EUROPEAN CHEMICALS AGENCY

Helsinki, 10 December 2019

Addressee: [redacted]

Decision number: CCH-D-2114494377-34-01/F
Substance name: 4-(1-methyl-1-phenylethyl)-N-[4-(1-methyl-1-phenylethyl)phenyl]aniline
EC number: 233-215-5
CAS number: 10081-67-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 28/03/2017
Registered tonnage band: 100-1000

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. **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;**

2. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD TG 201) with the registered substance with analytical monitoring of the test substance concentrations;**

3. **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;**

4. **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;**

5. **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;**

6. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance;**

7. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305) with the registered substance;**

8. **Identification of PNEC (Annex I, Section 3.3.1.): derive PNECs for soil - using the study giving rise to the highest concern according to Annex I and**

using the assessment factors recommended by ECHA, Section 3.1.5 *or* provide a detailed justification for not using the study giving rise to the highest concern and provide a detailed justification for not using the recommendations of ECHA guidance in PNEC derivation.

9. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment: generate an exposure assessment for all the exposure scenarios and derive the risk characterisation accordingly.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by ***17 December 2021***. You also have to 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 and advice and further observations are provided in Appendix 3.

Appeal

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

Authorised[1] by Wim De Coen, Head of Unit, Hazard Assessment

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

Appendix 1: Reasons

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

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

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. 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 XI, Section 1.2., weight of evidence. Hence, ECHA has evaluated your adaptation with respect to this adaptation.

You have provided the following justification for the adaptation: "*It is proposed to waive the pre-natal developmental toxicity study, as required in accordance with Section 8.7.2 of Column 1 Annex IX, based on the results of a 28-day repeated dose toxicity study combined with a screening study of reproductive/developmental toxicity and the toxicokinetic assessment showed no significant effect on reproductive ability, organ weight or histopathology of the ovary, delivery or maternal behaviour. The NOEL for reproductive / developmental toxicity was considered to be 50 mg/kg/day for both parents and offspring, the highest dose examined. In addition, an examination of reproductive organs was conducted in the toxicokinetics and 28-day studies and no effects were observed. On the basis of the fact that no effects are observed, and the substance is not structurally indicative of posing reproduction effects, this study is waived on animal welfare grounds.*"

ECHA understands that you conclude that the registered substance does not have a dangerous (hazardous) property with respect to pre-natal developmental toxicity.

To support your weight of evidence adaptation you have provided the following sources of information:

- Sub-acute toxicity study, OECD TG 407, with rats, oral route, made in 2008, GLP, with the registered substance, rel. 1,
- Screening study of reproductive/developmental, OECD TG 421, with rats, oral route, made in 2009, GLP, with the registered substance, rel. 1, and
- Toxicokinetics study OECD 417, with rats, oral route, made in 2008, GLP, with the registered substance, rel. 1.

a) ECHA's evaluation and conclusion of the information provided

Evaluation approach/criteria

An adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the

information from each single source alone is regarded insufficient to support this notion.

Your weight of evidence adaptation needs to address the specific dangerous (hazardous) properties of the registered substance with respect to pre-natal developmental toxicity study (EU B.31/OECD TG 414). Relevant elements are in particular exposure route, duration and levels, sensitivity and depth of investigations to detect pre-natal developmental toxicity (including growth, survival, external, skeletal and visceral alterations) and maternal toxicity.

Furthermore, the value of different pieces of the provided information needs to be assessed as indicated in ECHA Guidance on information requirements and chemical safety assessment Chapter R.4., Section 4.4 (version 1.1, December 2011). In particular relevance, reliability and consistency of results/data and coverage (completeness) need to be considered.

