ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 22 November 2017

Addressee: [redacted]

Decision number: CCH-D-2114375616-40-01/F
Substance name: Quaternary ammonium compounds, C20-22-alkyltrimethyl, chlorides
EC number: 271-756-9
CAS number: 68607-24-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 22.02.2016
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. **Robust study summary for long term toxicity test on aquatic invertebrates (Annex IX, Section 9.1.5. in conjunction with Annex I, Section 1.1.4.);**

2. **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 309). The biodegradation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study. The test results should correspond to the temperature of 12°C (285K);**

3. **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). The biodegradation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study. The test results should correspond to the temperature of 12°C (285K);**

4. **Identification of degradation products for the registered substance, including each constituent and relevant impurities present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable (Annex IX, Section 9.2.3.);**

5. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305). The bioaccumulation or bioconcentration of each constituent and impurity present in concentrations at or above 0.1% (w/w) shall be assessed. This can be done simultaneously during the same study. For the PBT/vPvB assessment, the bioaccumulation or bioconcentration potential of degradation products shall also be investigated.**

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 **29 May 2020**. 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 Kevin Pollard, Head of Unit, Evaluation E1

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

Appendix 1: Reasons

1. **Robust study summary for long term toxicity test on aquatic invertebrates (Annex IX, Section 9.1.5. in conjunction with Annex I, Section 1.1.4.)**

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.

Pursuant to Article 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of a robust study summary. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the Practical Guide on "*How to report robust study summaries*".

A long term aquatic invertebrate test is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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. Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 1.1.4. robust summaries are required of all key data used in the hazard assessment.

You have provided a study record for a Daphnia magna Reproduction Test (OECD TG 211) ([redacted], 2010) to meet the standard information requirement of Annex IX, Section 9.1.5.

However, ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the documentation of this study is insufficient and does not allow its use for hazard nor PBT assessment. In particular, the provided results are based on nominal concentrations instead of measured concentrations. Given the physico-chemical properties of the substance (water solubility: 0.01 g/L, Log Kow:3.29, surface active), and that at some of the vessels the measured concentration falls below [redacted]% of the nominal concentration, the OECD 211 TG states that "*results should be expressed in terms of the time-weighted mean*". Therefore, you need to provide a complete robust study summary with the end results (i.e. NOEC, ECx) based on measured concentrations for this study.

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.

In your comments to the draft decision, you agreed on providing the robust study summary in the updated dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: Robust study summary for the Daphnia magna Reproduction Test (Noack, 2010).

ECHA
EUROPEAN CHEMICALS AGENCY

2. Simulation testing on ultimate degradation in 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.

In the technical dossier you have provided a study record for a Simulation test – aerobic sewage treatment A: activated sludge units (OECD 303A). However, this study does not provide the information required by Annex IX, Section 9.2.1.2., because the OECD TG 303A cannot be used to cover the simulation testing on ultimate degradation in water endpoint, as indicated in the Guidance on Information requirement R7b v.4 (June 2017): "*Results from tests simulating the conditions in a sewage treatment plant (STP) (e.g. the OECD 303) cannot be used for assessing the degradation in the aquatic environment*" (R.7.9.5.1). Additionally, it states that "The OECD 303 test is not simulating conditions in the aquatic environment but in sewage treatment plants and consequently, results from this test are not valid for classification" (R.7.9.5), whereas the preferred test method Aerobic mineralisation in surface water – simulation biodegradation test (EU C.25/OECD 309) can be used for the CLP environmental classification. Furthermore, according to the guidance document the OECD 303 studies are not included in the relevant tests to assess persistence in the environment (R.7.9.5.2).

