. Therefore, given the deficiencies identified above, ECHA concludes that the one-generation reproductive toxicity study does not, on its own, provide the information required by Annex X, Section 8.7.3.

In addition, you indicate that "*REACH allows the assessment of the reproductive toxicity of a given chemical with the help of findings from studies with repeated administration.*" and support this statement by referring to three scientific publications; two on the use of information on histopathology and organ weights from repeated dose studies to assess in particular the male fertility (Mangelsdorf *et al.*, 2003; BAuA, 2003), and one to compare the NOAEL values from subchronic and two-generation reproductive toxicity studies (Janer *et al.*, 2007).

Observations on reproductive organs and tissues conducted in the context of repeated-dose toxicity studies, such as histopathology and information on reproductive organ weights, do constitute relevant information on morphology and integrity of reproductive organs. However these studies do not address functional fertility. Therefore, ECHA considers that information obtained from 28-day or 90-day repeated-dose toxicity studies does not address all relevant aspects of male or female fertility in order to conclude on hazardous properties of the registered substance.

In your adaptation argument you further state that "*exposure for 4 weeks suffices for an assessment of male fertility, although 90 day studies have been regarded as superior in the past because they cover a complete cycle of spermatogenesis (Mangelsdorf, 2003)*". ECHA notes that according to the authors' conclusions, four weeks exposure is sufficient for detecting male reproductive toxicants in histopathologic examinations. As explained above, histopathology alone does not provide sufficient information to conclude on the potential for effects on other aspects of male fertility.

The publication of Janer *et al.* (2007) mentioned in your adaptation argument reports the outcome of a comparison of results from two-generation reproductive toxicity and sub-chronic toxicity (90-day) studies conducted with the same substances. The authors concluded that, on average, for each pair of studies, there was a "*less than twofold*" difference between the NOAEL values. However, the authors also note that for some of the substances this difference in NOAELs between the two-generation reproductive toxicity and sub-chronic toxicity studies could be up to 10-fold. ECHA notes that there is no general information on differences of NOAEL values for reproductive toxicity between the 90-day studies and extended one-generation reproductive toxicity studies. More importantly, substance-specific information on both risk assessment and classification and labelling (including categorisation) is needed. Thus, general considerations of differences between the NOAEL values in various studies based on other substances do not provide reliable information to address the risk assessment and intrinsic hazardous properties of the registered substance.

In addition, about one-third of the substances did not show any evidence of toxicity in reproductive organs in the 90-day studies whereas fertility was affected in the related reproductive toxicity studies (Janer *et al.*, 2007). This observation appears to conflict with the conclusions of Mangelsdorf *et al.*(2003) and the BAuA (2003) report, which suggest that histopathology of the testes and weights of reproductive organs from repeated dose toxicity studies (28-day and 90-day) are more sensitive parameters than mating/fertility parameters measured in the reproductive toxicity studies.

The information requirement for an extended one-generation reproduction toxicity study encompasses a comprehensive assessment of reproduction toxicity with a focus on sexual function and fertility for both genders. Particularly, the consequences of toxicity to early

follicular development on fertility is not addressed because the default premating exposure duration in females is limited to two weeks according to OECD TG 415 and does not cover the full folliculogenesis. ECHA notes that the association between histopathology and fertility effects that you reported in your weight of evidence approach concerns mainly male fertility and, as also highlighted above, does not add substance-specific information to the weight of evidence regarding male or female fertility of your registered substance.

The information on effects on reproduction should be adequate for both the risk assessment as well as for classification and labelling, including categorisation. You have not provided reliable substance-specific justification substantiated with data why information from histopathology and organ weights alone would suffice for you substance for risk assessment and classification purposes and other aspects of reproduction do not have a role and do not need to be investigated.

In addition, the information requirement for an extended one-generation reproduction toxicity study also requires information on reproductive toxicity in offspring. Information on certain aspects of sexual function and fertility, including sexual maturation, is required from the F1 generation. The data obtained from the one-generation reproductive toxicity reported in the dossier and the additional information provided in your weight of evidence approach do not provide information on these aspects from the F1 generation up to their adulthood. Further, in this specific case, ECHA is of the opinion that there is also a need to investigate developmental neurotoxicity because the criteria to include the Cohorts 2A and 2B in an extended one-generation reproductive toxicity study are met, as further detailed below.

Taken together, ECHA considers that neither the individual pieces of evidence nor the total weight of evidence, including the information from the one-generation reproduction toxicity study, address critical elements expected to be investigated in an extended one-generation reproductive toxicity study and on which ECHA considers that information is necessary to conclude on the presence or absence of hazardous properties on reproduction. Therefore, ECHA concludes that the weight of the information that you have provided does not allow to conclude or assume that the registered substance has or has not hazardous properties on reproduction, as required by the provisions of Annex XI, section 1.2 of the REACH Regulation.

