ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 10 December 2019

Addressee: [redacted]

Decision number: CCH-D-2114493448-34-01/F
Substance name: BENZENESULPHONIC ACID
EC number: 202-638-7
CAS number: 98-11-3
Registration number: [redacted]
Submission number: [redacted]
Submission date: 08/11/2010
Registered tonnage band: Over 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. **Composition of the registered substance (Annex VI, Section 2.3.);**
   - **Nature of impurities, including isomers and by-products**
2. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. / OECD TG 471) with the registered substance;**
3. **In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method: OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487) with the registered substance;**
4. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the registered substance provided that the studies requested under 2. and 3. have negative results;**
5. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats with the registered substance;**
6. **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;**
7. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species (rat or rabbit), oral route with the registered substance;**
8. **Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: Fish, acute toxicity test, OECD TG 203) with the registered substance;**
9. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**

10. **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;**

11. **Robust study summary (RSS) for [redacted] ready biodegradability (Annex VII, Section 9.2.1.1.);**

    OR

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: DOC die-away test, OECD TG 301A) or

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: CO2 evolution test, OECD TG 301B) or

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: MITI test (I), OECD TG 301C) or

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Closed bottle test, OECD TG 301D) or

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Modified OECD screening test, OECD TG 301E) or

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Manometric respirometry test, OECD TG 301F) or

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD TG 310)

    with the registered substance.

You have to submit the requested information in an updated registration dossier by ***17 June 2022.*** You shall also update the chemical safety report, where relevant.

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.

This decision does not address the information requirement of the Extended one-generation reproductive toxicity study according to Annex X, Section 8.7.3. of the REACH Regulation.

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

INFORMATION ON SUBSTANCE IDENTITY

1. Composition of the substance (Annex VI, Section 2.3.)

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the identification of the registered substance.

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations. Therefore, Annex VI, section 2.3.2, requires information on the nature of the impurities present in the composition of the substance.

In line with paragraph 4.3 of the *Guidance for identification and naming of substances under REACH and CLP* (Version 2.1, May 2017), the following applies to all mono-constituent substances, including the registered substance:

- All the impurities present at ≥ 1 % shall be identified and reported individually; and
- All the impurities relevant for the classification and/or PBT assessment shall be identified and reported individually.

For each constituent, including the main constituent and any impurity, the typical, minimum and maximum concentration level shall be specified.

You reported your substance as a mono-constituent and in the composition, in IUCLID section 1.2, you reported one main constituent (Benzenesulphonic acid) with a minimum concentration of [redacted] and one impurity [redacted] with a maximum concentration of [redacted] Therefore, the sum of the minimum content of the main constituent and the maximum content of the reported impurity is [redacted]

ECHA notes that up to [redacted] of the composition has therefore not been accounted for and therefore potentially impurities of the substance may be missing from the reported composition.

ECHA therefore concludes that the compositional information has not been provided to the required level of detail, and the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity.

You are accordingly requested to revise the information on the composition of the registered substance in order to establish a precise chemical representation of what the substance consists of.

More specifically, you are requested to report the impurities which have not been potentially reported in section 1.2, and to provide for each impurity, the typical, minimum and maximum concentration levels.

You indicated in your comments to the draft decision your intention to update section 2.3 of the REACH registration to fully identity all impurities.

Further technical details on how to report the composition of substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" (version: 4.0, May

2017) on the ECHA website.

INFORMATION ON TOXICOLOGY AND ECOTOXICOLOGY

I. Grouping and read-across approach for (eco)toxicological information

Your registration dossier contains adaptation arguments which are based on a grouping and read-across approach in accordance with Annex XI, Section 1.5. of the REACH Regulation. You have grouped registered substances and formed a group (category) of 'aromatic sulphonic acid' to predict from data for reference substance(s) missing (eco)toxicological properties for other substances within this group (read-across approach).

You seek to adapt the information requirements for the following standard information requirements by grouping substances in the category and applying a read-across approach in accordance with Annex XI, Section 1.5:

i. *in vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.);
ii. *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.);
iii. sub-chronic toxicity study (90-days; Annex IX, Section 8.6.2.);
iv. pre-natal developmental toxicity study (Annex IX, Section 8.7.2.); and
v. pre-natal developmental toxicity study (Annex X, Section 8.7.2.).
vi. Short-term toxicity testing on invertebrates (Annex VII, Section 9.1.1);
vii. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2);
viii. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3);
ix. Ready biodegradability (Annex VII, Section 9.2.1.1);.

ECHA has considered the scientific and regulatory validity of your grouping and read-across approach in general before assessing the individual properties of the substance in section II of this appendix.

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category.

Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological or ecotoxicological property is reliable and should be based on recognition of the structural similarities and differences between the source and registered substances. This hypothesis explains why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

Due to the different nature of each endpoint and consequent difference in scientific considerations (e.g. key parameters, biological targets), a read-across must be specific to the endpoint or property under consideration. Key physicochemical properties may determine the fate of a compound, its partitioning into a specific phase or compartment and largely influence

the availability of compounds to organisms, e.g. in bioaccumulation and toxicity tests. Similarly, biotic and abiotic degradation may alter the fate and bioavailability of compounds as well as be themselves hazardous, bioaccumulative and/or persistent. Thus, physicochemical and degradation properties influence the human health and environmental properties of a substance and should be considered in read-across assessments. However, the information on physicochemical and degradation properties is only a part of the read-across hypothesis, and it is necessary to provide additional justification which is specific to the endpoint or property under consideration.

The ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis[2, 3] - (1) (Bio)transformation to common compound(s)- the read-across hypothesis is that different substances give rise to (the same) common compounds to which the organism is exposed and (2) Different compounds have the same type of effect(s)- the read-across hypothesis is that the organism is exposed to different compounds which have similar (eco)toxicological and fate properties as a result of structural similarity (and not as a result of exposure to common compounds).

Finally, Annex XI, Section 1.5. lists several additional requirements, which deal with the quality of the studies which are to be read across.

A. Scope of the category

You have provided a read-across justification document in the CSR (sections 0.1 and 0.2).

You have defined the structural basis for the category/grouping as "*sulphonic acids, a class of organic acids with the general formula R-S(=O)$_2$-OH, where* R "

You have identified the following substances as the 'Aromatic Sulphonic Acids (ASA)' category members:

[1] Toluene-4-sulphonic acid (EC No. 203-180-0, CAS No. 104-15-4);
[2] 2 (or 4)-toluene sulphonic acid (EC No. 274-893-2, CAS No. 70788-37-3);
[3] (Xylenes and 4-ethylbenzene) sulphonic acid (EC No. 701-247-3, CAS No. NS);
[4] Benzene sulphonic acid (EC No. 202-638-7, CAS No. 98-11-3);
[5] p-cumene sulphonic acid (EC No. 240-210-1, CAS No. 16066-35-6);
[6] Cumene sulphonic acid (EC No. 253-730-9, CAS No. 37953-05-2);
[7] Hydroxybenzensulphonic acid (EC No. 215-587-0, CAS No. 1333-39-7) and
[8] 4-hydroxybenzene sulphonic acid (EC No. 202-691-6, CAS No. 98-67-9).

