Helsinki, 03 November 2022

Addressees
Registrants of 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol listed in the last Appendix of this decision

Registered substance subject to this decision (the Substance)
Substance name: 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol
EC number: 201-236-9
CAS number: 79-94-7

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

DECISION ON SUBSTANCE EVALUATION

Under Article 46 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below:

A. Information required to clarify the potential risk related to PBT/vPvB

1. Bioaccumulation in fish (test method: EU C.13 / OECD TG 305), dietary exposure with both the transformation products of the Substance, monomethyl ether TBBPA (2,6-dibromo-4-[2-(3,5-dibromo-4-methoxyphenyl)propan-2-yl]phenol, CAS RN 146823-76-9) and bismethyl ether TBBPA (4,4'-(isopropylidene)bis[2,6-dibromoanisole], EC number 253-693-9, CAS RN 37853-61-5) specified as follows:
   - The transformation products must be ^{14}C radiolabelled with the radiolabel located in the most stable part of the molecule;
   - A separate exposure group must be included for each of the transformation products;
   - Growth-corrected, lipid-normalised kinetic BMFs and BCFs must be determined;
   - A homogeneous distribution of the test material in the fish feed must be ensured.

Deadline

The information must be submitted by **10 February 2025**.

Conditions to comply with the information requested

To comply with this decision, you must submit the information in an updated registration dossier, by the deadline indicated above. The information must comply with the IUCLID robust study summary format. You must also attach the full study report for the corresponding study/ies in the corresponding endpoint of IUCLID.

You must update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You will find the justifications for the requests in this decision in the Appendix entitled ''Reasons to request information to clarify the potential risk'.

You will find the procedural steps followed to reach the adopted decision and some technical guidance detailed in further Appendices.

Appeal

This decision 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 Mike Rasenberg, 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.

Basis for substance evaluation

The objective of substance evaluation under REACH is to allow for the generation of further information on substances suspected of posing a risk to human health or the environment ('potential risk').

ECHA has concluded that further information on the Substance is necessary to enable the evaluating Member State Competent Authority (MSCA) to clarify a potential risk and whether regulatory risk management is required to ensure the safe use of the Substance.

The ECHA decision requesting further information is based on the following:

(1) There is a potential risk to human health or the environment, based on a combination of hazard and exposure information;
(2) Information is necessary to clarify the potential risk identified; and
(3) There is a realistic possibility that the information requested would allow improved risk management measures to be taken.

The Appendices entitled 'Reasons to request information' describe why the requested information are necessary and appropriate.

Appendix A – Reasons to request information to clarify the potential risk related to PBT/vPvB properties

1. Potential risk

1.1 Potential hazard of the Substance

According to Annex XIII to REACH, the PBT/vPvB assessment shall take account of relevant transformation and/or degradation products of the Substance.

Following its assessment, the evaluating MSCA has identified potential hazard(s), which must be clarified, based on the available relevant information on the two transformation products of the Substance:

- monomethyl ether TBBPA (2,6-dibromo-4-[2-(3,5-dibromo-4-methoxyphenyl)propan-2-yl]phenol, CAS RN 146823-76-9; abbreviated as MME-TBBPA) and
- bismethyl ether TBBPA (4,4'-(isopropylidene)bis[2,6-dibromoanisole], EC number 253-693-9, CAS RN 37853-61-5; abbreviated as DME-TBBPA).

As also described in the previous decision from 23 March 2017, available studies from the open literature show that TBBPA can be converted to two distinct methylated transformation products, MME-TBBPA and DME-TBBPA. These transformation products are more hydrophobic and likely to be more persistent and bioaccumulative than TBBPA. Indeed, the available information shows that the two transformation products of the Substance may be PBT/vPvB substances, as both transformation products meet the PBT/vPvB screening criteria. Both transformation products have been detected in the environment and data from soil and sediment studies also indicate that they are persistent (George and Häggblom, 2008; Sun et al., 2014; Li et al., 2015).

