EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 19 January 2021

Addressees
Registrant (s) of JS_EC234-196-6 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
19/04/2013

Registered substance subject to this decision ("the Substance")
Substance name: N,N'-dimethyldiphenylthiuram disulphide
EC number: 234-196-6
CAS number: 10591-84-1

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 ***24 January 2024***.

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

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

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

2. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23./OECD TG 307) at a temperature of 12 °C

3. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12 °C

4. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)

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

Reasons for the request(s) are explained in the appendix entitled "Reasons to request information required under Annex IX of REACH".

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, 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.

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".

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 IX of REACH

1. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided the following information:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1, Column 2. In support of your adaptation, you provided the following justification: "*According to column 2 of REACH Annex IX, the registrant shall consider performing chronic studies if the outcome of the CSA indicates a need. No effects have been observed in aquatic studies up to the limit of the water solubility, neither in acute nor in chronic studies. No PNECs could be derived. It is concluded that no chronic hazard for fish exists*".

We have assessed this information and identified the following issue:

Annex IX, Section 9.1, Column 2 is not providing a possibility to omit the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your justification is therefore rejected.

In your comments to the draft decision you point out the very low water solubility of the Substance. Because of that very low solubility you claim that:

- it will not be possible to establish substance specific chemical analyses for ecotoxicological studies and that it will be difficult to measure the test concentrations;
- important losses of the test substance are to be expected during the preparation of the test solutions and during the test itself;
- a frequent renewal of the test medium will be necessary but that a static test would induce a high level of stress to the fish;
- a flow-through system would potentially not be feasible as an alternative.

We have assessed this information and identified the following issue:

Annex XI, Section 2 specifies the general rules for adapting the standard information requirement when testing is not technically possible. The guidance on the technical limitations of the test method given in the test guideline itself or in relevant guidance complementing the test guideline must always be respected.

You have not demonstrated that you have explored the different possibilities offered by OECD GD 23 or provided a justification in line with the recommendations of OECD GD 23.

Chapter 7.1 of OECD GD 23 provides general guidance on testing poorly/sparingly water-soluble substances. In particular, that guidance mentions newer techniques that may potentially be used to overcome the technical difficulties identified in your comments. Alternatively, OECD GD 23 indicates that where the dissolved fraction cannot be analytically measured (e.g. when solubility is below a quantifiable level) a justification should still be provided: e.g. a statement from an analytical chemist confirming that the analytical methods used were state of the art, a justification as to why lower detection limits were not feasible and a description of any preliminary analytical efforts. However, you have not addressed any of these. Therefore, you have not demonstrated that testing is not technically possible.

In addition in your comments to the draft decision, you invoke animal welfare as a reason to avoid the test.

It does not constitute as such a valid justification to omit the standard information requirements of Annexes VII – X or a valid adaptation to these information requirements.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

The Substance is difficult to test due to the low water solubility (<0.01µg/L). OECD TG 210 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must try to monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 210. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

2. Soil simulation testing

Soil simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.3.) for substances with a high potential for adsorption to soil.

The Substance has a low water solubility (<0.01µg/L), high partition coefficient (log K_{ow} 4.7) and high adsorption coefficient (log K_{oc} 4.6) and therefore has a high potential for adsorption to soil.

You have provided the following information:

i. an adaptation with the following justification: "*According to chapter 1 of REACH Regulation Annex XI, performing of a test is scientifically unjustified. In tests for ready biodegradation as well as in an inherent test no relevant signs for biodegradation were observed. For biodegradation, a certain level of water solubility is necessary so that bacteria may have access to the substance in the water phase. Therefore, it is not expected that biodegradation will occur in a simulation test*".

We have assessed this information and identified the following issues:

Under Section 1 of Annex XI to REACH, the study may be omitted if one of the following adaptations is provided:

- Use of existing data from experiments not carried out according to GLP or the test methods referred to in Article 13(3)
- Weight of evidence
- Qualitative or Quantitative structure-activity relationship ((Q)SAR)
- In vitro methods
- Grouping of substances and read-across approach

However, the adaptation you have provided does not relate to any of the adaptation possibilities offered by Section 1 of Annex IX to REACH.

You claim that no degradation of the Substance is to be expected in a simulation test because:
- No mineralisation was observed in the ready biodegradability test provided in you dossier, and
- you assume that the Substance would not be bioavailable to degrading micro-organisms because it is poorly soluble.