The substances are hereafter refered to as substance [1] to [8].

In your comments to the draft decision you discuss in further detail the similarity between the members of your category. You state, for example, that:

- it has been concluded in different reports that sulfonic acids behave in a toxicologically similar manner and that para-TSA (toluene sulphonic acid) can be used as a toxicological surrogate for BSA (benzene sulphonic acid).
- you acknowledge a slight increase of activity from BSA to CSA (cumene sulphonic acid) due to the alkyl substituents, which can increase the nucleophilicity of the benzene ring. However, you consider it negligible.

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)
[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://echa.europa.eu/publications/technical-scientific-reports

- the increase in carbon atoms from toluene to xylene and to cumene improve solubility in apolar solvents and reduce solubility in polar solvents like water. You state that the substances are highly water-soluble and expected to be rapidly excreted and minimally absorbed into systemic circulation.
- the substances have low octanol-water partitioning coefficients (Kow). Therefore, you indicate that they have similar behaviour in the environment due to their affinity for water phase and that bioaccumulation is not expected.
- the reactivity increases from the substance with the lowest acidity (HBSA; hydroxybenzene sulphonic acid) to the one with highest acidity (CSA) and therefore you consider that CSA and HBSA could be considered as the most representative substances of the group for the evaluation of human health effects and environmental distribution properties.
- HBSA could be considered one of the metabolites of BSA since usually the aromatic hydroxylation is the first reaction in the microbial and human metabolism (confirmed by the available data on TSA). Therefore, you say that HBSA has the highest water solubility and is the lowest bioavailable and CSA has the highest number of methyl groups with the most activated benzene ring.

You further provide information from the QSAR Toolbox, showing for example that there are no alerts for genotoxicity for any of the members of the category (or any of their corresponding salts), and that alerts for reprotoxicity are similar for the aromatic sulphonic acids and the hydrotropes.

i. Characterisation of the composition of the category members

The characterisation of the substances identified as members of a category needs to be as detailed as possible in order to confirm category membership and to assess whether the attempted predictions are not compromised by the composition and/or impurities. The information provided on the substance characterisation of the category members must establish a clear picture of the chemical structures of their constituents to establish the extent of qualitative and quantitative differences and similarities in the structure and in the composition of these substances. ECHA recommends to follow its Guidance for identification and naming of substances under REACH and CLP for all source substances within the category.

You have not addressed the composition of the category members in your read-across justification. However, information on composition for substances [1], [3], [4], [5] and [8] can be found in the IUCLID dossiers for the respective registrations.

The toluene-4, benzene, 4-hydroxybenzene and p-cumene sulphonic acids are mono-constituent substances whereas the (xylenes and 4-ethylbenzene) sulphonic acid is an UVCB substance.

Toluene-4, p-cumene- and 4-ethyl-benzene sulphonic acids are mainly in the form of [redacted] For xylene-sulphonic acid the alkyl groups are mainly in the [redacted]

ECHA considers the information provided in the technical dossiers with regard to the composition of the category members [1], [3], [4], [5] and [8] as sufficient to establish structural similarity (and structural differences) between the category members.

However, substances [2], [6] and [7] are not registered under REACH. Therefore, no information on their composition is available. As a consequence, ECHA considers that there is

no adequate information available to establish the extent of the similarity and of the differences in the structure and in the composition of these three substances.

ii. Applicability domain of the category

According to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6.2, Section R.6.2.4.1, (version 1.0, May 2008) a category hypothesis should address "*the set of inclusion and/or exclusion rules that identify the ranges of values within which reliable estimations can be made for category members for the given endpoint. These rules, can be described as the applicability domain for an endpoint and provide a means of extending the category membership to chemicals not explicitly included in the current definition of a category.*"

Furthermore, according to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6.2, Section R.6.2.1.2, (version 1.0, May 2008) "*a category evaluation does not necessarily result in all the individual substances included in the category evaluation being registered to the Agency, although the data from these substances will be included in the category report in support of the registration.*"

Based on your description of the structural basis of your grouping/category approach, ECHA understands that all category members share a common 'core structure' and that they vary only in terms of their alkyl- substitutions on the benzene ring. Furthermore, ECHA understands that the allowed substituents to the 'core structure' define the inclusion critera for the category membership. You have defined the structural basis for the category/grouping as "*sulphonic acids, a class of organic acids with the general formula R-S(=O)$_2$-OH, where R is usually a hydrocarbon (aromatic) side chain*".

Considering the UVCB nature of the (xylene and 4-ethylbenzene) sulphonic acid, ECHA considers that the the applicability domain of the category to be: sulphonic acids of benzene, hydroxybenzene, cumene, toluene, and xylene (containing up to [redacted] 4-ethylbenzene). The structural variation within the category is defined by the alkyl- (or hydroxy-) substituents on the core structure, i.e. benzene sulphonic acid. ECHA assessed your proposed predictions on this basis.

B. Prediction of toxicological properties

You have provided the following reasoning for the prediction of toxicological properties:

"*.....the acidity of the sulphonic acid group is not expected to change significantly among the five aromatic sulphonic acids.[.....] Thus the reactivity of the sulphonic acids are very similar and they can each be used as a surrogate for the others. A full set of 2010 guideline physical-chemical studies demonstrates the similar chemical and physical properties and behavior of the 5 sulphonic acids in the category. The sulphonic acid moiety is the primary driver for mammalian toxicity and any difference between the benzene, xylene, cumene, and toluene moieties would be insignificant given the relatively high level of corrosivity of all five substances in the category.*"

ECHA understands that you base your predictions on the assumption that different compounds have similar toxicological properties as a result of structural similarity. You assume that all substances will show the same type of effects for toxicological properties. ECHA notes the following shortcomings with regards to prediction of toxicological properties:

i. Insufficient information to support the claim of the same type of effects *for toxicological properties*

According to Annex XI, Section 1.5., '*Application of the group concept requires that [...] human health effects [...] may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).*'

A number of factors contributes to the robustness of the predictions made within a group. According to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6.2, Section R.6.2.1.5. (version 1.0, May 2008), one of these factors is the density and distribution of the available data across the category. In order to derive reliable prediction of the properties of the members of the category, adequate and reliable information covering the range of structural variations identified among the category members needs to be available.