One simulation study with MME-TBBPA and one with DME-TBBPA were requested in the previous decision from 23 March 2017 to initiate a sequential testing strategy to clarify the PBT/vPvB concern of these transformation products, starting with the persistency.

In this decision, representing the next sequential step in the PBT testing strategy, a bioaccumulation study is requested to clarify the bioaccumulation concern. Finally, based on the outcome of this study, further information on (eco)toxicity might be requested in a future decision, if needed, to conclude on the PBT properties of the transformations products.

a) [Potential] P/vP properties

If a substance fulfils the criteria in Section 1.1.1 or 1.2.1 of Annex XIII to REACH, it is considered that it has persistent (P) or very persistent (vP) properties. For the purpose of the P/vP assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.1 to Annex XIII, including results from simulation tests, must be considered.

Evidence based on experimental data

- MME-TBBPA

The OECD TG 309 study (2019) performed at 12°C and at 20°C showed some primary degradation but only a small degree of mineralization (<10%). The degradation showed biphasic degradation kinetics with an initial drop followed by a slower decline. The data was modelled in CAKE v3.4 using recovery correction for kinetic evaluation.

At 12°C
A fit with Double First-Order in Parallel (DFOP) showed an overall DT50 of 63.8 days with a slow k2 DT50 value above 10,000 days for the 12°C degree study.

The OECD TG 309 study was also modelled without the last data point at 90 days, as there was more parent than at 56 days, an indication that it could potentially be an outliner in the overall dataset. However, the 90-day data point was generated with a more elaborate experimental setup and gave a better recovery and correspondingly a lower loss of parent and should therefore not be dismissed. Modelled without the 90 days datapoint, the DFOP fit gave rise to an overall DT50 of 48 days with a slow k2 DT50 of 59.3 days.

At 20°C
In the 20°C study, a Hockey Stick (HS) fit showed an overall DT50 of 20.1 days with a slow k2 DT50 of 41.3 days. Applying a temperature correction (the Arrhenius equation) to extrapolate to 12°C, the k2 DT50 value increased to 87.75 days. According to the R.11 PBT guidance (ECHA, 2017), DT50 values predicted from the slow phase from DFOP or HS models should be preferred and used for comparison with the P/vP criteria.

Therefore, based on the weight of evidence from the experimental data and subsequent modelling, the evaluating MSCA considers that MME-TBBPA meets the criteria for P/vP.

- DME-TBBPA

In the OECD TG 307 study (2020) on DME-TBBPA, no significant degradation was observed in soil over 180 days. The evaluating MSCA considers that DME-TBBPA meets the criteria for P/vP.

Evidence based on model predictions

QSAR predictions from BIOWIN 4.10 and the Danish QSAR database are in line with the experimental data: they indicate persistency for the two transformation products.

- MME-TBBPA

Biowin1 (linear model) Probability of Rapid Biodegradation: 0.10
Biowin2 (non-linear model) Probability of Rapid Biodegradation: 0.00
Biowin3 Expert Survey Ultimate Biodegradation: 1.21
Biowin4 Expert Survey Primary Biodeg: 2.39
Biowin5 (MITI linear model) Prob. Biodeg: 0.08
Biowin6 (MITI non-linear model) Biodegradation Probability: 0.01
Danish QSAR database: Not Ready biodegradable

- DME-TBBPA

Biowin1 (linear model) Probability of Rapid Biodegradation: 0.11
Biowin2 (non-linear model) Probability of Rapid Biodegradation: 0.00
Biowin3 Expert Survey Ultimate Biodegradation: 1.06
Biowin4 Expert Survey Primary Biodeg: 2.41
Biowin5 (MITI linear model) Prob. Biodeg: 0.17
Biowin6 (MITI non-linear model) Biodegradation Probability: 0.01
Danish QSAR database: Not Ready biodegradable

Evidence based on other information

Both transformation products are detected in the environment and soil and sediment studies also indicate that they are persistent (George and Häggblom, 2008; Sun et al, 2014; Li et al, 2015).