Furthermore, you have sought to adapt this information requirement according to Annex IX, Section 9.2.1.2., column 2. You provided the following justification for the adaptation "*According Annex IX, Section 9.1.2.1 column 2 of the REACH Regulation 1907/2006/EC a Simulation test on ultimate biodegradation in surface water need not to be carried out if the substance is readily biodegradable.*"

According to Annex IX, Section 9.2.1.2, column 2 of the REACH Regulation, simulation testing on ultimate degradation in surface water does not need to be conducted if the substance is highly insoluble in water or is readily biodegradable. ECHA notes that based on the information you provided in the technical dossier, the registered substance has a low but significant water solubility of 10 mg/l and the substance cannot be concluded as readily biodegradable (*i.e.* Study 1: OECD 301B (2009) performed with the main constituent reached a 51% degradation on day 14. Thus, it did not reach the pass criteria of 60% degradation with in a 10 day window. Additionally, for a UVCB substance to be concluded as readily biodegradable, all its constituents need to be concluded as such (ECHA Guidance on Information Requirements R.11.4.1). Study 2: OECD 301B (1992) performed with the registered substance showed a maximum of 40% degradation after 28 days. Study 3: OECD 301D modified (2008) performed with the registered substance showed a maximum degradation of 50% after 28 days).

Additionally, you have sought to adapt the information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing the following information: "*... information is provided using read across. Read across from a similar Quat (HYEQS N, N'-Dimethyl-N''-2-Hydroxyalkyl-N''' (C12-14 alkyl) quat (CAS No. 85736-63-6) can be applied. The test system for HYEQS consisted of: 89% river water, 10% sewage effluent, and 1% combined activated sludge liquor. Biodegradation was determined by Liquid Scintillation Counting of 14C-HYEQS over a 21 day test duration. HYEQS degraded rapidly with a half-life of 0.61 days for loss of parent. No parent compound remained by day 5. The half-life of mineralization was 7.7 days (CO2 evolved), and by day 21 80% of the test substance had evolved as CO2. After 21 days, 0% remained as parent, 11.6% was present as metabolites, 8.4% was present in the solids, and 80% was evolved CO2".*

Annex XI, Section 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. You did not provide any scientific justification explaining why the prediction from HYEQS N, N'-Dimethyl-N''-2-Hydroxyalkyl-N''' (C12-14 alkyl) quat (CAS No. 85736-63-6) to the registered substance for this endpoint is possible. In particular, you have not provided a read-across justification document where e.g. the data matrix, structural similarities and dissimilarities would be recorded and discussed. Besides, you did not provide the study summary for the biodegradation test in surface water with the analogue substance *(HYEQS N, N'-Dimethyl-N''-2-Hydroxyalkyl-N''' (C12-14 alkyl) quat (CAS No. 85736-63-6)* in the dossier.

Therefore, ECHA is not in a position to conclude on the proposed read-across approach nor able to establish whether relevant properties of the registered substance can be predicted from those of the analogue substance. ECHA therefore rejects your proposed read-across adaptation.

As consequence of the situation as explained above, ECHA notes 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.

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

In your comments to the draft decision, you indicate your plan to perform an OECD 301B study and you propose to await the results before concluding on the necessity for preforming the OECD 309 study. ECHA reminds you that the information included in the dossier does not allow the conclusion of the substance being readily biodegradable which would allow adapting the current information requirement. Therefore testing according to OECD TG 309 is necessary.

In your comments you indicate your intention to update the currently missing information for the proposed read-across adaptation from HYEQS N, N'-Dimethyl-N''-2-Hydroxyalkyl-N''' (C12-14 alkyl) quat (CAS No. 85736-63-6) performed with the OECD TG 314D. Nevertheless, ECHA considers that results from a study according OECD TG 314 cannot be used on its own for PBT/vPvB assessment and may only be considered as a part of a weight-of-evidence approach.