In the read-across hypothesis, you assume, based on the available information, the same type of effects across the category. You provided:

- Repeated dose toxicity studies conducted with a (xylenes and 4-ethylbenzene) sulphonate and p-toluene sulfonic acid
- pre-natal developmental toxicity studies conducted with a (xylenes and 4-ethylbenzene) sulphonates in rats and rabbits;
- Reproductive and developmenal toxicity screening test conducted with p-toluene sulfonic acid as well as supporting toxicokinetic information available on toluene sulphonate; and
- In vivo micronucleus test with cumene sulphonate and calcium xylenesulphonate
- In vitro micronucleus tests with p-toluenesulfonic acid
- In vitro gene mutation study in bacteria with benzenesulfonic acid and p-toluenesulfonic acid (both studies not acceptable due to quality issues as described in section II)

ECHA notes that you predict (or propose to predict) the properties of the members of the category from data available mainly on (xylenes and 4-ethylbenzene) sulphonates and its salts, and to a lesser extent on toluene-4 sulphonic acid and its corresponding salt and on p-cumene sulphonate. Prediction is based on structural similarity and appears plausible if the available data allows for a side-by-side comparison of the toxicity profiles of the source and target substance.

However, there is very little data available on the target substances benzene, p-cumene and hydroxybenzene sulphonic acids to support such a prediction for the endpoints of mutagenicity, repeated dose toxicity, developmental toxicity and toxicity to reproduction. Therefore, ECHA considers that the available information does not cover the range of structural variations for those substances and hence there is no support for your claim of a regular pattern of similar ecotoxicological properties.

With regard to reading across from (xylenes and 4-ethylbenzene) sulphonic acid or sulphonate to toluene 4-sulphonic acid (and *vice versa*), ECHA notes that the results from the available reproductive and developmental toxicity screening test conducted with toluene sulphonic acid is consistent with the available repeated dose toxicity and pre-natal developmental toxicity studies conducted with (xylenes and 4-ethylbenzene) sulphonates. In both cases a lack of toxicity have been demonstated up to the limit dose. In addition, there is supporting toxicokinetic information available on toluene sulphonate which demonstrates that this substance is excreted unchanged in urine.

Therefore, ECHA considers it likely that the repeated dose, developmental toxicity and the toxicity to reproduction effects of toluene sulphonates may be predicted from (xylenes and 4-ethylbenzene) sulphonates. This conclusion is further supported by a 28-day repeated dose

toxicity study on toluene 4-sulphonic acid. However, for mutagenicity there is not a sufficient database to allow for a side-by-side comparison of the effects. Therefore, ECHA considers that, in the absence of any relevant mutagenicity data on toluene sulphonic acid, the available information does not support your claim of a regular pattern of same type of effects for with regard to mutagenicity. This issue is further discussed below and under the respective endpoints for genotoxicity.

With regard to reading across from a (xylenes and 4-ethylbenzene) sulphonate or toluene sulphonic acid to the p-cumene, benzene, and hydroxybenzene sulphonic acids (and *vice versa*) first for human health endpoints other than mutagenicity, ECHA notes that there is no relevant information to allow a side-by-side comparison of effects related to repeated dose toxicity, reproductive or developmental toxicity wich supports the read-across approach. Furthermore, there is no toxicokinetic information available on the substances that could have helped supporting the read-across approach.

Therefore, in the absence of any relevant repeated dose, reproductive or developmental data on p-cumene, benzene, and hydroxybenzene sulphonic acids, ECHA considers that there is no support for the read-across for these endpoints. A reproductive and developmental toxicity screening test (OECD TG 422) allows a screening level assessment of such effects and could potentially be used to support read-across for these endpoints, provided that the results obtained are consistent with those obtained with the source substances.

Secondly, for mutagenicity, ECHA notes that for p-toluenesulfonic acid, a xylenesulphonate, and a cumene sulphonate, that there are *In vitro* and *In vivo* micronucleus tests available. However, the *In vitro* tests for mutagenicity cover two aspects, chromosome aberration and gene mutation. There is no acceptable information available which would allow comparison of the gene mutation potential between these category members. In the absence of such data, ECHA considers that there is no support for your claim of a regular pattern of same type of effects with regard to potential to induce gene mutation for any of the category members.

Furthermore, for benzene sulphonic acid and hydroxybenzene sulphonic acid, there is no acceptable data available on chromosome aberration. In the absence of suitable "bridging information", ECHA considers that there is no support for your claim of a regular pattern of same type of effects with regard to that endpoint for benzene sulphonic acid and hydroxybenzene sulphonic acid.

ECHA has evaluated the information from QSAR Toolbox provided by you. We note that the lack of experimental results for many endpoints is a concern in this case. Generally, the purpose of QSAR Toolbox is to group substances with similar structures and profiling outcome to fill the data gaps with available experimental data. In this particular case, it appears this group of substances was grouped mainly on the basis of similar physical, structural and chemical properties, and consistent outcome from the QSAR Toolbox profilers within the group. The profilers are only indicative additional 'similarity measures'. Therefore the consistency within the profiling outcome have to be confirm by the consistency of the data from toxicological studies, and consequently reliable experimental data for category members must be available. Taking these considerations into account, this QSAR Toolbox category can be considered as a good starting point for category formation, but the available information is not sufficient to predict consistent toxicological behaviour of the category members.

In conclusion, ECHA considers that there is still no support for your claim of a regular pattern of same type of effects for the endpoints discussed above due to missing "bridging" information. In your endpoint-specific comments generation of such information is discussed, and ECHA has responded to those comments below under the respective endpoint requests.

C. Prediction of ecotoxicological and ready biodegradability properties

You have provided the following reasoning for the prediction of ecotoxicological properties and ready biodegradability properties: *"……the acidity of the sulphonic acid group is not expected to change significantly among the five aromatic sulphonic acids. [……] Thus the reactivity of the sulphonic acids are very similar and they can each be used as a surrogate for the others. A full set of 2010 guideline physical-chemical studies demonstrates the similar chemical and physical properties and behavior of the 5 sulphonic acids in the category.[…] The aromatic sulphonic acids are almost completely ionized in watery environments."*

Specifically for ready biodegradability, you claim in section 4.1.2.1.2 of the CSR that *"…seven biodegradation studies are performed with the closely related hydrotropes (the salts) for which was concluded that these are readily biodegradable. As the cation has limited affect on the biodegradation potential, and in principle the salts gets dissociated when in contact with water thus forming the acid, it is considered justified to conclude that these substances are readily biodegradable, taking into account all the available information."*

ECHA understands that you base your predictions on the assumption that different compounds have similar ecotoxicological and ready biodegradability properties as a result of structural similarity. ECHA notes the following shortcomings:

i. Insufficient information to support a claim of similar ecotoxicological and ready biodegradability properties

According to Annex XI, Section 1.5., *'Application of the group concept requires that […] environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).'*

A number of factors contributes to the robustness of the predictions made within a group. According to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6.2, Section R.6.2.1.5. (version 1.0, May 2008), one of these factors is the density and distribution of the available data across the category. In order to derive reliable prediction of the properties of the members of the category, adequate and reliable information covering the range of structural variations identified among the category members needs to be available.

Ecotoxicological properties

In the read-across hypothesis, you assume similar ecotoxicity properties across the category.