Hence, the information provided 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. Thus, an extended one-generation reproductive toxicity study according Annex X, Section 8.7.3. is required. The following refers to the specifications of this required study.

b) The specifications for the study design

Premating exposure duration and dose-level setting

To ensure that the study design adequately addresses the fertility endpoint, the duration of the premating exposure period and the selection of the highest dose level are key aspects to be considered. According to ECHA Guidance, the starting point for deciding on the length of premating exposure period should be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required because there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 6.0, July 2017).

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

If there is no existing relevant data to be used for dose level setting, it is recommended that results from a conducted range-finding study (or range finding studies) are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

Cohorts 2A and 2B

The developmental neurotoxicity Cohorts 2A and 2B need to be conducted in case of a particular concern on (developmental) neurotoxicity as described in column 2 of 8.7.3., Annex X. When there are triggers for developmental neurotoxicity, both the Cohorts 2A and 2B are to be conducted as they provide complementary information.

In the technical dossier you state that "*The test substance was shown to act as an antagonist at the nicotinic acetylcholine receptors in in vitro studies or when administered parenterally. However, no adverse effects in terms of neurotoxicity could be observed when given orally in repeated dose toxicity studies, indicating a rather poor uptake and limited bioavailability and/or fast metabolic transformation in less active metabolites.*" ECHA notes that you have provided several *in vitro* study reports, which show that the registered substance indeed is an inhibitor of the nicotinic acetylcholine receptors.

ECHA notes that existing information on the registered substance itself from a 28-day repeated dose toxicity study ([redacted] 1976; doses of 600, 1000 and 2000 mg/kg bw/day) shows evidence of adverse effects on the nervous system, such as ptosis of eye lids, muscular hypotonia, stiff movements and tremor, at all dose levels. Even though the high dose and mid dose caused mortality, these effects were observed also with the low dose without any systemic toxicity, and are thus considered as a particular concern.

ECHA further notes that a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) conducted with the assumed metabolite of the registered substance (2,2,6,6-tetramethylpiperidin-4-ol (HTMP), EC no 219-291-2) showed evidence of mydriasis (dilation of the pupil) and ptosis of eye lids in all doses (60, 200 and 600 mg/kg/day) and both sexes, in a dose-related manner.

In addition, ECHA notes that a repeated dose 28-day oral toxicity study (OECD TG 407) with Reaction mass of bis(1,2,2,6,6-pentamethyl-4-piperidyl) sebacate and methyl 1,2,2,6,6-pentamethyl-4-piperidyl sebacate (EC no 915-687-0), which is a structural analogue to the registered substance, showed evidence of retarded or no adaptation of the pupil to light at 750 mg/kg/day (male) and 1000 mg/kg/day (females).

The muscles that control the size of the pupil are controlled by the sympathetic or para-sympathetic nervous system. The concern for developmental neurotoxicity is therefore supported by the observed physiological changes in neuronally controlled muscle function/activity.

ECHA concludes that the developmental neurotoxicity Cohorts 2A and 2B need to be conducted because there is a particular concern on (developmental) neurotoxicity based on the results from the above-identified *in vivo* studies and from non-animal approaches on the registered substance itself, its assumed metabolite and a substance structurally analogous to the registered substance.

The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

Species and route selection

According to the test method EU B.56./ OECD TG 443, the rat is the preferred species. On the basis of this default assumption, ECHA considers that testing should be performed in rats.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

In the comments to the draft decision you agree to perform the test with the registered substance.

c) Outcome

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation; and
- Cohorts 2A and 2B (Developmental neurotoxicity).

Notes for your consideration

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B and/or Cohort 3 if new information becomes available after this decision is issued to justify such an inclusion. Inclusion is justified if the new information shows triggers which are described in column 2 of Section 8.7.3., Annex X and further elaborated in ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 6.0, July 2017).

You may also expand the study to address a concern identified during the conduct of the extended one-generation reproduction toxicity study and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the expansion must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

5. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a long-term toxicity on fish in the dossier that would meet the information requirement of Annex IX, Section 9.1.6.1 / 9.1.6.2 / 9.1.6.3.

Instead, you have sought to adapt this information requirement. You provided the following justification for the adaptation "*Data on the long-term toxicity to daphnids is available ([redacted] 2000). The results of short-term toxicity studies to fish and daphnids demonstrated that the L(E)C50-values were found to be in the same range. Hence, it is assumed that the result of a long-term fish study would also be in the same range as the result of the provided long-term toxicity study to daphnids.*

Therefore, and for reasons of animal welfare, no long-term toxicity study to fish is provided." While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex IX, Section 9.1.6.1., Column 2.

