Helsinki, 26 January 2021

Addressees
Registrant(s) of JS_451-160-7 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
29/05/2019

Registered substance subject to this decision ("the Substance")
Substance name: 2,4,7,9-Tetramethyl-4,7-decanediol
EC number: 451-160-7
CAS number: 17913-76-7

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***31 January 2024***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from all the Registrants subject to Annex VIII of REACH

1. Adsorption/ desorption screening (Annex VIII, Section 9.3.1.; test method: OECD TG 106)

2. Simulation testing on ultimate degradation in surface water also requested below (triggered by Annex VIII, Section 9.2.)

3. Identification of degradation products also requested below (triggered by Annex VIII, Section 9.2.)

4. Bioaccumulation in aquatic species also requested below (triggered by Annex I, Sections 0.6.1. and 4; Annex XIII, Section 2.1.)

B. Information required from all the Registrants subject to Annex IX of REACH

1. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12 °C

2. Identification of degradation products (Annex IX, 9.2.3.; test method:EU C.25./OECD TG 309)

3. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: OECD TG 305)

Reasons for the request(s) are explained in the following appendices:

- Appendices entitled "Reasons to request information required under Annexes VIII to IX of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

The studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes".

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Christel Schilliger-Musset, Director of 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 A: Reasons to request information required under Annex VIII of REACH

1. Adsorption/ desorption screening

Adsorption/desorption screening is an information requirement under Annex VIII to REACH (Section 9.3.1.).

You have provided an OECD TG 121 study as a key study with the Substance.

We have assessed this information and identified the following issue:
The OECD TG 121 method is not suitable for some classes of chemicals, for instance surface active substances (ECHA Guidance R.7a, Section R.7.1.15.3).

The study you have provided was conducted according to OECD TG 121.

Based on the information in your dossier, you report that the surface tension of the Substance is 33.4 mN/m.

The information included in your dossier indicates that the Substance has surface active properties. Therefore the results of the study conducted according to OECD TG 121 are not considered reliable and are rejected.

Therefore the information requirement is not fulfilled.

In your comments to the draft decision, you agree to carry out a study on adsorption/desorption using a batch equilibrium method.

Batch equilibrium method (OECD 106) is to be used for surface active substances, as indicated in the ECHA Guidance on information requirements and chemical safety assessment (version 6.0., July 2017), Chapter R.7a, Section R.7.1.15.3.

2. Simulation testing on ultimate degradation in surface water

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

You have provided the following information in the dossier on the degradation simulation in water: *"According to REACh regulation, Annex IX, 9.2, further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The exposure assessment demonstrated, that the risk for environment is controlled and thus, there is no need for further testing of biodegradation."*

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (*i.e.* <60/70% degradation in an OECD 301 A-F), and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:

- for some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid;

Your registration dossier provides the following:

- The Substance is not readily biodegradable (43,8 % degradation after 28 days in OECD TG 301F);
- The Substance is a surfactant and therefore high potential for bioaccumulation cannot be excluded based on water-octanol partitioning coefficient.

Furthermore, the information in your dossier is currently incomplete and therefore:

- it is not possible to conclude on the persistence of the Substance (see Appendix B, Section 1 of this decision)
- there is no adequate data to conclude on bioaccumulation potential of the Substance (see AppendixB, Section 3 of this decision).

The information above indicates that the Substance is a potential PBT/vPvB substance.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

For ECHA's response, to your comments to the draft decision regarding this request, see request B.1. below.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix B, Section 1 .

3. Identification of degradation products

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

You have provided the following information in the dossier on the degradation products: "*According to REACh regulation, Annex IX, 9.2, further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The exposure assessment demonstrated, that the risk for environment is controlled and thus, there is no need for further testing of biodegradation.*"

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance (itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product) is a potential PBT/vPvB substance (ECHA Guidance R.11.4).

As already explained in the Appendix A, Section 2, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation including identification of degradation products.