ECHA notes that you propose to predict the properties of the members of the category from data available mainly on toluene-4-sulphonic acid, on salts of (xylenes and 4-ethylbenzene) sulphonic acid, and on benzene sulphonic acid. However, based on the information provided in the technical dossier of category members, there is very little data available on the category members to support such a prediction for the aquatic toxicity endpoints of algae growth inhibition, short-term toxicity testing on aquatic invertebrates, and short-term toxicity testing on fish, as explained below:

- short-term toxicity testing on fish: data is only available for one member of the category, toluene-4-sulphonic acid.

- short-term toxicity testing on aquatic invertebrates: one reliable study is available for

one member of the category, benzene sulphonic acid (key study). A study is available also on toluene-4-sulphonic acid, but with an exposure duration of 24h ('weight of evidence' study). According to the ECHA guidance R7b (Section R.7.8.4.1), 24 hour values can have considerable variability in the repeatability of results and should not be compared to 48 hour values. Therefore ECHA considers that this study on toluene sulphonic acid cannot be used to compare with the study on benzene sulphonic acid.

- algae growth inhibition: meaningful data for comparison are available only on two category members, i.e. toluene-4-sulphonic acid and (xylenes and 4-ethylbenzene) sulphonic acid. There is also an algae study available for benzene sulphonic acid (key study), but the study has not been performed in optimal pH conditions (i.e. pH of 3 and 5 at the two highest test concentrations, which might have influenced the results), hence its results cannot be compared to those of studies with the other two category members.

Consequently, the data density across the category members is limited in the aquatic toxicity endpoints. In particular, for 4-hydroxybenzene sulphonic acid and p-cumene sulphonic acid, no aquatic toxicity data is available. With such limited reliable information available on the aquatic toxicity, no quantitative trend between the category members can be established for these endpoints.

Therefore, ECHA considers that the available information does not cover the range of structural variations and hence there is no support for your claim of a regular pattern of similar ecotoxicological properties.

In response to the additional information provided in your comments on the draft decision, you acknowledge that no tests are available for 4-hydroxybenzene sulphonic acid and you indicate that new tests will be performed in order to strengthen the validity of the category. In your endpoint-specific comments generation of such information is discussed.

Furthermore, you consider that the read-across between toluene-4-sulphonic acid and benzene sulphonic acid is acceptable and you claim that the presence of methyl group on the benzene rind does not significantly impact the ecotoxicological profile of the substance. However, ECHA notes that you do not provide any evidence to support your claim.
In particular, ECHA considers that there is still no support for your claim of a regular pattern of same type of effects for the endpoints discussed above due to missing "bridging" information. As a consequence, ECHA notes that the read-across between 4-hydroxybenzene sulphonic acid and benzene sulphonic acid, as well as, benzene sulphonic acid and toluene-4-sulphonic acid is not acceptable based on the information currently available.

ECHA acknowledges that in your comments on the draft decision you indicate your intention to strengthen the read-across approach after new data for the registered substance (or its corresponding salt) become available. However, you do not specify which substance you want to test in the long-term studies. Since this information and an updated read-across justification for the long-term aquatic toxicity endpoints is not yet available, ECHA cannot currently assess whether your choice of appropriate tests and use read-across adaptations for the long-term aquatic toxicity endpoints would be acceptable.

ECHA will evaluate your information after the deadline of this decision according to the specific rules of column 2 adaptations in Annex IX/X, and in support of an adaptation according to Annex XI, section 1.5.

For your consideration, ECHA notes there may be information available on these substances

that has not been included in the technical dossier nor in the data matrix for ecotoxicity even though such data may be relevant. For instance, in your read-across justification you propose read-across between each individual sulphonic acid and the corresponding ammonium, calcium, potassium and sodium salts (defined as "hydrotropes" or "sulphonates" in your read-across justification document). However, ECHA notes that there are aquatic toxicity studies available in the technical dossiers of the corresponding salts that have not been considered and reported in the technical dossier of the acid (e.g. short-term fish and short-term *Daphnia* studies on (xylenes and 4-ethylbenzene) sulphonate, short-term *Daphnia* study on sodium toluene sulphonate). Since these additional studies on salts have not been included in the technical dossiers of the registered substance, they could not be taken into account when assessing the scientific and regulatory validity of your grouping and read-across approach of the 'aromatic sulphonic acid (ASA) ' category.

Ready biodegradability property

In the read-across hypothesis, you assume the same ready biodegradability properties across the category. You further argue that this is supported by the available studies on the various category members and their salts which demonstrate the ready biodegradability of the substances.

ECHA notes that you propose to predict the ready biodegradability properties of the "aromatic sulphonic acid" category members based on the available data on the category members and their corresponding salts.

ECHA accepts read-across between the "aromatic sulphonic acids" and their corresponding ammonium, calcium, potassium and sodium salts provided that the source study is adequate and reliable for the endpoint concerned.

ECHA notes that the source study on sodium salt of toluene 4-sulphonic acid is valid and shows that this substance is ready biodegradable. You use this study in order to conclude on this endpoint for all category members. However, ECHA notes that, for the reasons explained in request 11 below, all the other studies available on the category members and their corresponding salts are either not adequate (in total twelve studies) or the information provided is insufficient to make an independent assessment of the study (three studies).

Since adequate information on ready biodegradability is currently available only for one category member, ECHA considers that the available information does not cover the range of structural variations and hence there is no support for your claim of a regular pattern of similar ready biodegradability properties.

ii. Inconsistency between the read-across hypothesis and the experimental results for ready biodegradability endpoint

Annex XI, Section 1.5 of the REACH Regulation requires that "Substances whose [..] ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group". According to the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6.2, Section R.6.2.2.2, (version 1.0, May 2008) "a demonstration of consistent trends in the behaviour of a group of chemicals is one of the desirable attributes of a chemical category and one of the indicators that a common mechanism for all chemicals is involved". The observation of a deviation in a trend among some members of a category is a warning sign. An explanation for this deviation in the trend resulting in a contradiction between the similarities in properties claimed in the read-across hypothesis and the observation of different properties needs to be provided and

supported by scientific evidence.

In the read-across hypothesis, you assume the same ready biodegradability properties across the category. You further argue that this is supported by the available studies on the various category members and their salts which demonstrate the ready biodegradability of the substances.

ECHA notes that the source study on sodium salt of Toluene-4-sulphonic acid is valid and shows that this substance is ready biodegradable. Regarding the other source studies available for this endpoint, for the reasons explained in request 11 below ECHA considers that twelve of them are not adequate, while three of them (OECD 301D studies) are insufficiently reported hence their reliability cannot be currently assessed.

In addition, ECHA notes that the results of the three OECD 301D studies show that salts of cumene-, (xylenes and 4-ethylbenzene) sulphonic acids as well as benzene sulphonic acid are not ready biodegradable. Although ECHA cannot currently establish the reliability of these three OECD 301D studies, you consider them reliable since you have assigned Klimisch score 2. The results of these three OECD 301D studies contradict your hypothesis that the category members are ready biodegradable. Therefore, ECHA considers that you have not demonstrated that the read-across is supported.