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6.1., Column 2. In your adaptation you refer to low relative species sensitivity within acute toxicity tests. According to ECHA *Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4)*, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

You concluded in your current chemical safety assessment attached to your technical dossier, that the risks are controlled based on data provided for acute toxicity on all three trophic levels and long-term toxicity on algae and aquatic invertebrates. ECHA notes that the risk assessment you refer to in your adaptation is based on a PNEC with an assessment factor of 10, justified by the following *"Acute tests for all three trophic levels plus a chronic long-term test to Daphnia and the NOEC of the algae test (which is the most sensitive species) are available. PNEC derivation is based on the NOEC of the algae study (0.188 mg/L) and an assessment factor of 10 according to table R.10-4, Nota d, of REACH guidance document R10. As algae are more sensitive to the test item than fish (based on the results of the acute studies), it is assumed that a further long-term result in fish would not be lower than the data already available."* ECHA notes that according to ECHA *Guidance on information requirements and chemical safety assessment (May 2008), Chapter R10 (Section R.10.3.1.2, including Table R.10-4),* an assessment factor of 10 will normally only be applied when long-term toxicity results (e.g. EC10 or NOECs) are available from at least three species across three trophic levels (e.g. fish, Daphnia, and algae or a non-standard organism instead of a standard organism). In the absence of long-term toxicity data on fish, the assessment factor of 10 is unjustified. A data set including long-term toxicity results from aquatic invertebrates and algae would currently merit a use of an assessment factor of 50 based on the ECHA Guidance cited above. An assessment factor of 50 applies to the lowest of two long term results (e.g. EC10 or NOECs) covering two trophic levels when such results have been generated covering that level showing the lowest L(E)C50 in the short-term tests.

Based on the deficiencies stated above, your risk characterisation is not reliable and therefore your adaptation of the information requirement cannot be accepted.

In the comments to the draft decision, you indicate that you consider the requested chronic study in fish neither meaningful nor necessary. In particular in your comments you argue that the algae growth inhibition study used in PNEC derivation is considered reliable, and that the AF of 10 is considered appropriate.

ECHA notes that the algae growth inhibition study was addressed in an earlier dossier evaluation decision CCH-D-0000004521-82-03/F and the outcome of the assessment under Article 42(2) is that this endpoint is compliant but with deviations (see further under Appendix 2).

Regarding the use of AF of 10 you state in your comments that "*the data available comprise two long-term results from species representing two trophic levels (Daphnia and algae). This would suggest the use of an assessment factor of 50 according to the guidance cited above*". ECHA acknowledges that, as indicated in ECHA *Guidance on information requirements and chemical safety assessment (May 2008), Chapter R10 (Section R.10.3.1.2, including Table R.10-4),* an AF of 50 is appropriate if valid long-term toxicity data on two trophic levels are available.

If the recommended AF of 50 were applied, you note that the current risk assessment would deliver RCRs greater than 1. You argue that you consider a lower AF (AF 10) appropriate, which would lead to RCRs below 1, "*based on the results of the acute aquatic toxicity studies with the registration item*". You "*believe(s) that a chronic fish study would not reveal a NOEC lower that the one obtained from the algae study*", even though "*the difference between the EC50 in algae and the LC50 in fish does not reach a factor of 10*" but the "*respective factor exceeds 6, which is considerable*".

ECHA points out that the justification to use a lower assessment factor of 10 is not supported by evidence. Your argument to use the lower AF than recommended is based on an assumption that algae is the most sensitive species in the chronic studies if it is found to be the most sensitive species in the acute studies. ECHA notes that the AFs are designed not only to cover variation arising from interspecies differences in sensitivity but also from extrapolation from acute to chronic effects, which is by nature species/endpoint specific.

An acute-to-chronic ratio cannot be assumed to be standard across species for several reasons. 1) Mode of action of a substance may influence some species/endpoints more than others and this sensitivity may not be detected in acute studies measuring different endpoints. 2) The measured effects in fish short-term study are only lethality in 96-h while in chronic studies the fish toxicity is measured by several sublethal endpoints such as hatching and growth within a much longer time period than 96-h (>28-d depending on the species). In contrast for algae, the chronic NOEC and acute EC50 are derived from the same study, i.e. from same endpoints and same duration (72-h NOEC versus EC50 of growth inhibition). Therefore it may be that that the acute-to-chronic ratio for algae is smaller than for fish. Consequently, your claim that "*a chronic fish study would not reveal a NOEC lower that the one obtained from the algae study*" is not self-evident nor supported by evidence.