For ECHA's response, to your comments to the draft decision regarding this request, see request B.1. below.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix B, Section 2 .

4. Bioaccumulation in aquatic species

Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1 and 4 to REACH).

You have provided the following information in the dossier on bioaccumulation:

- Key study with an analogue, Surfynol 124 (non-guideline study - Bioconcentration test of chemical substances in fish and shellfish, 2010);and
- Key study: QSAR estimation of bioconcentration factors (by BCFBAF v3.01 model) for the Substance.

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4).

As already explained in the Appendix A, Section 2 above, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for bioaccumulation investigation.

Therefore, the CSA indicates the need for further investigation on bioaccumulation in aquatic species.

For ECHA's response, to your comments to the draft decision regarding this request, see request B.3. below.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix B, Section on 3.

EUROPEAN CHEMICALS AGENCY

Appendix B: Reasons to request information required under Annex IX of REACH

1. Simulation testing on ultimate degradation in surface water

Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

You have provided the following an adaptation under Annex IX, Section 9.2., Column 2 with the following justification: *"According to REACh regulation, Annex IX, 9.2, further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The exposure assessment demonstrated that the risk for environment is controlled and thus, there is no need for further testing of biodegradation"*

We have assessed this information and identified the following issues:

Under Section 9.2., Column 2 of Annex IX to REACH, the study may be omitted if the CSA does not indicate the need for further biotic degradation testing. The CSA does indicate such need (Annex I, Section 4; Annex XIII, Section 2.1) if, for instance, the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4). This is the case if the Substance itself or any of its constituent, impurity or transformation/degradation product present in concentration ≥ 0.1% (w/w) meets the criteria already listed in Appendix A, Section 2.

You adapted this information by indicating that the exposure assessment demonstrates that the risk for the environment is controlled.

However, without assessing whether risks are controlled, as already explained in the Appendix A, Section 2. above, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation.

Consequently, you have not demonstrated that the CSA does not indicate the need for further biotic degradation testing and your adaption is rejected.

In your comments to the draft decision, you indicate that the data is requested in order to clarify the potential PBT/vPvB properties of the substance. You propose to employ a stepwise approach, i.e. first clarify the bioaccumulation potential of the substance and based on the outcome of it to conclude, whether further examination on degradation of the substance is needed to clarify whether the substance fulfills the PBT/vPvB criteria. You state that if the substance does not fulfil the B criterion, the PBT/vPvB characteristics do not apply and consequently a generation of further data for the PBT/vPvB assessment are not necessary.

According to the Annex XIII PBT/vPvB assessment shall also take account of the PBT/vPvB properties of relevant constituents of a substance and relevant transformation/degradation products. Therefore, after addressing bioaccumulation potential of only of the major constituent or of some of constituents of the Substance, may be not possible to conclude if the Substance is a potential PBT/vPvB substance and consequently, not possible to justify omission of the simulation degradation testing and identification of degradation products.

Study design

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. Therefore:

- You must perform the OECD TG 309 test, by following the pelagic test option with

natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11).

- You must perform the test at the temperature of 12°C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8). Performing the test at this temperature is in line with the applicable test conditions of the OECD TG 309.

Non-extractable residues (NER) must be quantified in all simulation studies. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11).

2. Identification of degradation products

Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

You have adapted this information requirement according to Annex IX, Section 9.2., Column 2 with the following justification: ""*According to REACh regulation, Annex IX, 9.2, further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The exposure assessment demonstrated, that the risk for environment is controlled and thus, there is no need for further testing of biodegradation.*"

We have assessed this information and identified the following issues:

Under Section 9.2., Column 2 of Annex IX to REACH, the study may be omitted if the chemical safety assessment (CSA) does not indicate the need for further biotic degradation testing. The CSA does indicate such need (Annex I, Section 4; Annex XIII, Section 2.1) if, for instance, the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4). This is the case if the Substance itself or any of its constituent, impurity or transformation/degradation product present in concentration ≥ 0.1% (w/w) meets the criteria already listed in Appendix A, Section 2.