Evaluation of the provided information

In the technical dossier you have provided study records for a sub-acute toxicity study (OECD TG 407), for a "reproduction/ developmental toxicity screening test" (test method: OECD TG 421) and for a toxicokinetics study (OECD TG 417). These studies are of adequate reliability and provide information that is relevant for the endpoints covered in those tests. However, these studies, when taken together in a weight of evidence approach, are not considered sufficient to conclude on the PNDT information requirement. More notably, these studies do not provide the information required by Annex IX, Section 8.7.2., because they do not cover key parameters of a pre-natal developmental toxicity study, such as examinations of foetuses for skeletal and visceral alterations. Therefore, your adaptation of the information requirement is rejected.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation, you refer to a sub-chronic toxicity study made with the registered substance. ECHA notes that a sub-chronic toxicity study does not meet the information requirement of the pre-natal develomental toxicity, because the reproductive cycle and the effects on the offspring are not covered in a sub-chronic toxicity study.

ECHA observes that the data density across the category seems limited based on the information provided in the read-across justification document provided with your comments and in the technical dossier(s) of the category members. According to the data matrix, which you have provided in your comments, only one PNDT study is available, which may not be enough to document similarity or trend among the category of the substances. Furthermore, some physico-chemical properties such as water solubility and vapour pressure of the target substance seems to differ from those of the source substances. Therefore, you have currently not established how to obtain a reliable prediction for toxicological properties of the target substance.

Additionally, as the approach and the data presented in the comments (including robust study summaries of the studies on the analogue substance(s)) are currently not provided in the registration dossier, ECHA cannot fully evaluate the information and draw conclusion on the read-across approach proposed. ECHA will make a full assessment of your updated dossier in the follow-up process according to Art 42 of the REACH Regulation.

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) Chapter R.7a, Section 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.

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.

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. 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.

Column 2 of Annex VII, Section 9.1.2 specifies that the study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.

In the technical dossier you have provided a study record for toxicity to aquatic algae and cyanobacteria ([redacted] 2005) However, this study does not provide the information required by Annex VII, Section 9.1.2., because it is considered to be not reliable as no analytical measurements have been performed. As already demonstrated in long-term toxicity study on daphnia, the substance tends to disappear from the test system with the recovery rate less than 80%, indicating the need to perform analytical measurements to confirm the test concentrations.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you note that this group of substances is not known for its toxicity to algae and given the low water solubility, it is likely that any results would be higher than the water solubility limit. As a result, you propose that this request should be omitted from the testing requirements.

ECHA notes, that you claim in your comments in the read-across justification that "*with increasing molecular weight, the toxicity to aquatic organisms decreases*". However, there are test results available only for two substances in this group having an EC50 > 100 mg/l. As the results for the registered substance are not considered acceptable for the reasons stated above, it is therefore currently not possible to establish a trend for aquatic algae. ECHA also notes that from the information provided in the comments there is no further data available for long-term toxicity on other aquatic taxonomic groups (fish and daphnia) for other substances in the group. As the substance is poorly water soluble, the short-term aquatic toxicity studies are not reliable and not a correct measure for this kind of substances. Hence you have not provided evidence to support the claim that with increasing molecular weight, the toxicity to aquatic organisms decreases. Therefore, ECHA may currently not use the data on other analogue substances to fulfil the data gap for this substance.

Additionally, as the approach and the data presented in the comments (including robust study summaries of the studies on the analogue substance(s)) are currently not provided in the registration dossier, ECHA cannot fully evaluate the information and make conclusions on the read-across approach proposed. ECHA will assess the read-across approach in the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI, Section 1.5 are met.

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 ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

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: Algae growth inhibition test, EU C.3./OECD TG 201) with analytical monitoring of the test substance concentrations.

Notes for your consideration

Due to the low solubility of the substance in water (<0.0067 mg/l) and possible volatility (6.67 hPa) 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).

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

"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 sought to adapt this information requirement. You provided the following justification for the adaptation: *"No toxicological effects with fish are noted at the limit of solubility in water in acute studies, and as such, it is proposed that longer term effects are unlikely to be prominent. The substance is classified for environmental effects; however this is based only on the fact that it may be persistent. No toxicity to aquatic species has been noted in any of the tests conducted. On animal welfare grounds and the fact that the testing will not contribute to the overall classification, this test is waived."*

However, ECHA notes that the substance is poorly water soluble (WS < 0.0067 mg/l), hence long-term aquatic testing is justified and cannot be waived on the basis of animal welfare. As the registered substance has a reported low water solubility, long-term studies are indicated.