Based on the argument that algae is the most sensitive species, you conclude that "*there is a (valid) risk assessment available demonstrating that neither fish in particular nor the environment in general are at risk due to the use of the registration item. The registrant notes that the RCRs resulting from this assessment are well below 1 for all uses and all protection targets, respectively*". ECHA notes that such conclusion for no risk is based on an AF which is not justified and supported by evidence, as described above. ECHA considers that, as described in the draft decision, your specific adaptation for this endpoint is not justified.

As explained above, the information provided 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.

ECHA notes that in your comments on the draft decision (DD) submitted during the commenting phase on the Proposal for Amendment submitted by Member State Competent Authorities you indicated that in your comments on the initial DD you had provided ECHA with inaccurate information concerning the risk assessment. You indicate that you will update the environmental risk assessment using an appropriate Assessment Factor (AF), an AF of 50, which in your understanding would lead to no risks. ECHA notes that no dossier update has been submitted. Any dossier updates and adaptations therein will be assessed by ECHA at the follow up stage.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R7b, Figure R.7.8-4).*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 4.0, June 2017).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration

Regarding conclusion of the risk assessment, the need to perform long-term toxicity testing on fish may become unnecessary after degradation data from simulation studies requested in this draft decision (requests 6-8) become available in the technical dossier allowing you to update the predicted environmental concentrations (PEC) and risk assessment.

Furthermore, ECHA refers to above for the discussion on the use of an appropriate Assessment Factor in the environmental risk assessment. ECHA notes also that according to ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. However, if based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However,

if a risk is indicated, the long-term fish study needs to be conducted.

Due to the high adsorption potential of the registered substance 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* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

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

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. 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.

You have not provided any study record of simulation testing on ultimate degradation in water in the dossier that would meet the information requirement of Annex IX, Section 9.2.1.2, for the registered substance.

Instead, you have sought to adapt this information requirement according to Annex IX, Section 9.2., column 2. You provided the following justification for the adaptation "*According to Annex IX further biotic degradation testing shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the degradation of the test substance and its degradation products. Since the Risk Characterisation Ratio of the risk assessment is below 1 for the sediment compartment, no further degradation studies are provided.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2., column 2 because the information provided in the CSA is not complete due to the data gaps in aquatic toxicity addressed in section 5 of the current decision. Hence, ECHA considers that the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products.

Furthermore, according to Annex IX, section 9.2.1.2., column 2 of the REACH Regulation, the simulation testing on ultimate degradation in water does not need to be conducted if the substance is highly insoluble in water or the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not highly insoluble in water (water solubility = 18.8 mg/L at 23 °C, OECD TG 105) and is not readily biodegradable (biodegradation percentage of 24% (20.3 mg/L) and 10%(10.7 mg/L) after 28 days, OECD TG 301B). Consequently, the specific rules for adaption presented in column 2 of Annex IX, section 9.2.1.2.of the REACH Regulation also do not apply.

Thus, the justification for the adaptation provided by you does not meet the criteria of the specific adaptation rules of Column 2 of Annex IX, section 9.2. Therefore, your adaptation of the information requirement cannot be accepted.

In the comments to the draft decision, you agree that more insight into the fate of the substance and the properties of its degradation products might be desirable. You provided attachments to the comments, which describe analyses using *in-silico* tools and provide information on degradation of the parent/registered substance and the PBT potential of the degradation products.

ECHA acknowledges that the information provided regarding degradation of the parent/registered substance and the P and B potential of the degradation products may allow a conclusion that the potential degradation products of the registered are not PBT/vPvB. ECHA however notes that in order to adapt the information requirements on simulation testing as per column 2 of Section 9.2 in Annex IX of the REACH Regulation, the whole chemical safety assessment according to Annex I needs to be considered.

The information you provided in your comments does not remove the need for further degradation testing for the purpose of risk characterisation as described in Section 6 of Annex I of the REACH Regulation, considering that all relevant information on aquatic toxicity and resulting PNEC derivation is currently not adequately reflected in the CSA (see under request 5 above). Furthermore, if a correct assessment factor for the current data set on aquatic toxicity is used, the risk characterisation indicates a risk and thus the CSA/Annex I would indicate the need to investigate further the degradation of the substance. ECHA further notes that, in accordance with Annex I, Section 4, of the REACH Regulation, the new information on PBT properties of the degradation products should be taken into consideration also for the PBT assessment of the registered substance.

In the comments to the draft decision you also indicate a disagreement to the deficiencies identified by ECHA in the current specific adaptation for this endpoint. You disagree with this view by stating that the CSA and the corresponding risk assessment are valid and adequate to sufficiently justify that an in depth evaluation of the degradation products of the substance is not needed. ECHA considers the deficiencies identified in the request 5 are still applicable.

Consequently ECHA considers that the adaptation of this information requirement is equally unjustified as this information requirement is dependent on risk assessment which includes uncertainties as described in request 5 of this decision.