This is because the information generated by an OECD TG 314D compliant study is not equivalent to a simulation study on degradation in the environment, since it does not employ relevant environmental conditions for assessing the persistence of the substance in the compartments relevant for the PBT/vPvB assessment, *i.e.* take place in natural surface water, sediment or soil. Furthermore, it is also not relevant for classification & labelling, because it provides information neither on ready biodegradability nor on degradation rates in individual environmental compartments (i.e. natural surface water, sediment or soil). This is also reflected in the ECHA Guidance on Information Requirements and Chemical Safety Assessment R11. (version 3.0, June 2017)

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 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 3.0, February 2016) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (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). The biodegradation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

3. 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. 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 9.2., column 2. You provided the following justification for the adaptation *"According Annex IX, Section 9.1.2.1 column 2 of the REACH Regulation 1907/2006/EC a Sediment simulation test need not to be carried out if the substance is readily biodegradable."*

According to Annex IX, Section 9.2.1.4, column 2 of the REACH Regulation, sediment simulation testing 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, as already described in section 2 above.

Additionally, you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing the following information:"... *Read across from a similar Quat (HYEQS N, N'-Dimethyl-N''-2-Hydroxyalkyl-N''' (C12-14 alkyl) quat (CAS No. 85736-63-6) can be applied.*

The biodegradation of HYEQS in sediment was not tested. But a Half-life of HYEQS for soil (median of 3 soil half-lives) of 6.2d was derived from an OECD 307 Aerobic Soil transformation study (see IUCLID Section 5.2.3). Based on EChA REACH Guidance R.16 Environmental Exposure Assessment, Section R.16.4.4.5 (version 3.0, February 2016) the HYEQS Soil half-life of 6.2 d may also be applied for aerobic sediment if no other data are available".

Annex XI, Section 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. You did not provide any scientific justification explaining why the prediction from HYEQS N, N'-Dimethyl-N''-2-Hydroxyalkyl-N''' (C12-14 alkyl) quat (CAS No. 85736-63-6) to the registered substance is possible. In particular, you have not provided a read-across justification document where e.g. the data matrix, structural similarities and dissimilarities would be recorded and discussed. Besides, you have sought to adapt the information requirement, sediment simulation test, with information on soil simulation test, while you did not provide any justification on the validity of this adaptation.

Therefore, ECHA is not in a position to conclude on the proposed read-across approach nor able to establish whether relevant properties of the registered substance can be predicted from those of the analogue substance. The proposed read-across has therefore to be rejected.

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.

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.

In your comments to the draft decision, you indicate your plan to perform an OECD 301B study and you propose to await the results before concluding on the necessity for the OECD 308. ECHA reminds you that the information included in the dossier does not allow the conclusion of the substance being readily biodegradable, which would allow adapting the current information requirement.Therefore testing following the OECD TG 308 is necessary.

In your comments you indicate your plan to update the technical dossier with a read across justification document clarifying why HYEQS can be used as a read across substance and why information on soil simulation test can be used to adapt the information requirement, sediment simulation test (ECHA REACH Guidance R.16 Environmental Exposure Assessment, Section A.16-3.2.2 (version 3.0 February 2016)). However, ECHA reiterates that information on sediment simulation testing is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment. Therefore, ECHA cannot currently judge if this information requirement can be adapted based on the information on the soil simulation test on HYEQS, and therefore OECD 308 testing is necessary.

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.16-9 (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). The biodegradation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

Notes for your consideration (Sections 2 & 3)

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 both 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.

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

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 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.

ECHA notes that the registration dossier does not contain information on the degradation products or an acceptable adaptation for this standard information requirement pursuant to the specific adaptation rules of Column 2 of Annex IX, Sections 9.2 or 9.2.3. or the general adaptation rules of Annex XI.

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, as already described in section 2 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.

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 Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Impurities present in concentrations at or above 0.1 % (w/w) are deemed to be relevant constituents of the substance. Indeed, Section R.11.4.1 (page 33) of REACH Guidance document R.11 on PBT/vPvB assessment (version 2.0, November 2014) indicates that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*". Therefore degradation products should be identified for each constituent and relevant impurity present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to identify the degradation products of the registered substance subject to the present decision including each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable. This should be done by using an appropriate analytical method. When analytically possible, the identification, stability, behaviour, molar quantity of the metabolites relative to the parent compound should be evaluated. In addition, the degradation half-life, log Kow and potential toxicity of the metabolites may also be investigated.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation, you disagree with "*ECHA to identify the degradation products because the tests are not necessary for the time being*", and you propose to await the results of the proposed new test according to OECD TG 301B.