Furthermore, ECHA notes that due to lack of effects in short-term studies it is not possible to determine the sensitivity of species. Therefore, the Integrated testing strategy (ITS) outlined

in 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), is not applicable in this case and the long-term studies on both invertebrates and fish need to be conducted. As for the PNEC derivation for water toxicity information, this should at least cover species of three trophic levels: algae/aquatic plants, invertebrates, and fish..

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you propose to use read across approach to address this endpoint with admitting at the same time that there is insufficient information available within the category. As further consideration you refer to the short-term aquatic effects of the different category members. You also refer to chronic effects noted in daphnia and refer to a comparison paper on species sensitivity of daphnia and fish in acute and chronic testing. Lastly you state that the risk refinement is not necessary as the RCR's generated against the PNEC indicate that there is no risk for the environmental endpoint. As a result, you propose that this request should be omitted from the testing requirements as effects at the limit of solubility are unlikely and the test is not needed to refine hazard and risk.

ECHA notes, the following:

Firstly, there is not long-term data on fish for any of the category members, hence it is not possible to use read-across for this endpoint.

Secondly, as already explained above, as the substance is poorly water soluble, the short-term aquatic toxicity studies are not reliable and not a correct measure for this kind of substances.

As already explained above, the ITS does not apply and long-term testing is necessary to be conducted both on daphnia and fish.

The comparison paper on species sensitivity of daphnia and fish in acute and chronic testing provides statistical analysis and summary for evaluated substances under REACH without further substance specific data.

Lastly, in relation to the exposure assessment ECHA notes that you state in the CSR (section 10) that "*There is considered to be no risk to environmental organisms, as the substance does not demonstrate hazardous effects*" that is in conflict with your statement that RCR's do not indicate the risk. Moreover, the release factors are for several exposure scenarios set to 0 without further explanation how 100% RMM efficiency has been achieved. Therefore you have not calculated RCR values for environmental compartments. Hence, ECHA concludes that the exposure assessment is not reliable and cannot be used to adapt form the information requirement.

Therefore, your adaptation of the information requirement 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 requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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

Due to the low solubility of the substance in water and possible volatility 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).

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

"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. The registered substance has low water solubility (<0.0067 mg/L), high partition coefficient (log Kow 7,9) and high adsorption coefficient (log Koc, soil 6.54), 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 sought to adapt this information requirement. You provided the following justification for the adaptation: *"As the substance does not display biodegradation in the screening studies, it can be assumed to not biodegrade within other media. The substance can be deemed to be "not readily biodegradable" in this media, and hence is persistent within the environment."*

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 9.2.1.3., column 2.

According to Annex IX, Section 9.2.1.3, column 2 of the REACH Regulation, simulation testing on soil does not need to be conducted if the substance is readily biodegradable or if direct or indirect exposure of soil is unlikely. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in biodegradation screening test (OECD 301D), 5% DOC removal in 28 days.

Regarding the exposure to soil, the substance has a low water solubility of <0.0067mg/l, high partition coefficient (log Kow 7.9) and high adsorption coefficient (log Koc 6.54) indicating adsorptive properties. Furthermore, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which soil exposure cannot be excluded e.g. Environmental Release Category (ERC) 8a and 8d. ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

ECHA notes also that you have not provided adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products. As explained further below, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you propose to use read across approach to address this endpoint with admitting at the same time that there is insufficient information available within the category. As further consideration you refer to the ECHA Guidance on PBT assessment Figure R.11-3 and hydrolysis data together with information on exposure and test results on terrestrial organisms. As a result, you propose that this request should not be required.

ECHA notes, the following:

Firstly, as there is soil simulation study available only for one category member (QSAR calculation), it is not possible to use this in the read-across approach and to establish a trend.