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

ECHA notes that your comments on the draft decision submitted during the commenting phase on the Proposals for Amendment submitted by Member State Competent Authorities concerning an update of the environmental risk assessment have been addressed above in request 5.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Aerobic mineralisation in surface water – simulation

biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

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 the 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 309. Therefore, the test should be performed at the temperature of 12°C.

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. 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."

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309).

7. Soil simulation testing (Annex IX, Section 9.2.1.3.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.3. of the REACH Regulation for substances with a high potential for adsorption to soil. ECHA notes that the registered substance has high adsorption coefficient (Log Koc, soil of 4.2), indicating high adsorptive properties. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of soil simulation testing in the dossier that would meet the information requirement of Annex IX, Section 9.2.1.3.

Instead, you have sought to adapt this information requirement according to Annex IX, Section 9.2., column 2. You provided the following justification for the adaptation *"According to Annex IX further biotic degradation testing shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the degradation of the test substance and its degradation products. Since the Risk Characterisation Ratio of the risk assessment is below 1 for the soil compartment, no further degradation studies are provided."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.3., column 2 because the PNEC for soil has been calculated from the aquatic PNEC by using the equilibrium partitioning method, but the information provided in the CSA is not complete due to the data gaps in aquatic toxicity addressed in section 5 of the current decision). Hence, ECHA considers that the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products.

Furthermore, according to Annex IX, section 9.2.1.3., column 2 of the REACH Regulation, soil simulation testing does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure to soil is unlikely. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable (biodegradation percentage of 24% (20.3 mg/L) and 10% (10.7 mg/L) after 28 days, OECD TG 301B). In addition, based on the uses reported in the technical dossier, ECHA observes potential for exposure to soil for scenario 5: Wide dispersive outdoor use of long-life plastic articles and materials with low release (ES5) and scenario 6: Wide dispersive indoor use of long-life plastic articles and materials with low release (ES 6). Consequently, the specific rules for adaption presented in column 2 of Annex IX, section 9.2.1.3.of the REACH Regulation currently also do not apply.

Thus, the justification for the adaptation provided by you does not meet the criteria of the specific adaptation rules of Column 2 of Annex IX, section 9.2. Therefore, your adaptation of the information requirement cannot be accepted.

In the comments to the draft decision, you indicate a disagreement to the deficiencies identified by ECHA in the current specific adaptation for this endpoint. You consider that the CSA and the corresponding risk assessment are valid and adequate. In addition, in your comments to request 6 of the current decision, you provide information on the degradation of the parent registered substance and on the PBT potential of the degradation products. You consider that the reasons provided in your comments are sufficient to justify that information on the degradation of the substance is not needed. ECHA has addressed your comments on the requested simulation tests under request 6 above and considers that the adaptation of this information requirement is not currently supported by the information provided in the comments to the draft decision nor in the technical dossier.

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

ECHA notes that your comments on the draft decision submitted during the commenting phase on the Proposals for Amendment submitted by Member State Competent Authorities concerning an update of the environmental risk assessment have been addressed above in request 5.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Aerobic and anaerobic transformation in soil (test method EU C.23. / OECD TG 307) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.3.

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 307. 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic and anaerobic transformation in soil (test method: EU C.23./OECD TG 307)

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

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Sediment simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.4. of the REACH Regulation for substances with a high potential for adsorption to sediment. ECHA notes that the registered substance has high adsorption coefficient (Log Koc, soil of 4.2), indicating high adsorptive properties. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of sediment simulation testing in the dossier that would meet the information requirement of Annex IX, Section 9.2.1.4.

Instead, you have sought to adapt this information requirement according to Annex IX, Section 9.2., column 2. You provided the following justification for the adaptation *"According to Annex IX further biotic degradation testing shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the degradation of the test substance and its degradation products. Since the Risk Characterisation Ratio of the risk assessment is below 1 for the sediment compartment, no further degradation studies are provided".*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.4., column 2 because the PNEC for sediment has been calculated from the aquatic PNEC by using the equilibrium partitioning method, but the information provided in the CSA is not complete due to the data gaps in aquatic toxicity addressed in section 5 of the current decision. Hence, ECHA considers that the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products.

Furthermore, according to Annex IX, section 9.2.1.4., column 2 of the REACH Regulation, sediment simulation testing does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure to sediment is unlikely. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable (biodegradation percentage of 24% (20.3 mg/L) and 10% (10.7 mg/L) after 28 days, OECD TG 301B). In addition, based on the uses reported in the technical dossier, ECHA observes potential for exposure to sediment for scenario 5: Wide dispersive outdoor use of long-life plastic articles and materials with low release (ES5) and scenario 6: Wide dispersive indoor use of long-life plastic articles and materials with low release (ES6). Consequently, the specific rules for adaption presented in column 2 of Annex IX, section 9.2.1.4.of the REACH Regulation currently also do not apply.