However, the absence of mineralisation does not imply that no primary or partial degradation could occur and that no degradation products could be formed.

Furthermore, the low water solubility of the Substance may limit its bioavailability to micro-organisms from the water phase, but the Substance has a high potential for adsorption to soil. Many microorganisms can form a biofilm around the soil particles and produce extracellular enzymes and biosurfactants that may help to degrade even highly insoluble substances.

On this basis, your adaptation is rejected and the information requirement is not fulfilled.

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 307 test using four soils representing a range of relevant soils (*i.e.* varying in their organic content, pH, clay content and microbial biomass).

- 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 307.

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).

3. Sediment simulation testing

Sediment simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.4.) for substances with a high potential for adsorption to sediment.

The Substance has a low water solubility (<0.01µg/L), high partition coefficient (log K_{ow} 4.7) and high adsorption coefficient (log K_{oc} 4.6) and therefore has a high potential for adsorption to sediment.

You have provided the following information:

i. an adaptation under Annex XI, Section 2 with the following justification: "*According to section 2 of REACH Annex XI, performing of a study is technically not feasible. The substance has the following known properties:*
   1. *no sign of biodegradation in a ready test*
   2. *extremely low water solubility of < 0.01 µg/L. This low limit of detection*

has been achieved through high-level analytical instrumentation. Even when using radiolabelled material (e. g. 14C-labelled) the method would not sensitive enough in order to measure the concentration in water below the water solubility including describing degradation of transport to other compartments".

We have assessed this information and identified the following issues:

Under Section 2 of Annex XI to REACH, the study may be omitted if it is technically not possible to be conducted: e.g. very volatile, highly reactive or unstable substances cannot be used, if mixing of the substance with water may cause danger of fire or explosion, if the radio-labelling of the substance is not possible.

However, the adaptation you have provided does not relate to any of those situations.

The absence of mineralization observed in the ready biodegradability study provided in your dossier does not make a simulation test technically impossible to conduct.

Similarly, the poor water solubility of the Substance does not prevent you from conducting a simulation test in sediment. The Substance has a high potential for adsorption to sediment, and is expected to distribute mainly to the solid phase of the sediment. It is possible to use a radiolabelled material and to measure the proportion of the applied radioactivity extracted from the sediment, in the volatile traps, in the non-extractable residues and potentially from CO_2 if mineralisation occurs. Extractions are generally done with organic solvents, so should be feasible regardless of the water solubility of the Substance.

Therefore, you have not demonstrated that a simulation test in sediment is technically not possible.

On this basis, your adaptation is rejected and the information requirement is not fulfilled.

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 308 test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture.

- 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 308.

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).

4. Identification of degradation products

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

You have provided no information on the identity of transformation/degradation products for the Substance.

Therefore, this information requirement is not met.

This information is required for the purpose of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance.

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 studies requested in Sections A.2 and A.3 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 studies according to OECD TG 307 and 308 (Sections A.2 and A.3) must be conducted at 12°C and at test material application rates reflecting realistic assumptions. 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) and at higher application rate (*e.g.* 10 times).

5. Bioaccumulation in aquatic species

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

You have adapted this standard information requirement according to Annex XI, Section 1.2. of REACH (weight of evidence). In support of your adaptation, you have provided the following sources of information:

i. a QSAR prediction using model BCFBAF v3.01, regression model (in software EPI Suite v4.11,
ii. an experimental study (OECD 305C) conducted with read-across substance dibenzothiazyl disulfide (MBTS).

We have assessed this information and identified the following issues:

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory information requirement. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to

conclude that the Substance has or has not the dangerous property investigated by the required study.

i. QSAR prediction

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when an adequate justification is provided and the following cumulative conditions are met:

1. results are derived from a QSAR model whose scientific validity has been established;
2. the substance falls within the applicability domain of the QSAR model;
3. adequate and reliable documentation of the applied method is provided; and
4. the results are adequate for classification and labelling and/or risk assessment.

Furthermore, Section 2.1. of Annex XIII requires that you must generate 'assessment information' (as described in Section 3.2 of Annex XIII), such as a bioaccumulation study, if the results from screening information (as described in Section 3.1 of Annex XIII) indicate that the Substance may have PBT or vPvB properties. Section 2.1. of Annex XIII further specifies that assessment information does not have to be generated for the purpose of the PBT/vPvB assessment only if screening information does not indicate potential P or B properties.