Secondly, ECHA notes that you refer to previous version of R.11 guidance. The version 3.0 from 28 June 2017 specifically mentions that "*Concern for P/vP screening cannot be removed by significant and substantial loss of the parent substance by hydrolysis alone. Careful consideration of the hydrolysis test is required (for example mass balance is needed to address concerns for losses by volatilisation or absorption to glassware). Rapid hydrolysis also needs to be shown across all environmentally relevant pH. Additional evidence is also needed to examine whether the fate properties of the substance would cause attenuation of the hydrolysis rate in sediment or soil, or whether DOC would similarly affect the rate in aquatic media such as river or sea water. Additional studies, e.g. examining the influence of dissolved organic carbon / adsorption processes on hydrolysis rates, may be necessary for this. The degradation half-lives obtained in a hydrolysis test cannot be compared to the persistence criteria of Annex XIII. As abiotic degradation is primary degradation, careful consideration will need to be given to the potential formation of stable degradation products with PBT/vPvB properties. Hydrolysis products should be identified in accordance with the recommendations contained in the test guidelines (e.g. OECD TG 111).* "

ECHA notes that hydrolysis is not fast nor rapid and you have not identified the hydrolysis products. ECHA agrees that the substance shows some degradation, however the information is not conclusive to conclude on the P/vP properties.

In relation to the exposure assessment ECHA notes that you state in the CSR (section 10) that "*There is considered to be no risk to environmental organisms, as the substance does not demonstrate hazardous effects*" that is in conflict with your statement that RCR's do not indicate the risk. Moreover, the release factors are for several exposure scenarios set to 0 without further explanation how 100% RMM efficiency has been achieved. Therefore you have not calculated RCR values for environmental compartments. Hence, ECHA concludes that the exposure assessment is not reliable and cannot be used to adapt form the information requirement. Additionally, as the approach and the data presented in the comments for

qualitative exposure assessment are currently not provided in the registration dossier, ECHA cannot fully evaluate the information and make conclusions on the approach proposed. ECHA will assess the approach in the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI, Section 3 are met.

Lastly, ECHA confirms that the last dossier update is from 2017 containing the test results for the terrestrial tests (performed in 2016) as noted by the registrant. Those test results cannot be used to confirm the absence nor existence of the P properties of the substance.

Therefore, your adaptation of the information requirement 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 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).

Notes for your consideration

Before conducting the requested tests 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.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above is 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.

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

"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. The registered substance has low water solubility (<0.0067 mg/L), high partition coefficient (log Kow 7,9) and high adsorption coefficient (log Koc, soil 6.54), 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 sought to adapt this information requirement. You provided the following justification for the adaptation: *"As the substance does not display biodegradation in the screening studies, it can be assumed to not biodegrade within other media. The substance can be deemed to be "not readily biodegradable" in this media, and hence is persistent within the environment."*.

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 9.2.1.4., column 2.

According to Annex IX, Section 9.2.1.4, column 2 of the REACH Regulation, simulation testing on soil does not need to be conducted if the substance is readily biodegradable or if direct or indirect exposure of sediment is unlikely. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in biodegradation screening test (OECD 301D), 5% DOC removal in 28 days.

Regarding exposure of sediment, the substance has a low water solubility of <0.0067mg/l, high partition coefficient (log Kow 7.9) and high adsorption coefficient (log Koc 6.54) indicating adsorptive properties. Furthermore, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which sediment exposure cannot be excluded e.g. Environmental Release Category (ERC) 8a and 8d. ECHA therefore considers that you have not demonstrated that sediment exposure is unlikely.

ECHA notes also that you have not provided adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products. As explained further below, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you propose to use read across approach to address this endpoint with admitting at the same time that there is insufficient information available within the category. As further consideration you refer to the ECHA Guidance on PBT assessment Figure R.11-3 and hydrolysis data together with information on exposure. As a result, you propose that this request should not be required.

ECHA notes, the following:

Firstly, as there is sediment simulation study available only for one category member (QSAR calculation), it is not possible to establish a trend and to use it in a read-across approach.
Secondly, ECHA notes that the registrant refers to previous version of R.11 guidance. The version 3.0 from 28 June 2017 specifically mentions that "*Concern for P/vP screening cannot be removed by significant and substantial loss of the parent substance by hydrolysis alone. Careful consideration of the hydrolysis test is required (for example mass balance is needed to address concerns for losses by volatilisation or absorption to glassware). Rapid hydrolysis also needs to be shown across all environmentally relevant pH. Additional evidence is also needed to examine whether the fate properties of the substance would cause attenuation of the hydrolysis rate in sediment or soil, or whether DOC would similarly affect the rate in aquatic media such as river or sea water. Additional studies, e.g. examining the influence of dissolved organic carbon / adsorption processes on hydrolysis rates, may be necessary for this. The degradation half-lives obtained in a hydrolysis test cannot be compared to the persistence criteria of Annex XIII. As abiotic degradation is primary degradation, careful consideration will need to be given to the potential formation of stable degradation products with PBT/vPvB properties. Hydrolysis products should be identified in accordance with the recommendations contained in the test guidelines (e.g. OECD TG 111).* "

ECHA notes that hydrolysis is not fast nor rapid and you have not identified the hydrolysis products. ECHA agrees that the substance shows some degradation, however the information is not conclusive to conclude on the P/vP properties.

In relation to the exposure assessment ECHA notes that you state in the CSR (section 10) that "*There is considered to be no risk to environmental organisms, as the substance does not demonstrate hazardous effects*" that is in conflict with your statement that RCR's do not indicate the risk. Moreover, the release factors are for several exposure scenarios set to 0 without further explanation how 100% RMM efficiency has been achieved. Therefore you have not calculated RCR values for environmental compartments. Hence, ECHA concludes that the exposure assessment is not reliable and cannot be used to adapt form the information requirement. Additionally, as the approach and the data presented in the comments for qualitative exposure assessment are currently not provided in the registration dossier, ECHA cannot fully evaluate the information and make conclusions on the approach proposed. ECHA will assess the approach in the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI, Section 3 are met.

Therefore, your adaptation of the information requirement 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 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

Before conducting the requested tests 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.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above is 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.

6. Identification of degradation products (Annex IX, 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The biodegradation section in the technical dossier does not contain any information in relation to the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement. "

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in biodegradation screening test (OECD 301D), 5% DOC removal in 28 days, as also outlined in Sections 4 and 5 above.

Furthermore, ECHA notes that you have not provided any justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to provide information on the degradation products. ECHA considers that this information is needed in relation to the PBT/vPvB assessment and risk assessment.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you propose to use read across approach to address this endpoint with admitting at the same time that there is insufficient information available within the category. As further consideration you refer to the ECHA Guidance on PBT assessment Figure R.11-3 and ECHA Guidance R7.b. As a result, you propose that information on this endpoint should not be required.

ECHA notes, the following:

Firstly, as there is no data available about the degradation products of the category members, it is not possible to establish a trend and to use it in a read-across approach.
Secondly, ECHA notes that the registrant refers to previous version of R.11 guidance. The version 3.0 from 28 June 2017 specifically mentions that "*Concern for P/vP screening cannot be removed by significant and substantial loss of the parent substance by hydrolysis alone. Careful consideration of the hydrolysis test is required (for example mass balance is needed to address concerns for losses by volatilisation or absorption to glassware). Rapid hydrolysis also needs to be shown across all environmentally relevant pH. Additional evidence is also needed to examine whether the fate properties of the substance would cause attenuation of the hydrolysis rate in sediment or soil, or whether DOC would similarly affect the rate in aquatic media such as river or sea water. Additional studies, e.g. examining the influence of dissolved organic carbon / adsorption processes on hydrolysis rates, may be necessary for this. The degradation half-lives obtained in a hydrolysis test cannot be compared to the persistence criteria of Annex XIII. As abiotic degradation is primary degradation, careful consideration will need to be given to the potential formation of stable degradation products with PBT/vPvB properties. Hydrolysis products should be identified in accordance with the recommendations contained in the test guidelines (e.g. OECD TG 111).* "

ECHA notes that hydrolysis is not fast nor rapid and you have not identified the hydrolysis products. ECHA agrees that the substance shows some degradation, however the information is not conclusive to conclude on the P/vP properties.

ECHA notes that the registrant refers to the previous version of the R.7b guidance. The information on degradation products is necessary to complete the CSA in terms of PBT assessment as already mentioned above.