Thus, the justification for the adaptation provided by you does not meet the criteria of the specific adaptation rules of Column 2 of Annex IX, section 9.2. Therefore, your adaptation of the information requirement cannot be accepted.

In the comments to the draft decision, you indicate a disagreement to the deficiencies identified by ECHA in the current specific adaptation for this endpoint. You consider that the CSA and the corresponding risk assessment are valid and adequate. In addition, in your comments to request 6 of the current decision, you provide information the degradation of the parent registered substance and on the PBT potential of the degradation products. You consider that the reasons provided in your comments are sufficient to justify that information on the degradation of the substance in sediment is not needed. ECHA has addressed your comments on the requested simulation tests under request 6 above and considers that the adaptation of this information requirement is not currently supported by the information provided in the comments to the draft decision nor in the technical dossier.

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

ECHA notes that your comments on the draft decision submitted during the commenting phase on the Proposals for Amendment submitted by Member State Competent Authorities concerning an update of the environmental risk assessment have been addressed above in

request 5.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24. / OECD TG 308) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.4.

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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic and anaerobic transformation in aquatic sediment systems (test method: EU C.24./OECD TG 308).

Notes for your consideration for simulation test requests 6, 7 and 8

The identification of degradation products also needs to be performed, according to REACH Annex IX, 9.2.3 specifications. You may obtain this information from the simulation study also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

Before conducting the requested simulation tests (requests 6-8 of this decision) you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 3.0, June 2017) on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use

and release patterns which could significantly influence the environmental fate of the registered substance.

Furthermore, regarding conclusion of risk assessment, the need to perform the simulation tests may become unnecessary after data from toxicity studies requested in this decision (sections 5 and 9) become available in the technical dossier and an application of a relevant assessment factor to derive a reliable PNEC, allowing you to update the risk assessment.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above 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, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

9. Long-term toxicity testing to sediment organisms (Annex X, Section 9.5.1.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Long-term toxicity to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. 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.

ECHA notes that you have sought to adapt the long-term toxicity testing on sediment organisms according to Annex X, 9.5.1. column 2, using the following justification: "*The test substance is not supposed to be directly applied to sediment. According to the Mackay Level I distribution modeling the test item will predominantly be distributed in the compartment water. Additionally, according to Annex X long-term toxicity tests for sediment organisms shall be proposed if the result of the Chemical Safety assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on sediment organisms. Since the Risk Characterisation Ratio of the risk assessment is below 1 for the sediment compartment, no studies are provided.*"

ECHA notes further that in order for an adaptation of Annex X, 9.5.1. column 2 provisions to be justified, you would have to demonstrate by means of the Chemical Safety Report (CSR) that the conditions of an adaptation possibility (Annex XI) are fulfilled. In establishing this, in some cases and as explained in ECHA Guidance on information requirements and chemical safety assessment (R.7b, version 4.0, June 2017, Section R.7.8.), you may use the EPM as part of a weight-of-evidence to adapt the standard information requirement.

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex X, Section 9.5.1., column 2 because the PNEC for sediment has been calculated from the aquatic PNEC by using the equilibrium partitioning method, but it is not possible to derive a correct PNEC in the absence of valid information on aquatic toxicity addressed in this decision (section 5). Hence, no valid risk characterisation is provided in the technical dossier for the sediment compartment.

ECHA notes that you have not demonstrated that available data would lead to the conclusion that the substance is or is not toxic to sediment organisms (Annex XI, 1.2.). In fact, the present substance has a high potential to adsorb to sediment (Log Koc, soil of 4.2). Therefore, as the standard information requirements for long-term sediment testing have not been adapted in a justified manner, testing is required.

Therefore, your adaptation of the information requirement cannot be accepted.

In the comments to the draft decision, you indicate a disagreement to the deficiencies identified by ECHA in the current specific adaptation for this endpoint. You state that the CSA and the corresponding risk assessment indicating RCRs below 1 are valid and adequate to sufficiently justify that long-term toxicity testing on sediment organisms is not necessary.

ECHA considers the deficiencies identified in the request 5 of the draft decision are still applicable.

Consequently ECHA considers that the adaptation of this information requirement is still unjustified as the information requirement is dependent on the aquatic toxicity data where deficiencies have been identified (see request 5 of this decision).

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

ECHA notes that your comments on the draft decision submitted during the commenting phase on the Proposals for Amendment submitted by Member State Competent Authorities concerning an update of the environmental risk assessment have been addressed above in request 5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Sediment-water Chironomid toxicity using spiked sediment (Test method: OECD TG 218) *or* Sediment-water Lumbriculus toxicity test using spiked sediment (Test method: OECD TG 225) *or* Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD TG 233).