You adapted this information by indicating that the exposure assessment demonstrates that the risk for the environment is controlled.

However, without assessing whether risks are controlled, as already explained in the Appendix A, Section 2 above, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation including identification of degradation products.

Therefore, you have not demonstrated that the CSA does not indicate the need for further biotic degradation testing including identification of degradation products and your adaption is rejected.

For ECHA's response, to your comments to the draft decision regarding this request, see request B.1. above.

On this basis, the information requirement is not fulfilled.

Study design

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in Appendix B Section 1 or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Appendix B Section 1) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, *e.g.* 20°C) and at higher application rate (*i.e.* > 100 µg/L).

3. Bioaccumulation in aquatic species

Bioaccumulation in aquatic species is a standard information requirement under Annex IX to REACH (Section 9.3.2.).

In the registration dossier you have provided the following information on bioaccumulation:

- Adaptation for this information requirement by using Grouping of substances and read-across approaches under Annex XI, Section 1.5. and in support of your adaptation you have provided following information for this endpoint in your dossier:
    - Key study with Surfynol 124 (non-guideline study - Bioconcentration test of chemical substances in fish and shellfish, 2010);and

- Adaptation for this information requirement by using Qualitative or quantitative structure-activity relationship (QSAR) under Annex XI, Section 1.3. and in support of your adaptation you have provided following information for this endpoint in your dossier:
    - Key study: QSAR estimation of bioconcentration factors (by BCFBAF v3.01 model) for the Substance.

We have assessed this information and identified the following issues:

(a) Assessment of the Grouping of substances and read-across approach, in light of the requirements of Annex XI, Section 1.5.

You have adapted the standard information requirement by applying a read-across approach in accordance with Annex XI, Section 1.5.

ECHA has considered the scientific and regulatory validity of your read-across approach in general before assessing the specific standard information requirements in the following paragraphs.

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. 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.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

You have provided a read-across justification document in IUCLID Section 13.

You read-across between 2,5,8,11-tetramethyldodec-6-yne-5,8-diol (EC 269-348-01) Surfynol 124 as source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of bioaccumulation in aquatic species of the Substance:
"*Data generated with the source substance 2,5,8,11-tetramethyldodec-6-yne-5,8-diol are used only to support the general low acute toxicity and to address bioaccumulation. Since 2,5,8,11tetramethyldodec-6-yne-5,8-diol has longer side chains and, thus a higher log Kow, it can be considered as a worst case with respect to bioaccumulation for the target substance.*"

You have provided the following reasoning which refers to the prediction of toxicological properties, but ECHA understands should also be considered for prediction of bioaccumulation of the Substance:
"*This read-across is based on the hypothesis that source and target substances have similar toxicological properties because - [...] manufactured from similar precursors under similar conditions – [...] structural similarities with common functional groups: [...] acetylene group as core structure, however, in the target substance this acetylene group has been fully hydrogenated during the manufacturing process; geminal hydroxyl groups on the alpha carbon atoms; distal to the geminal hydroxyl groups is an isobutyl group (methyl isopropyl) – [...] similar physicochemical properties and thus, show a similar toxicokinetic behaviour – [...] expected to undergo similar metabolism.".*

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted based on a worst-case approach.

ECHA notes the following shortcomings with regards to the prediction of the ecotoxicological properties.

1. *Supporting information*

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[2]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include information to confirm your claimed worst-case prediction.

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

As indicated above, your read-across hypothesis is based on the assumption that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm a conservative prediction of the properties of the Substance from the data on the source substance(s). Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

In your read-across hypothesis, you indicate that *"Since the source substance 2,5,8,11-tetramethyldodec-6-yne-5,8-diol has a higher log Know (4.79) than the target substance 2,4,7,9-tetramethyldecane-4,7-diol (3.8), the source substance can be considered to be a worst case for bioaccumulation. The BCF of 2,5,8,11tetramethyldodec-6-yne-5,8-diol was determined to be < 24."*

In the registration dossier you note that source and target substances are surfactants.