ECHA reminds you that the information included in the dossier does not allow the conclusion of the substance being readily biodegradable, which would allow adapting the current information requirement. Therefore the identification of degradation products is necessary.

In addition, you indicate that an enhanced biodegradation test according OECD TG 301D is available. In this study is reported: "*A biodegradation percentage of > 60 % can be achieved in the Closed Bottle test inoculated with river water or sludge after an incubation period of 8 weeks. This proves of non persistence of this substance". According to table R.11.4, Chapter R.11.4.1.1 of the ECHA Guidance document on PBT/vPvB assessment (Version 3.0 –June 2017) the conclusion is "Not P and not vP" if the screening result is "biodegradable".* "

ECHA considers that test substances that degrade in these enhanced biodegradation screening tests can not be considered readily biodegradable (unless ready biodegradability without enhancements, *i.e.* in a standard ready biodegradation test, is shown).

Furthermore, ECHA considers that positive results from enhanced screening tests cannot be used on their own and may only be considered as a part of a weight-of-evidence approach to conclude that a substance is not P/vP. This is reflected in the ECHA Guidance on Information Requirements and Chemical Safety Assessment R7b and R11.

ECHA notes that the provided information does not allow to conclude on the full degradation of the registered substance, and therefore there is still an information gap and it is necessary to identify the degradation products.

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.

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

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.

"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.

You have sought to adapt this information requirement according to Annex IX, Section 9.3.2., column 2. You provided the following justification for the adaptation : "*C20/22 ATQ is a quaternary substance and positively charged. It is known that ionic compound have a low potential to cross membranes. In addition C20/22 ATQ has a low measured Log Kow of 3.3 (see IUCLID Section 4.7) and therefore a bioaccumulation potential (water & sediment) is unlikely.*
The statement given above fulfills the requirement for waiving as given in 1907/2006/EC Annex IX, Column 2, 9.3.2: The study need not be conducted if the substance has a low potential for bioaccumulation and /or a low potential to cross biological membranes."

ECHA notes that the registered substance has surface active properties (47.0 mN/m) and therefore, log Kow "is *not a valid descriptor for assessing the bioaccumulation potential. Information on bioaccumulation of such substances should therefore take account of other descriptors or mechanisms than hydrophobicity.*" (ECHA Guidance R.11.4.1.2, v.3.0 June 2017). You also sought to adapt by stating that "*It is known that ionic compound have a low potential to cross membranes".* ECHA is not able to assess the veracity of this general statement, as you have not included any scientific evidence to support it.

Furthermore, ECHA notes that the publicly available report "*Quaternary ammonium compounds. Analyses in a Nordic cooperation on screening*" (Kaj et al., TemaNord 2014:556, http://norden.diva-portal.org/smash/get/diva2:760465/FULLTEXT01.pdf) shows the existence of the main constituents (ATAC C20 & C22) of the registered substance in fish tissues sampled in the European Nordic countries. ATAC C20 & C22 were found in frequencies of 100% in fish liver and in concentrations up to 160 & 5400 ng/g, respectively; and in fish muscle tissue at concentrations up to 1.8 & 30 ng/g, respectively. These monitoring data raise concern on the bioaccumulation property of the registered 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 requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

It should also be noted that according to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Impurities present in concentrations at or above 0.1 % (w/w) are deemed to be relevant constituents of the substance. Indeed, Section R.11.4.1 (page 33) of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) indicates that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*".

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.

In your comments to the draft decision, you do not agree with ECHA's position on the relevance of log Kow for assessing bioaccumulation potential for the registered substance. You consider that "*the Log Kow is a valid descriptor for assessing the bioaccumulation potential if the determination of the values is done as described above [derived from solubility in octanol and water assessment of solubility/cmc].*".