D. Conclusion

ECHA accepts read-across between the "aromatic sulphonic acids" and their corresponding ammonium, calcium, potassium and sodium salts provided that the source study is adequate and reliable for the endpoint concerned.

- *Read-across for toxicological endpoints*

Reading across form (xylene and 4-ethyl benzene) sulphonates to toluene sulphonic acid (and *vice versa*), for repeated dose toxicity, developmental toxicity and toxicity to reproduction "bridging infromation" is available and as a result ECHA accept the proposed read-across. However, ECHA considers that due to missing "bridging infromation" it is not possible to establish a scientifically credible link between the target and source substances which would allow to predict the outcome of the *in vitro* mutagenicity tests. Concequently, read-across is rejected for mutagenicity.

Reading across form (xylene and 4-ethyl benzene) sulphonates and toluene sulphonic acid to p-cumene, benzene, and hydroxybenzene sulphonic acids (and *vice versa*), ECHA considers that due to missing "bridging information" it is not possible establish a scientifically credible link between the target and source substances which would allow to predict the outcome of the *in vitro* mutagenicity tests, repeated dose toxicity, developmental toxicity studies, and toxicity to reproduction studies. Concequently, read-across is rejected for these endpoints.

For benzene sulphonic acid and hydroxybenzene sulphonic acid, read-across for chromosome aberration is furthermore rejected in the absence of suitable "bridging information".

- *Read-across for ecotoxicological and ready biodegradability endpoints*

ECHA considers that due to missing "bridging information" it is not possible to establish a scientifically credible link between the category members which would allow to predict the outcome of the algae growth inhbition, short-term fish and short-term *Daphnia* studies. Consequently, the proposed read-across is rejected.

ECHA concludes that, due to insufficient reliable information and contradicting information, your proposed prediction for ready biodegradability is not supported. Consequently, the proposed read-across is rejected.

II. Specific considerations on the information requirements

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 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.

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

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing studies conducted with other category members. However, for reasons explained in section I as well as further below, none of these studies (alone or combined) meet the standard information requirement of Annex VIII, Section 8.4.1. Consequently, your adaptation of this information requirement according to Annex XI, Section 1.5. is rejected. Additional reasons for rejecting the submitted data are provided below.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

You have provided the following study records:

i. [redacted] (1988), key study, Reliability 2, according to GLP, *in vitro* gene mutation study in bacteria (similar to OECD TG 471), p-toluenesulfonic acid (EC no 203-180-0) was tested in five strains of *S. typhimurium* (TA 1535, TA 1537, TA 1538 TA 98 and TA 100), metabolic activation; and according to OECD TG 471, (*in vitro* gene mutation study in bacteria rel. 2, GLP compliant, 1988, [redacted] Metabolic activation missing for the positive controls (strains TA100, TA1535 and TA 1537).

ii. [redacted] (1988), supporting study, Reliability 2, not according to GLP, *in vitro* gene

mutation study in bacteria (non-guideline), benzenesulfonic acid (EC no 202-638-7) was tested in four strains of *S. typhimurium* (TA97, TA98, TA100, and TA1535), metabolic activation only for the highest dose.

According to paragraph 13 of the current OECD TG 471 test guideline (updated 1997) at least five strains of bacteria should be used: S. typhimurium TA1535; TA1537 or TA97a or TA97; TA98; TA100; S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101). This includes four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by *E.coli* WP2 strains or *S. typhimurium* TA102 which have an AT base pair at the primary reversion site.

You have provided a studies none of which included tests with strains *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101). In addition, both tests deviate form the OECD TG 471 in terms of the required positive controls with metabolic activation and metabolic activation used in all dose groups.

Therefore, the provided studies do not provide the information required by Annex VIII, Section 8.4.1., nor can it be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2. of the REACH Regulation.Consequently there is an information gap and it is necessary to provide information for this endpoint.

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

In your comments to the draft decision you agree to perform the requested test.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14. / OECD TG 471).

3. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

An "In vitro cytogenicity study in mammalian cells or an in vitro micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. 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 XI, Section 1.5. of the REACH Regulation by providing study records by providing a studies conducted with other category members. However, as explained above (section I), your adaptation of the information requirement is rejected.

The studies provided in the technical dossier are listed below:

i. [redacted](1988), key study with the analogue substance p-toluenesulfonic acid (EC no 203-180-0) according to OECD TG 473 (*in vitro* mammalian chromosomal aberration test, rel. 2, GLP compliant).

ii. [redacted](1991), key study with the analogue substance sodium cumenesulphonate (EC no 248-983-7) according to OECD TG 474 *(in vivo* mammalian erythrocyte micronucleus test, rel. 2, GLP compliant, 1991, [redacted]

iii. [redacted] (1994), supporting study with the analogue substance calcium xylenesulphonate (EC no 248-829-9) according to TG EPA OTS 798.5385 (*in vivo* mammalian cytogenetic tests: bone marrow chromosomal analysis, rel.2, GLP compliant, 1994, [redacted])

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

ECHA considers that the *in vitro* mammalian chromosome aberration test (test method OECD TG 473) and the in vitro mammalian cell micronucleus test (OECD TG 487) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

In your comments to the draft decision you agree to perform the requested test.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered subject to the present decision: *In vitro* mammalian chromosome aberration test (test method: OECD TG 473) or in vitro mammalian cell micronucleus study (test method: OECD TG 487).

4. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained.

ECHA notes that the registration dossier does not contain study records or adaptataions according to Column 2 of Annex VIII, Section 8.4.3. or according to Annex XI for this endpoint. Adequate information *on in vitro* gene mutation in mammalian cells will however need to be present in the technical dossier for the registered substance to meet this information requirement provided that the studies requested under [1] and [2] have negative results. ECHA set the deadline for provision of the information to allow for sequential testing.

Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the in vitro mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476) and the in vitro mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

In your comments to the draft decision you agree to perform the requested test.

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: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490) provided that the studies requested under [2] and [3] have negative results.

5. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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 XI, Section 1.5. of the REACH Regulation by providing the below listed study records. However, as explained above, your adaptation of the information requirement is rejected.