As explained in the section on assessment of QSAR below, such estimations and prediction of bioaccumulation based on Kow are not reliable for the surfactants. Thus, information used by you to support your hypothesis that target substance is the worst-case for the prediction of bioaccumulation of the Substance is not reliable.

In the absence of such reliable supporting information, you have not established that the source substance Surfynol 124 constitutes a worst-case for the prediction of the property under consideration of the Substance. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

2. Quality of the source study

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should:
- be adequate for the purpose of classification and labelling and/or risk assessment; and
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

According to the provisions of Annex IX, Section 9.3.2. information on bioaccumulation in aquatic species as specified in the OECD TG 305 shall be provided. In the dossier you indicated that the route of exposure is 'feed', so ECHA understands that the test with dietary exposure of fish was performed. To comply with OECD TG 305 requirements the following requirements must be met:

- Coverage of the key parameter which is the bioaccumulation potential of the test substance in whole fish, which must be determined based on the following parameters:
  1) the uptake rate constant (k_1) and loss rate constants including the depuration rate constant (k_2), and/or
  2) the kinetic bioconcentration factor (BCF_K), and/or
  3) the dietary biomagnification factor (BMF).

- For a test to be valid the following conditions apply:
  1) the concentration of the test substance in fish food before and at the end of the uptake phase is within a range of ± 20% (based on at least three samples at both time points);
  2) a high degree of homogeneity of substance in the spiked food is demonstrated (i.e. less than ± 15% from the mean in at least three sample);

3) concentrations of test substance is below detection level, or only at typical trace levels, in un-spiked food or control fish tissues;
4) Mortality or other adverse effects/disease in both control and test group fish should be ≤10% at the end of the test.

- a study can be terminated at the end of the uptake period (or with the second depuration sample) only if:
  1) all validity criteria are fulfilled, and
  2) the lack of uptake is not due to some other shortcoming of the test, and
  3) appropriate justification is provided (*e.g.* analysis of faeces for undigested test substance as part of a "mass balance" approach);
- the analytical method used for the quantification of the test material in the feed and in fish tissues is described;
- the BCF/BMF is based on the total concentration in the fish (*i.e.* per total wet weight of the fish);
- tabulated test material concentration data in fish, mean measured concentration at end of uptake, the derived (overall) depuration rate constant and concentration in fish at start of depuration phase are provided;
- the results of the determination of the test substance in test and control diets at least in triplicate are reported;
- method of estimation of the corresponding BCF value from the dietary test is reported.

However, you have provide a study record without information on the above key parameters and validity criteria.

Without this information, you have not demonstrated that study fulfils the OECD TG 305's key parameters and validity criteria.

On this basis your adaptation under Annex XI, Section 1.5 is rejected.

(b) Assessment of the QSAR under Annex XI, Section 1.3.

You have adapted the standard information requirements by applying a QSAR adaptation in accordance with Annex XI, section 1.3.:

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following cumulative conditions are met, in particular:

- the results are adequate for classification and labelling and/or risk assessment.

In this respect, a low log Kow (*i.e.* log Kow < 3) may be used to support low potential for bioaccumulation if the partitioning to lipids is the sole mechanism driving the bioaccumulation potential of a substance. For some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes). For this reason log Kow is not considered a valid descriptor of the bioaccumulation potential for such substances (ECHA Guidance R.7c, Appendix R.7.10-3).

In the registration dossier you have provided estimation of bioaccumulation potential (bioconcentration factor (BCF) by BCFBAF v3.011 model). For the estimation of the BCF you note that equations based on Kow are used.

In the registration dossier you note that Substance are surfactant. There is no evidence provided in the dossier that the partitioning to lipids is the sole mechanism driving the bioaccumulation potential of these substances.