However, ECHA acknowledges that the registrant is planning to update the dossier with the prediction for the degradation products following a technique such as the EAWAG-BBD Pathway Prediction System, with subsequent assessment of the degradants via the use of accepted (Q)SAR models. ECHA will assess the approach in the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI are met.

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.

Regarding appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the metabolite may be investigated. You may obtain this information from the relevant degradation studies also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

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:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

Notes for your consideration

Before providing the above information you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b., Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

7. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

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 XI, Section 1.3.

You have provided QSAR predictions as a part of WoE approach to predict the bioaccumulative properties of the registered substance.

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI, Section 1.3. because of the following reasons. You have used as additional input parameter a logKow higher than the experimental logKow given in the dossier (and higher than the predicted one by the software itself) for the estimation of bioconcentration factor (BCF) by the BCFBAF model. This leads to a BCF predicted to be relatively low, while the prediction with the measured logKow indicates much higher BCF values. Taking into account the uncertainty of the measured logKow, the predicted BCF of the main constituent could be either very low or above the vB threshold of 5000. Because of this uncertainty, the prediction cannot be considered to be adequate for the purpose of risk assessment and PBT/vPvB assessment.

The prediction of the bioaccumulation potential with the CAESAR software was done with the first version of the software, which had some shortcomings. The updated software indicates low reliability of the predicted BCF for the main constituent.

In addition, the QSAR Toolbox v3.4 predicts that the substance is potentially a protein binder (via Michael type addition to quinoid structures). The reliability of predictions for BCF with QSARs is lower for molecules that can bind to proteins, adding to the overall uncertainty of these predictions.

While the predictions for the main constituent are well reported, they cannot be considered to be reliable and adequate.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you propose to use read across approach to address this endpoint with admitting at the same time that there is insufficient information available within the category. As further consideration you refer to the ECHA Guidance on PBT assessment Figure R.11-3 together with the information on exposure. As a result, you propose that information on this endpoint should not be required.

ECHA notes, the following:

Firstly, as you have not proposed further justification why the read-across would be acceptable and as the approach and the data presented in the comments (including robust study summaries of the studies on the analogue substance(s)) are currently not provided in the registration dossier, ECHA cannot fully evaluate the information and make conclusions on the read-across approach proposed. ECHA will assess the read-across approach in the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI, Section 1.5 are met.

ECHA agrees that the substance shows some degradation, however the information (as already explained in the previous endpoints above) is not conclusive to conclude on the P/vP properties. Hence it cannot be used to waive the testing need for B assessment.

In relation to the exposure assessment ECHA notes that you state in the CSR (section 10) that "*There is considered to be no risk to environmental organisms, as the substance does not demonstrate hazardous effects*" that is in conflict with your statement that RCR's do not indicate the risk. Moreover, the release factors are for several exposure scenarios set to 0 without further explanation how 100% RMM efficiency has been achieved. Therefore you have

not calculated RCR values for environmental compartments. Hence, ECHA concludes that the exposure assessment is not reliable and cannot be used to adapt form the information requirement. Additionally, as the approach and the data presented in the comments for qualitative exposure assessment are currently not provided in the registration dossier, ECHA cannot fully evaluate the information and make conclusions on the approach proposed. ECHA will assess the approach in the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI, Section 3 are met.

Therefore, your adaptation of the information requirement 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 requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible. If you decided to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision. You shall also attempt to estimate the corresponding BCF value from the dietary test data by using the approaches given in Annex 8 of the OECD 305 TG and in OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation, ENV/JM/MONO (2017)16. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.

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
Bioaccumulation in fish: aqueous or dietary bioaccumulation fish test (test method: OECD TG 305)

Notes for your consideration

Before conducting the above test you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.11.4. and Figure R.11-4 on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. In particular, you are advised to first conclude whether the registered substance may fulfil the REACH Annex XIII criteria of being persistent or very persistent, and then to consult the PBT assessment for Weight-of-Evidence determination and integrated testing strategy for bioaccumulation assessment. You should revise the PBT assessment when information on bioaccumulation is available.

8. **Identification of PNEC (Annex I, Section 3.3.1.): derive PNECs for soil - using the study giving rise to the highest concern according to Annex I and using the assessment factors recommended by ECHA, Section 3.1.5 *or* provide a detailed justification for not using the study giving rise to the**

highest concern and provide a detailed justification for not using the recommendations of ECHA guidance in PNEC derivation.