The studies submitted in the registration dossier are:

1. [redacted](1990), supporting study with the analogue substance p-toluene sulfonic acid (CAS no.104-15-4) according to OECD TG 407 (28 day subacute repeated dose toxicity study in rat, rel.2,GLP compliant, 1990, [redacted]

2. [redacted]1969), supporting study with the analogue substances sodium xylene sulphonate (CAS no 1300-72-7) performed similar to OECD TG 408 (90-day subchronic repeated dose toxicity study in rat,rel. 2, non-GLP compliant)

3. [redacted](1980) supporting study with the analogue substances sodium xylene sulphonate (CAS no 1300-72-7), no guideline specified (90-day subchronic repeated dose toxicity studies in mice, rel. 2, non GLP compliant)

4. [redacted](1980) supporting study with the analogue substances sodium xylene sulphonate (CAS no 1300-72-7) performed similar to OECD 408 guideline (90-day subchronic repeated dose toxicity studies in rat, rel. 2,non-GLP compliant)

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

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 5.0, December 2016) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely, potential inhalation-specific effects are already addressed by deriving a long-term DNEL for inhalation. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

According to the test method OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

In your comments on the draft decision you proposes a stepwise testing strategy for this endpoint, starting with an OECD 422, Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test. You indicate that there might be an available test for this endpoint (OECD 422) within the HPV programme with the registered substance. In case a test is not available or reliable, you propose to cover this endpoint by a new test with the registered substance. ECHA agrees with the first step of your testing

strategy.

As a second step you propose that the OECD 422 screening study could be used to justify read-across to existing OECD 408 studies for other members of your category (or their corresponding salts). You also indicate that the OECD 422 screening study could potentially be used to cover this endpoint and to verify if there is a concern. However, ECHA would like to stress that the repeated dose toxicity study (OECD 408) cannot be replaced by an OECD 422 screening study.

Depending on the outcome of the OECD 422 screening study you will either have to justify read-across to existing OECD 408 studies for other members of your category (or their corresponding salts), or perform a new study with your registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: OECD TG 408) in rats.

Notes for your considerations:

The Extended one-generation reproductive toxicity study (EOGRTS) according to Annex X, Section 8.7.3., is not part of this decision because the results of the Sub-chronic toxicity study (90-day) are considered crucial to inform on the study design of the EOGRTS. Therefore, the results of the Sub-chronic toxicity study (90-day) should be used, among other relevant information, to decide on the study design of the EOGRTS.

ECHA may therefore launch a separate compliance check at a later stage addressing the EOGRTS information requirement.

Alternatively, you may also consider submitting a testing proposal for an Extended one-generation reproductive toxicity study together with the results of the requested Sub-chronic toxicity study (90-day). The testing proposal should include a justification for its study design following ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017), taking into account the results of the Sub-chronic toxicity study (90-day).

6. 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 provided a study record of a non-guideline pre-natal developmental toxicity study with the analogous substance [redacted]

ECHA has evaluated your adaptation according to Annex XI, Section 1.5. of the REACH Regulation (Grouping of substances and read-across). However, as explained above, your adaptation of the information requirement according to Annex XI, Section 1.5. is rejected.

Therefore, 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 liquid, ECHA concludes that testing should be performed by the oral route.

In your comments on the draft decision you proposes a stepwise testing strategy for this endpoint, starting with an OECD 422, Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test on the registered substance. ECHA agrees with the first step of your testing strategy.

As a second step you propose that the OECD 422 screening study could potentially be used to cover this endpoint and to verify that there is a concern. You also indicate that a new OECD 443 study could be used to evaluate reproductive and developmental toxicity However, ECHA would like to stress that the pre-natal developmental toxicity study (OECD 414) cannot be replaced by an OECD 422 screening study or an OECD 443 study. Depending on the outcome of the OECD 422 screening study you will either have to justify read-across to existing OECD 414 studies for other members of your category (or their corresponding salts), or perform a new study with your registered substance.

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

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

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

The technical dossier does not contain information on a pre-natal developmental toxicity study with the registered substance. Furthermore, adapting this information requirement according to Annex XI, Section 1.5. of the REACH Regulation is rejected as explained above in section I.

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

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

In your comments on the draft decision you propose a similar testing strategy as for request 6 above. ECHA's response under request 6 is also relevant for this endpoint.

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: OECD TG 414) in a second species (rabbit or rat) by the oral route.

Notes for your consideration

You are reminded that before performing a pre-natal developmental toxicity study in a second species you must consider the specific adaptation possibilities of Annex X, Section 8.7., column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species with other available information enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

8. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. 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 XI, Section 1.5. of the REACH Regulation by providing the following study record:

1. Key study on the analogue substance toluene 4-sulphonic acid according to EPA OTS 797.1400 (Fish Acute Toxicity Test): [redacted] rel 2, Non-GLP compliance

However, as explained above, your adaptation of the information requirement according to Annex XI, Section 1.5. is rejected.

Therefore, 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 acute toxicity test (test method EU C.1. / OECD TG 203) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.3.

In your comments and in your attachment on the draft decision you agree that there is a data gap for this endpoint. You indicate that there might be an available test with the registered substance for this endpoint (OECD 203) within the HPV programme. In case a test report is not available or reliable, you propose to cover this endpoint by using the available study on

the analogue substance toluene sulphonic acid (TSA). However, as explained in section 'Grouping and read-across approach' above, ECHA cannot assess whether your porposal to use read-across adaptations for this endpoint would be acceptable, based on the currently available information.

In addition, ECHA notes in your attachment, you have summarised your testing strategy for each substance in this group. ECHA notes you have stated you will undertake a test in the group member using an OECD TG 201 for this endpoint. However, ECHA notes that the specific OECD TG guidline for this endpoint is OECD TG 203.

ECHA will evaluate your information after the deadline of this decision.

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, acute toxicity test (test method: EU C.1./OECD TG 203).

9. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

"Long-term toxicity testing on aquatic invertebrates" 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.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.5., column 2. You provided the following justification for the adaptation: *"An environmental risk assessment has indicated that the members of the Aromatic Sulphonic Acids category do not pose a risk to the aquatic environment for all relevant uses. In Annex IX of Regulation (EC) No 1907/2006 it is laid down that chronic toxicity tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further. Since the chronic testing would not change the outcome of the environmental risk assessment no additional chronic testing on aquatic invertebrates appears to be justified."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2. Firstly, as discussed in request 8. above, the short-term fish information you have used as basis for PNEC derivation and the current Chemical Safety Assessment (CSA) for environment cannot be considered acceptable. Secondly, the ready biodegradability data available in the technical dossier cannot be considered reliable, as discussed in request 11. below. As a result, the exposure assessment based on the conclusion that the substance is ready biodegradable is currently not reliable. For these two reasons, the Chemical Safety Assessment (CSA) including the exposure assessment and the risk characterisation sections cannot, with the available information, be used to adapt this information requirement.

However, as explained above, your adaptation of the information requirement according to Annex XI, Section 1.5. is rejected.

Therefore, 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) *Daphnia magna* reproduction test (test method EU

C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

In your comments and in your attachment on the draft decision you propose a stepwise testing strategy for this endpoint.

You agree to first complete the requirement on short-term aquatic study (request 8). In addition, you inidcate that if the updated CSA shows that further investigation of effects on aquatic organism(s) is required, you indicate that you will perfom the appropriate long-term test(s).

ECHA agrees that an Integrated Testing Strategy (ITS) can be used to determine the order of the studies to be performed and the necessity to conduct the long-term toxicity testing on aquatic invertebrates and on fish, as explained in the *Note for your consideration* below.
In addition, ECHA notes as stated above, you need to also consider the current exposure assessment based on the conclusion that the substance is ready biodegradable is currently not reliable.