Notes for your consideration

The Sediment-water Chironomid toxicity using spiked sediment (OECD TG 218), Sediment-water Lumbriculus toxicity test using spiked sediment (OECD TG 225) and Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD TG 233) are in principle each considered capable of generating information appropriate for the fulfilment of the information requirements for sediment long-term toxicity testing. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity, substance properties and uses.

ECHA considers that it is your responsibility to choose the most appropriate test protocol and to give a justification for the choice. You may carry out more than one of the sediment tests defined in Section II above if you consider that further testing is required. While ECHA

at this stage only requires one test, based on newly available data it may consider whether further tests are required to fulfil the standard information requirement.

Furthermore, both water and sediment exposure scenarios are described in the OECD TG 233. You are advised to consult OECD TG 233 and the ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b (Section R.7.8.10.1) for the selection of the appropriate method of spiking.

Regarding conclusion of risk assessment, the need to perform long-term sediment toxicity study may become unnecessary after aquatic hazard data becomes available (request 5) allowing you to update the risk assessment.

10. Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4)

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

You have adapted the standard information requirements of Annexes IX and X, section 9.4. using the following justification: "*An OECD-SIDS (SIAM 26, 2008) is available. According to this document the exposure to the environment is considered to be low and the available data are regarded to be sufficient for the ecotoxicological assessment of the test substance. Therefore the test substance is of low priority for further work. As a result of these data no further studies concerning terrestrial toxicity are provided*".

In your justification you refer to the SIDS INITIAL ASSESSMENT PROFILE (SIAM 26, 16-18 April 2008) indicating that the exposure to the environment is considered to be low ECHA notes that you have not attached the document to your technical dossier. Nevertheless as the document is publicly available, ECHA notes that in the SIDS assessment profile it is described that "*Exposure of the environment may occur during production and industrial use of the substance and by leaching waste at landfills. Emission to wastewater from contact of extruded plastics with cooling water and cleaning of equipment at sites of industrial production and use is considered the most relevant route of exposure of the environment.*" Also some emission factors are provided "*for a representative scenario*" and it is concluded that "*exposure of the environment from production and industrial use of bis-TMPS is considered to be very low*".

ECHA acknowledges that according to the Annex IX to REACH Regulation, column 2 of section 9.4, terrestrial toxicity studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. In ECHA *Guidance on Information Requirements and Chemical Safety Assessment*, Chapter R.7c (version 3.0, June 2017), section 7.11, it is described that in general, it is assumed that soil exposure will occur unless it can be shown that there is no sludge application to land from exposed STPs and that aerial deposition are negligible and the relevance of other exposure pathways such as irrigation and/or contact with contaminated waste is unlikely. In case of readily biodegradable substances which are not directly applied to soil it is generally assumed that the substance will not enter the terrestrial environment and as such there is no need for

testing of soil organisms is required. Furthermore, other parameters (e.g. low log Koc/Pow) should be considered regarding the exposure pathway via STP sludge.

As the substance is not readily degradable and you have not shown that the sludge would not be applied to land from exposed STP in all the exposure scenarios. ECHA further notes that in your technical dossier there are identified wide dispersive consumer uses of the substance in e.g adhesives and sealants, coatings and paints, thinners, paint removes, fillers, putties, plasters, modelling clay .

ECHA considers that based on the information provided in your technical dossier direct and indirect exposure of the soil compartment is likely, and thus the terrestrial toxicity studies need to be conducted.

In your adaptation you also indicate that based on the SIDS assessment profile "*the available data are regarded to be sufficient for the ecotoxicological assessment of the test substance*". ECHA notes that in the SIDS assessment profile only aquatic toxicity data is available and no data is present for toxicity to terrestrial organisms. ECHA hence considers this not relevant for the present endpoint and as fully discussed in this section toxicity testing of terrestrial organisms is required for the registered substance.

ECHA also notes that based on substance properties the substance has high adsorption potential. Regarding the adsorptivity of the substance, the logKoc which you report in the IUCLID dossier is 4.20. Furthermore, the substance is ionisable, which itself would indicate high adsorption according to the abovementioned Table R.7.11-2 in ECHA Guidance R.7c (version 3.0 July 2017). Furthermore, in the SIDS assessment profile a log Kow of 6.5 (KOWWIN v.1.67) and 7.3 ([redacted] v.8.14) have been calculated for the neutral species. The measurements for the neutral species is recommended by the OECD TG 107. In your IUCLID dossier section 4.7 Partition coefficient, you report a study where the aqueous phase was buffered to pH 7. This indicates that most of the substance has not been in neutral form during testing (pKa= 9.5 - 11 at 25 °C) and thus the logKow estimations in the SIDS assessment profile, indicating high adsorptivity, are likely more accurate.