Therefore, QSAR estimation of BCF based on Kow is not reliable. Consequently, the results of such QSAR estimation is not adequate for classification and labelling and/or risk assessment.

On this basis your adaptation under Annex XI, Section 1.3 is rejected.

In your comments to the draft decision, you note that you will first revise the robust study summary (RSS) of the existing study for the analogue substance and check, whether this study fulfills the information requirement. Additionally, you state you will strengthen the read-across approach for this information requirement. Furthermore, you agree to perform bioaccumulation in aquatic species study, if the existing data do not fulfill the information requirement.

It is in your discretion to generate and provide the necessary supporting information in order to justify your read-across adaptation. If you do so, you are responsible for demonstrating the fulfilment of the requirements of Section 1.5 of Annex XI to REACH. If it fails and the resulting data does not support, or even contradict, your read-across hypothesis, you remain responsible for complying with this decision by the set deadline.

Study design

Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (ECHA Guidance R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test substance in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH.

You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

Appendix C: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[3].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[4].

[3] https://echa.europa.eu/practical-guides
[4] https://echa.europa.eu/manuals

Appendix D: General recommendations when conducting and reporting new tests for REACH purposes

A. Strategy for the PBT/vPvB assessment

You are advised to consult ECHA Guidance R.7b (Section R.7.9.), R.7c (Section R.7.10) and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

Appendix E: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 5 November 2019.

The decision making followed the procedure of Article 51 of the REACH Regulation, as described below:

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

ECHA took into account your comments and did not amend the request(s) but amended the deadline.

Deadline to submit the requested information in this decision

The timeline indicated in the draft decision to provide the information requested is 27 months.

In your comments on the draft decision, you requested an extension of the timeline to at least 30 months for the information requested under A.2-3 and B.1-2. You justified your request on the following grounds:

> *"The timeline of 18 months for the simulation testing on ultimate degradation in surface waterand identification of degradation products indicated in the draft decision for submitting the update of the registration dossier containing the information required is too short. Please note, that this substance is considered as difficult to analyze due to its surface-active properties. From experience we are aware that we need to develop and validate sophisticated analytical methods, which is time consuming and will extend the timeframe of the study enormously. Further, this requested test is of a complex nature which requires careful planning and selection of a reliable testing facility who is able to carry out such tests. Experience shows that these activities require a considerable period of time. Last not least, if the proposed sequential testing approach is implemented, also the timeline has to be extended accordingly. For these studies, at least 24 months have to be calculated including experimental setup, synthesis of the radiolabeled substance, analytical work and reporting. It is not clear, if experienced laboratories are able to start such type of studies immediately. Additionally there are the same data requests in other draft decisions on compliance checks for the same group of substances, all within the category. These are: EC 204-809-1; EC 500-022-5; EC 451-160-7 and EC 269-348-0. So it would be best to perform this type of study for all of the relevant substances in the same laboratory. Which might be difficult to deal in parallel and needs additional time for the laboratory. Therefore, we ask to prolong the timeline to at least 30 months."*

In support of your request you provided document from the test laboratory justifying the extension of the deadline. In the document it is explained that the degradation testing might take between 16-26 months.

It is not clear from the documentation whether longer or shorter degradation testing period would be needed for the Substance. Therefore, in order not to delay a testing mean duration

of 21 months for the degradation testing is granted with additional 3 months to cover necessary administrative steps. As the deadline in the decision accommodates sequential testing, 6 additional months granted for the degradation testing are added to the overall deadline. In respect of the sequential testing, as noted in the Appendix D above, it is advised to first conclude whether the Substance (including relevant constituents and relevant transformation/degradation products) fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation.

Therefore, on these grounds, ECHA has partially granted the request and set the deadline to provide requested information to 33 months.

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 F: List of references - ECHA Guidance[5] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[6]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[6]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[7]

[5] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[6] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix G: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.