ECHA notes you have not specified the test substance to test the long-term studies in your comments or your attachment. However, as stated above, ECHA highlights that this request for this endpoint is for the registered substance or the corresponding salt.

ECHA will evaluate your information after the deadline of this decision.

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: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

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

You have sought to adapt this information requirement according to Annex IX, Section 9.1.6., column 2. You provided the following justification for the adaptation: "*An environmental risk assessment has indicated that the members of the Aromatic Sulphonic Acids category do not pose a risk to the aquatic environment for all relevant uses. In Annex IX of Regulation (EC) No 1907/2006 it is laid down that chronic toxicity tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on fish.(..)* "

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2. As already discussed in request 9. above, the risk characterisation is currently not reliable. Therefore, the CSA cannot be currently used to adapt the current information requirement.

However, your adaptation of the information requirement is rejected.

Therefore, 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, Section R.7.8.4.1.*

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).

In your comments on the draft decision you proposes a stepwise testing strategy for this endpoint and for Long-term toxicity testing on aquatic invertebrates (request 9). ECHA's response under request 9 also applies to this endpoint.

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).

Note for your consideration for requests 8-10

Before conducting the tests requested above under requests 9. and 10., you shall consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Section R.7.8.5 to determine the necessity to conduct the long-term toxicity testing on aquatic invertebrates and on fish.

Concerning the order of studies to be conducted, you may first complete the requirements on short-term aquatic study requested under request 8. and on ready biodegradability requested under request 11. in this decision, and subsequently update the CSA according to Annex I of the REACH Regulation.

If you come to the conclusion that no further investigation of chronic effects on aquatic organisms is required, you shall update your technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.5 and 9.1.6. taking into account the new data generated by the short-term aquatic studies requested by the present decision and exposure assessment and risk characterisation.

On the other hand, if after the update of the CSA you come to the conclusion that the long-term toxicity tests are still required to refine the risk assessment, you should further consider

the Integrated Testing Strategy (ITS) for aquatic toxicity as described 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). According to the ITS, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially less sensitive than other trophic levels (i.e. fish, invertebrates, algae), long-term studies may be required on both fish and invertebrates. In such case, according to the ITS, the long-term *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

11. Robust study summary (RSS) for [redacted] ready biodegradability (Annex VII, Section 9.2.1.1.);

OR

Ready biodegradability study (Annex VII, Section 9.2.1.1.)

"Ready biodegradability" is a standard information requirement as laid down in Annex VII, section 9.2.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have provided the following sixteen study summaries to fulfill the Annex VII section 9.2.1.1. information requirement of Ready biodegradability (IUCLID section 5.2.1):

1. Weight of evidence on the analogue substance sodium toluene sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted], rel 2, GLP compliant: result: 99.8% degradation after 28d.
2. Weight of evidence on the analogue substance sodium cumene sulphonate according to OECD Guideline 301D (Ready Biodegradability: Closed Bottle Test): [redacted] reliability 2, GLP compliance: not specified, result: 50% degradation after 28d.
3. Weight of evidence on the analogue substance sodium cumene sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted], reliability 2, GLP compliance: yes, result: >100% degradation after 28d.
4. Weight of evidence on the analogue substance calcium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 2, GLP compliance: yes, result: 69-87% degradation after 29d.
5. Weight of evidence on the analogue substance sodium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301 D (Ready Biodegradability: Closed Bottle Test): [redacted] reliability 2, GLP compliance: not specified, result: 40% degradation after 28d.
6. Weight of evidence on the analogue substance sodium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 2, GLP compliance: not specified, result: 86-88% degradation after 28d.
7. Weight of evidence on the analogue substance sodium (xylenes and 4-ethylbenzene) sulphonate according to OECD Guideline 301B (Ready Biodegradability: CO2 Evolution Test): [redacted] reliability 2, GLP compliance: yes, result: 83-85% degradation after 28d.
8. Weight of evidence on the registered substance benzenesulphonic acid according to

OECD Guideline 301D (Ready Biodegradability: Closed Bottle Test): [redacted] reliability 2, GLP compliance: not specified, results: 54% degradation after 28d (inherently biodegradable).

9. Weight of evidence on the registered substance benzenesulphonic acid according to EU method C.6 (Degradation: Chemical Oxygen Demand): [redacted] reliability 4, GLP compliance: not specified, results: 98.5 % degradation after 120 hours and inherently biodegradable.
10. Other information on the registered substance benzenesulphonic acid, No guideline available: [redacted] reliability 4, GLP compliance: not specified, results: No degradation observed.
11. Other information on the registered substance benzenesulphonic acid, No guideline available:: [redacted] reliability 4, GLP compliance: no, results: Test substance is reported to be biodegradable.
12. Other information on the registered substance benzenesulphonic acid, no guideline followed: [redacted] reliability 4, GLP compliance: not specified, results: No degradation was observed.
13. Other information on the analogue substance hydroxybenzene sulphonic acid, no guideline specified: [redacted] reliability 4, GLP compliance: no, conclusion: The test cannot be used to evaluate the biodegradability of the test substance.
14. Weight of evidence on the analogue substance toluene-4-sulphonic acid according to EU method C.6 (Degradation: Chemical Oxygen Demand): [redacted] reliability 4, GLP compliance: not specified, results: 98.7% degradation after 120h.
15. Weight of evidence on the analogue substance toluene-4-sulphonic acid, Publication, no guideline indicated: [redacted] reliability 4, GLP compliance: not specified, results: 90 % degradation (no duration mentioned).
16. Supporting study on the analogue substance toluene-4-sulphonic acid, Sccondary source literature review: [redacted] reliability 4, GLP compliance: not specified, conclusuion: p-toluene solphonic acid is readily biodegradable.

ECHA agrees that studies no 9-16 are not reliable (Klimisch score 4) since they do not give sufficient experimental details. Thus, they do not provide the information required by Annex VII, Section 9.2.1.1. and therefore ECHA has not evaluated them further.

ECHA acknowledges that you have intended to submit the results from study no 1-8, in a weight of evidence (WoE) approach as made possible by the provisions of Annex XI section 1.2. ECHA understands that you seek to adapt this information requirement for ready biodegradability according to Annex XI, Section 1.2., weight of evidence. Hence, ECHA has evaluated your adaptation with respect to this provision.

ECHA notes that an adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the 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.

However, ECHA notes that while you have indicated that a weight of evidence approach has been submitted, you have not provided any explanation or justification on how the sources of information/studies that you have provided enable to conclude on the endpoint. In addition, studies 1 to 8 do not provide the information required by Annex VII, Section 9.2.1.1., as

explained in details below.

Therefore, the general rules for adaptation laid down in Annex XI, Section 1.2. of the REACH Regulation are not met and your adaptation of the information requirement is rejected.