ECHA acknowledges that according to the Annex IX to the REACH Regulation, column 2 of section 9.4, in the absence of toxicity data for soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. However, ECHA notes that considering the properties of the registered substance, the EPM is not recommended for the following reasons. According to Table R.7.11-2 of the ECHA *Guidance on Information Requirements and Chemical Safety Assessment* (Chapter R.7c, version 3.0 July 2017), the registered substance belongs to soil hazard category 4 because there is an indication that the substance is very toxic to aquatic organisms (EC50 from algal toxicity study 0.705 mg/L) and there is an indication for high adsorption.

ECHA considers that the registered substance belongs to soil hazard category 4 based on its aquatic toxicity and adsorption potential. Thus the EPM is not recommended for the substance and terrestrial toxicity testing according to the standard information requirements of Annex IX and X is required.

In conclusion, your justification for waiving does not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptation cannot be accepted.

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

According to section R.7.11.5.3., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), substances that are ionisable or have a log Kow/Koc >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil as described above in this request. Therefore ECHA considers that the column II adaptation for Annex IX, section 9.4 regarding long-term testing instead of short-term testing, is applicable to this substance.

ECHA notes that long-term tests are suitable to simultaneously address the information requirements of section 9.4. of Annexes IX and X.

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

The earthworm reproduction test (OECD TG 222) and Enchytraeid reproduction test (OECD TG 220) are both 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. You are to apply the most appropriate and suitable test guideline among those listed above.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 222), or Enchytraeid reproduction test (test method: OECD TG 220).

11. Long-term toxicity testing on plants (Annex X, Section 9.4.6).

"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.

You have adapted the standard information requirements of Annexes IX and X, section 9.4. using the following justification: *"An OECD-SIDS (SIAM 26, 2008) is available. According to this document the exposure to the environment is considered to be low and the available data are regarded to be sufficient for the ecotoxicological assessment of the test substance. Therefore the test substance is of low priority for further work. As a result of these data no further studies concerning terrestrial toxicity are provided."*

As fully explained in request 10 above terrestrial toxicity testing for the registered substance is indicated based on exposure and substance properties. Your justification for waiving does hence not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, or the general adaptation rules of Annex XI and cannot be accepted.

As established within the request 10 above, the Guidance advocates performing long-term toxicity tests according to the information requirements of Annex X and that the lowest value obtained should be used to derive the PNEC soil.

OECD TG guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. 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 TG 208 guideline. You 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, you are requested to submit the following information derived with the registered substance subject to the present decision: Terrestrial plants, growth test (test method: OECD TG 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).

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

"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.

You have adapted the standard information requirements of Annexes IX and X, section 9.4. using the following justification: *"An OECD-SIDS (SIAM 26, 2008) is available. According to this document the exposure to the environment is considered to be low and the available data are regarded to be sufficient for the ecotoxicological assessment of the test substance. Therefore the test substance is of low priority for further work. As a result of these data no further studies concerning terrestrial toxicity are provided."*
As fully explained in request 10 above terrestrial toxicity testing for the registered substance is indicated based on exposure and substance properties. Your justification for waiving does hence not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, or the general adaptation rules of Annex XI and cannot be accepted.

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

ECHA notes that the tests requested under requests 10 and 11 above are not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

According to section R.7.11.3.1. of the above-mentioned guidance, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 216).

Deadline to submit the requested information in this decision

In the draft decision communicated to you and to the Member State Competent Authorities (MSCAs) the time indicated to provide the requested information was 30 months from the date of adoption of the decision. In your comments on the draft decision submitted during the commenting phase on the Proposal for Amendment submitted by MSCAs you requested an extension of the timeline to 42 months. You justified this request by lack of laboratory capacity and time needed for characterisation of the test material. You included a statement from the laboratory as a further proof. Based on this statement ECHA has granted the request and has modified the decision setting the deadline to 42 months.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 6 September 2016.

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

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

You provided comments on the draft decision.

ECHA took into account your comments and amended the request(s).

The request for a Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Algae growth inhibition test, EU C.3./OECD TG 201) was removed from the draft decision considering your comments on the draft decision and the outcome of the assessment under follow up dossier evaluation under an Article 42(2) of dossier evaluation decision CCH-D-0000004521-82-03/F; the outcome of the assessment under Article 42(2) is that this endpoint is compliant but with deviations. ECHA notes that such deviations may be addressed in the context of follow-up and, where needed, result in the opening of another compliance check on this endpoint.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

You provided comments only on the draft decision. Your 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-57 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported 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 the substance tested in the new test(s) 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) 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 test(s) to be assessed.