Therefore, as long as a piece of screening information indicates that the Substance could potentially be persistent (P) and bioaccumulative (B), then assessment information needs to be generated.

This is the case if the Substance, a constituent, an impurity or a transformation/degradation product meets the following screening criteria (see ECHA Guidance R.11, Section R.11.4):

- The Substance is potentially bioaccumulative or very bioaccumulative:
  - E.g. log Kow > 4.5 or potential for bioaccumulation in air-breathing organisms (log Kow >2 and log Koa >5)

- The Substance is potentially persistent or very persistent:
  - E.g. the Substance not readily biodegradable according to OECD 301 or OECD 310 test(s)

For the B/vB assessment, results from a bioconcentration or bioaccumulation study in aquatic species constitutes assessment information for B or vB properties (Section 3.2.2. of Annex XIII of REACH). However, QSAR predictions are not mentioned as possible assessment information for the PBT/vPvB assessment. (Q)SAR models may however be used together with other information in a Weight-of-Evidence approach (see ECHA Guidance R.11, Section R.11.4.1.2.10).

Screening information provided in your dossier indicates that:
- the Substance has a log Kow 4.7, and
- the Substance showed no mineralisation after 28 days in a OECD 301D test.

You have also reported a BCF value of 586 for the Substance. This value was calculated using the regression method of the BCFBAF v3.01 model (in software EPI Suite v4.11) and using the experimental log Kow value of 4.7 as input parameter to this model.

The experimental log Kow value of 4.7 is a valid piece of screening information which indicates that the Substance could be bioaccumulative or very bioaccumulative.

Similarly, the Substance is not readily biodegradable, indicating that the Substance could be in addition persistent or very persistent.

The BCF value of 586 is regarded as 'screening information' (Section 3.1, Annex XIII of REACH), not as 'assessment information' (Section 3.2, Annex XIII of REACH) as it is based on a QSAR prediction.

The information you have provided cannot reverse the conclusion that the Substance may have PBT/vPvB properties, since there is already valid screening information (log Kow of 4.7 and the absence of degradation observed in the ready biodegradability test) to establish this.

Therefore, the provided information indicates that the Substance is potentially PBT/vPvB, and further information on bioaccumulation is required for the PBT/vPvB assessment.

In your comments to the draft decision you address ECHA's assessment of your QSAR prediction. You acknowledge that every model prediction has uncertainties but consider that the prediction from model BCFBAF v3.01 is reliable enough to conclude that the Substance is not bioaccumulative. You claim that the BCF value of 586 is sufficiently distant to the threshold values of 2000 or 5000 for respectively the B and vB assessments.

The uncertainties of a model prediction are due in part to the limited size of the training set (the sampling error) but also to the intrinsic variability of the data. The sampling error decreases when the size of the training set increases, but even when the training set is large, the intrinsic variability of the data remains and needs to be taken into account. Both aspects of these uncertainties can be quantified with a tolerance interval. From the training set provided in the help file of the BCFBAF v3.01 model, it is possible to calculate the tolerance interval for your prediction. For a log Kow of 4.7, the prediction for log BCF is 2.77 and the upper bound of the 95% tolerance interval (1-sided, significance level: 5%) is 3.74 (in the log scale). In the linear scale, this corresponds to a predicted BCF of 586 with an upper bound 95% tolerance interval of 5496 (1-sided, significance level: 5%). This indicates that, with a confidence level of 95%, it can be estimated from the model that there is an estimated 5% probability that BCF would be higher than 5496 for a substance with a log Kow value of 4.7. More specifically for the purpose of the PBT/vPvB assessment, it can be calculated that the probability that BCF exceeds 2000 for a substance with a log Kow of 4.7 is 19.7% with 95% confidence. Similarly, the probability (with 95% confidence) that BCF exceeds 5000 for a substance with a log Kow of 4.7 is 5.8%. Based on those calculated probabilities, ECHA still considers that it is not unlikely that BCF could exceed the threshold values of 2000 or even 5000 for respectively the B and vB assessments.

iii. Read-across from MBTS

b) Read-across hypothesis

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled to apply grouping and read-across. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological ecotoxicological and environmental fate 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).