In addition, ECHA notes that you have sought to adapt the information requirement for ready biodegradability according to Annex XI, Section 1.5. of the REACH Regulation by providing seven studies on the salts of "sulphonic acid" category members (studies no 1-7). However, as explained above, your adaptation of the information requirement according to Annex XI, Section 1.5. is rejected. Moreover, as described below, studies no 2 to 7 do not provide the information required by Annex VII, Section 9.2.1.1., because the information reported is insufficient to make an independent assessment of the study (study no 2 and 5), or they are not adequate (studies no 3-4, 6-7).

Finally, regarding study no 8 on the registered substance as described below, it does not provide the information required by Annex VII, Section 9.2.1.1., because the information reported is insufficient to make an independent assessment of the study.

Specifically, ECHA has identified the following issues regarding the provided studies:

a) Studies not adequate due to significant deviations from standard test guidelines and due to missing information

For studies no 3-4 and no 6-7 ECHA has identified the following deficiencies:

- Adaptation of the inoculum

According to par. 18 of OECD TG 301, the inoculum used should not be pre-adapted to the test substance. For studies no 3 and 7, you report "adaptation not specified" for the inoculum, but you indicate that the inoculum used in these studies was acclimated in SCAS units for 9 days. ECHA considered this treatment as a not acceptable deviation from the requirements of OECD TG 301, as also explained in ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017) Section R.7.9.4.1. Therefore, studies no 3 and no 7 cannot be considered adequate to conclude on this endpoint.

- No duplicates

According to par. 12 of OECD TG 301, determinations should be carried out at least in duplicate. However, in studies no 3 and no 6 only one flask was used per test substance concentration. ECHA considers that this a significant deviation from OECD TG 301, also because results in replicates are needed to verify the validity of the ready biodegradability tests as described in par. 24 of OECD TG 301. Therefore, studies no 3 and 6 cannot be considered adequate to conclude on this endpoint.

- Concentration of inoculum

The inoculum concentrations of studies no 4 and no 6 are not compliant with the test conditions specified in Table 2 of OECD TG 301, since you report that the cell concentration was "*5.2 x 10-7*" cfu/mL in study 4 and "*10x8 germs viable*"/mL in study 6, while it should be between 10^7 and 10^8 cells/L. ECHA considers these inoculum concentrations as a significant deviation from the requirements of OECD TG 301, and you have not explained

how this deviation might have affected the results. Therefore, studies no 4 and 6 cannot be considered adequate to conclude on this endpoint.

- Missing information to assess the validity and reliability of the study

  ECHA notes that for studies no 3-4 and no 6-7 you have not provided all information required in paragraph 27 of the OECD TG 301, Art. 3(28) of REACH and in ECHA's Practical Guide 3 "*How to report robust study summaries*". In particular, the following information is missing:

  - Detailed description of the test substance
    For all mentioned studies, composition of the test material is not provided, hence it is not possible to verify whether the test material is representative of the registered substance.

  - Detailed description of the inoculum
    You have not specified whether the inoculum was pre-adapted in studies no 4 and 6, and you have not provided information on inoculum concentration in studies no 3 and 7. In the absence of this information, it is not possible to verify whether the test conditions would comply with the requirement of par. 18 of OECD TG 301 regarding inoculum adaptation and of Table 2 of OECD TG 301 regarding inoculum concentration.

  - Number of replicates per test substance concentration
    For study you have not reported the number of flasks per concentration, hence ECHA cannot verify whether it would comply with the requirements of par. 12 of OECD TG 301.

  - Any deviations in the standard test protocols

  - A clear reporting of the test results including all raw data in a tabular form
    In the absence of this information, ECHA cannot verify that the validity critieria, as defined in paragraphs 24 and 25 of OECD TG 301, have been fulfilled.

Due to the deficiencies listed above, ECHA concludes that studies no 3-4 and no 6-7 are not adequate and hence cannot be used to conclude on this endpoint nor to adapt the standard information requirment according to Annex XI, Section 1.5..

b) Insufficient information provided to assess the studies

Under Article 3(28) of the REACH Regulation, a Robust study summary "*means 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*".

Specifically, for studies no 2 (on salt of the registered substance), no 5 (on (xylenes and 4-ethylbenzene) sulphonate) and no 8 (on benzene sulphonic acid or phenol sulphonic acid), ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the information provided in the robust study summary is insufficient to allow an independent assessment of these studies.

In this regard, ECHA notes that the Robust study summaries do not include critical information required in the OECD TG 301 and in ECHA's Practical Guide 3 "*How to report robust study*

summaries", which is needed to assess the validity and reliability of the studies. This critical information concerns in particular:

- Details on the test substance (e.g. composition for all studies, as well as substance identification for study no.8 (i.e. benzene sulphonic acid or phenol sulphonic acid));
- Details on inoculum (concentration and any pre-conditioning treatment);
- Information on the test design as specified in the OECD TG 301 and any deviations in the standard test protocols;
- clear reporting of the test results (e.g. all raw data in a tabular form).

Due to the absence of this critical information, the robust study summaries of studies no 2, 5, and 8 cannot be relied on for an independent assessment of the properties of the registered substance. As a consequence, while as explained above studies no 2 and 5 on the analogue substances cannot be used to adapt the information requirement according to Annex XI, Section 1.5., for study no 8 it cannot be established whether the information requirement is met.

Conclusions

ECHA has evaluated according to the criteria in Annex XI, 1.2. and Annex XI, 1.5. concluded that the studies considered alone or in combination do not provide the information required by Annex VII, Section 9.2.1.1.

In conclusion, 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.

Furthermore, ECHA notes that you have considered the registered substance readily biodegradable in your chemical safety assessment (CSA). ECHA considers that reliable information is missing for such conclusion for the risk assessment of the registered substance, and therefore this conclusion must be rejected.

In your comments and in your attachment to the draft decision, you agree with this request. You indicate that there you will evaluate the study report in order to find missing information. In addition, ECHA notes in your attachment, you have summarised your testing strategy for each substance in this group.

In order to allow an independent assessment of the study no 8 submitted, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to provide complete robust study summary for the study: [redacted] with the above missing information for the study.

Alternatively, if you cannot submit a complete RSS or the RSS indicates that the study is not reliable as per the criteria indicated above and/or not adequate to fulfil the information requirement, 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:

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: DOC die-away test, OECD TG 301A) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: CO2 evolution test, OECD TG 301B) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: MITI test (I), OECD TG 301C) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Closed bottle test, OECD TG 301D) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Modified OECD screening test, OECD TG 301E) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Manometric respirometry test, OECD TG 301F) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD TG 310).

Regarding the test method, depending on the substance profile, you may conclude on ready biodegradability, by applying the most appropriate and suitable test guideline among those listed in the ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) and in the paragraph below. The test guidelines include the description of their applicability domain.

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 24 July 2018.

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 within 30 days of the notification.

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.