However, ECHA notes that log Kow may as such not be suitable for the determination of the bioaccumulation potential of surfactants (ECETOC, 2014)[2]. The bioaccumulation of surfactants in fish actually shows no correlation with log Kow. More specifically, a number of linear alkyl chain surfactants are readily bio-transformed in fish, so that the actual value of bioaccumulation may be lower than predicted from the respective log Kow. On the other hand, surfactants may adsorb to food and can contribute to an increased intake via the diet, independently of the log Kow of the substance (Treu et al. 2015)[3]. Cationic surfactants in particular may bind to negatively charged sites like fish mucous. Equilibrium values and depuration times are expected to be larger for such substances. Therefore, ECHA considers that the log Kow value is not a suitable parameter to assess the bioaccumulation potential of the substance and threshold values based on log Kow, *e.g.* those defined for the 'B' and 'vB' criteria, are regarded as not applicable to surface-active substances.

[2] ECETOC, 2014. Information to be considered in a weight-of-evidence-based PBT/vPvB assessment of chemicals (Annex XIII of REACH) Special Report No. 18. Eureopean Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC).
[3] G. Treu, W. Drost, U. Jöhncke, C. Rauert and C. Schlechtriem, 2015. The Dessau workshop on bioaccumulation: state of the art, challenges and regulatory implications. Environmental Sciences Europe. 27:34

In your comments to the draft decision, you additionally include a literature review on the bioconcentration behaviour of similar molecules to C22-ATQ. Among the provided results, the highest experimental BCF values are for the longest carbon chained substances, C16-18 being the longest carbon chain molecule reported. ECHA notes that the BCF-value of 1962 provided for the C16-18 substance is close to the B threshold while the registered substance has a still longer C20-22 carbon chain and hence most probably a higher bioaccumulation potential. Additionally, you have not demonstrated how the provided information could allow to conclude on bioaccumulation of the registered substance subject to this decision.

In addition, you stated that *"aquatic systems is not the right compartment because of the adsorption behavior of the registration substance".* ECHA notes that you may chose to perform the OECD 305 test through either the aqueous or dietary exposure. In any case, ECHA expects an explanation from you for the route chosen.

Following on a proposal for amendment (PfA) submitted by a Member State Competent Authority ECHA notes the following. ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) defines 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. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.

In your comments on the PfA you state that *"aqueous testing may not be the right compartment because of the adsorption behavior of the registration substance".* You consider that for the registered substance, a catinonic surfactant, *"It will not be possible to achieve a steady state concentration in a flow-through system"* and conclude that *"a dietary study may be the better system for such kind of difficult to test substances".* ECHA notes that as indicated above while the aqueous route is the preferred for the PBT assessment, you may also fulfill the present information requirement by carrying out the study using the dietary route of exposure, bearing in mind the requirements identified in the paragraph above. ECHA does acknowledge that based on paragraph 12. of the OECD TG 305 the aqueous route may not be most suitable for surfactants. ECHA also advises you to consult the ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.11* (version 3.0, June 2017) for further advice.

In summary, ECHA notes that the provided information does not allow to conclude on the bioaccumulation of the registered substance in aquatic species, and therefore there is still an information gap and it is necessary to provide information on bioaccumulation.

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). The bioaccumulation or bioconcentration of each constituent and impurity present in concentrations at or above 0.1% (w/w) shall be assessed. This can be done simultaneously during the same study. For the PBT/vPvB assessment, the bioaccumulation or bioconcentration potential of degradation products shall also be investigated.

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. You should revise the PBT assessment when information on bioaccumulation is available.

Appendix 2: Procedural history

The scope of this compliance check decision is limited to the standard information requirements of Annexes VII to X, Section 9 of the REACH Regulation (ecotoxicological and environmental fate information).

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 4 November 2016.

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

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

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-55 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.