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological, ecotoxicological or an environmental fate property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the

substances[2]. It should explain why the differences in the chemical structures should not influence the toxicological, ecotoxicological or environmental fate properties or should do so in a regular pattern.

You read-across between the structurally similar substances, dibenzothiazyl disulfide (MBTS), EC No. 204-424-9 (CAS No. 120-78-5) as source substance and the Substance as target substance.

Your read-across hypothesis is that the structural similarity and the physico-chemical similarity between the source substance and your Substance constitute a sufficient basis for predicting the bioaccumulation of your Substance.

However, while structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar bioaccumulation properties. In particular, the source substance (MBTS) is a di-benzothiazole disulfide, whereas the target substance is a thiuram disulfide. These are distinct chemical functional groups. MBTS is a heterocyclic aromatic compound but the target substance is not. As such, differences in the reactivity, stability and properties, including bioaccumulation, of the two substances can be expected. Therefore, the differences in the chemical structures of the source and target substances may influence the bioaccumulation properties of the two substances.

Physico-chemical similarity does not necessarily lead to predictable or similar bioaccumulation properties either. In particular, while both the source substance and the Substance have similar log Kow values, source substance MBTS in aqueous solutions is hydrolysed within a few days[3]. The fast hydrolysis of MBTS may limit its bioaccumulation. In contrast, no information on hydrolysis is provided for the Substance and fast hydrolysis of the Substance cannot be assumed. Therefore, it is not possible to predict the bioaccumulation properties of the Substance from the data for the source substance.

c) Adequacy and reliability of 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 have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

The source study that you have used in your read-across approach, (Biodegradation and Bioaccumulation. Data of Existing Chemicals Based on the CSCL Japan, MITI, Ed. by CITI, Ministry of International Trade & Industry Japan, 1992), has been performed according to OECD Guideline 305 C (Bioaccumulation: Test for the Degree of Bioconcentration in Fish).

Only a general description of the test procedure is given without mentioning experimental details.
Therefore it is not possible to verify that the key parameters of the test guideline were covered and that the validity criteria were met.

d) Conclusion on the read-across

As explained above, you have not provided a well-founded hypothesis to establish a reliable prediction for bioaccumulation. Furthermore, the adequacy and the reliability of the source study could not be assessed. Therefore your read-across approach is rejected.

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[2] *Guidance on information requirements and chemical safety assessment*, Chapter R.6: QSARs and grouping of chemicals.

[3] See page 182 of European Commission (2008). European Union Risk Assessment Report N-Cyclohexylbenzothiazole-2-sulphenamide. Contact Point: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) Chemikalien, Anmeldung und Zulassung (Federal Institute for Occupational Safety and Health Division for Chemicals and Biocides Regulation) 44149 Dortmund (Germany. Report date: 2007-10-22).

iii. Weighing assessment

As explained above, you have adapted the standard information requirement with a weight of evidence approach relying on two pieces of information: a QSAR result and a read-across from dibenzothiazyl disulfide (MBTS). However, the QSAR result is not reliable enough to be used as assessment information, as defined in Section 3.2, Annex XIII of REACH, for the PBT/vPvB assessment. As for your read-across, it is neither relevant for predicting the bioaccumulation of the Substance as you did not provide a founded hypothesis, nor reliable as the source study lacks critical documentation on the experimental details.

In addition, in your comments to the draft decision, you invoke animal welfare as a reason to avoid the test.

This does not constitute as such a valid justification to omit the standard information requirements of Annexes VII – X or a valid adaptation to these information requirements.

In addition in your comments to the draft decision, you state that there are no effects observed for aquatic testing, that with a low solubility it seems unlikely that the Substance would have any effect on fish, and that there is no indication that fish are more sensitive than other taxons.

However, those considerations are not related to the information requirement for bioaccumulation in aquatic species. The bioaccumulation potential of a substance needs to be investigated independently from its ecotoxicity. As specified in OECD TG 305, the concentration(s) of the test substance should be selected to be below its chronic effect level.

On this basis, your adaptation is rejected and the information requirement is not fulfilled.

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 B: 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[4].

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[5].

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

Appendix C: 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 D: 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 08 July 2019.

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).

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 E: List of references - ECHA Guidance[6] 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)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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[9]

[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[9] 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 F: Addressees of this decision and their corresponding information requirements

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.