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

Annex I, Section 3.3.1. of the REACH Regulation requires to establish a PNEC for each environmental sphere based on the available information and to use an appropriate assessment factor to the effect values.

The ECHA *Guidance on information requirements and chemical safety assessment,* Chapter R.10 provides further details and specifically provides default assessment factors that should be applied to derive PNECs.

Further, pursuant to Annex I, Section 3.3.2. if it is not possible to derive the PNEC, then this shall be clearly stated and fully justified.

ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment, Section B.8.4. (pages 47 to 48) (version 2.1, December 2011) states that "*if no adverse effects have been observed in studies at the highest recommended concentration/doses tested, this would normally indicate that no hazard has been identified and no DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect or protection target would not be needed*".

ECHA observes that you have not derived PNEC for soil and justified that by the statement that no hazard was identified for terrestrial organisms. However, ECHA notes that adverse effects were observed in some terrestrial toxicity studies reported in the registration dossier. In particular, e.g in the long-term toxicity study on terrestrial invertebrates a NOEC of 62.5 mg/kg dry soil and the LOEC of 125 mg/kg dry soil, based on the number of juveniles, were obtained for the earthworms; and in the toxicity study on terrestrial plants a NOEC and LOEC of 63 and 125 mg/kg, respectively, were obtained for Lycopersicon esculentum (tomato). ECHA considers that observed toxicity to terrestrial organisms in the reported studies indicate the substance to be hazardous to the terrestrial organisms and enables derivation of the PNEC for soil. Therefore, ECHA concludes that hazard to terrestrial organisms was identified and your justification for not deriving PNEC for soil is not acceptable. In addition, ECHA would also like to point out that the absence of classification is not a reason to justify the missing PNECs.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you agree to derive PNEC for soil as requested.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to derive PNECs for soil:
- using the study giving rise to the highest concern according to Annex I, Section 3.1.5 and revise the risk characterisation accordingly *or* provide a detailed justification for not using the study giving rise to the highest concern;
- using the default assessment factors and other recommendations of ECHA Guidance R.10 and revise the risk characterisation accordingly *or* provide a detailed justification on how the chosen approach meets the general requirements for identification of the PNEC as described in Section 3.3. of Annex I if not using the recommendations of ECHA Guidance R.10 for PNEC derivation.

Notes for your consideration

The results of the studies requested with this decision shall be taken into account when revising the PNECs.

9. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment: generate an exposure assessment for all the exposure scenarios and derive the risk characterisation accordingly.

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

Annex I, Section 5 of the REACH Regulation requires the registrants to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Annex I, Section 6 of the REACH Regulation requires the registrants to characterise the risk for each exposure scenario and to consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in Section 5 of the same Annex have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment, Section B.8.4. (pages 47 to 48) (version 2.1, December 2011) states that "*if no adverse effects have been observed in studies at the highest recommended concentration/doses tested, this would normally indicate that no hazard has been identified and no DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect or protection target would not be needed*".

In the CSR you provided, the exposure assessment for the environment is missing. You claimed that no exposure assessment is necessary for the environment by stating that no hazard was identified in the environmental hazard assessment.

However, ECHA notes that adverse effects were observed in some environmental toxicity studies reported in the registration dossier. In particular, e.g in the long-term toxicity study on terrestrial invertebrates a NOEC of 62.5 mg/kg dry soil and the LOEC of 125 mg/kg dry soil, based on the number of juveniles, were obtained for the earthwarms; and in the toxicity study on terrestrial plants a NOEC and LOEC of 63 and 125 mg/kg, respectively, were obtained for Lycopersicon esculentum (tomato).

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you agree to provide environmental exposure assessment as requested.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to generate an exposure assessment for all the exposure scenarios and revise the risk characterisation accordingly.

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 10 October 2017.

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

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

ECHA took into account your comments and did not amend the requests.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

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

3. In relation to the information required by the present decision, the sample of the substance used for the new tests 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 tests 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 tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.