Conclusion

Based on the available experimental data for the transformation products MME-TBBPA and DME-TBBPA, and on model predictions performed with the transformation products, the evaluating MSCA considers that the available information is sufficient to assess the persistency of the Substance at this step of the evaluation.

b) [Potential] B/vB properties

If a substance fulfils the criteria in Section 1.1.2 or 1.2.2 of Annex XIII to REACH, it is considered that it has bioaccumulative (B) or very bioaccumulative (vB) properties. For the purpose of the B/vB assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.2 of Annex XIII, including bioconcentration factor (BCF) values must be considered. If no such data are available, it is necessary to consider the screening information of Section 3.1.2. to Annex XIII, such as QSAR predictions.

Evidence based on experimental data

- MME-TBBPA

No test data or field investigations of bioaccumulation or food-chain transfer are available. MME-TBBPA has a logKow value of 6.5 (pH=5), 6.4 (pH=7) and 4.7 (pH=9), respectively. Thus, the logKow value is above the screening criterion of logKow > 4.5, which indicates a potential for bioaccumulation.

As noted in the ECHA PBT guidance (R.11): "*based on a screening threshold value, a substance could be either B or vB when its (estimated) Log Kow is > 4.5. In this case, if a substance meets the screening criterion for B or vB and it is also shown to be or likely to be (very) persistent, further consideration of its bioaccumulation potential is warranted.*"

- DME-TBBPA

No test data or field investigations of bioaccumulation or food-chain transfer of this transformation product are available.

Evidence based on model predictions

- MME-TBBPA

The potential for bioaccumulation is supported by the observed BCF and BAF values predicted by BCFBAF v3.02 as presented below:

BCF = 586-9030 L/kg ww
BCF Arnot-Gobas method (upper trophic) inc. biotrans. = 2062-5656
BCF Arnot-Gobas method (upper trophic) exc. biotrans. = 4554-18660
BAF Arnot-Gobas method (upper trophic) inc. biotrans. = 2387-343300
BAF Arnot-Gobas method (upper trophic) exc. biotrans. = 33570-6968000

Thus MME-TBBPA fulfils the screening criterion for bioaccumulative and/or very bioaccumulative substances, B/vB.

- DME-TBBPA

The QSAR predictions (using KOWWIN vl.69 and VEGA 1.1.1) yield a logKow value of 5.69-8.33. Thus, the estimated logKow is above the screening criterion of logKow > 4.5, which indicates a potential for bioaccumulation.

The potential for bioaccumulation is supported by the observed BCF and BAF values predicted by BCFBAF v3.02 as presented below:

BCFfish = 2640-2970 L/kg ww
BCF Arnot-Gobas method (upper trophic) inc. biotrans. = 2066-16510
BCF Arnot-Gobas method (upper trophic) exc. biotrans. = 2242-18250
BAF Arnot-Gobas method (upper trophic) inc. biotrans. = 844800-8560000
BAF Arnot-Gobas method (upper trophic) exc. biotrans, = 1140000-9596000

Thus, DME-TBBPA fulfills the screening criterion for bioaccumulative and/or very bioaccumulative substances, B/vB.

Conclusion

The available information from the two transformation products suggests that the Substance may have potential B/vB properties. However, the available information is not sufficient to draw a conclusion on the bioaccumulation potential. Therefore further information is needed on bioaccumulation of the transformation products, MME-TBBPA and DME-TBBPA, to clarify the potential hazard.

c) [Potential] T properties

If a substance fulfils the criteria in Section 1.1.3 of Annex XIII to REACH, it is considered that it fulfils the toxicity (T) criterion. For the purpose of the T assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.3 of Annex XIII must be considered, such as results of long-term toxicity tests.

Evidence based on experimental data

No experimental toxicity data in aquatic or mammalian species are available for MME- and DME-TBBPA.

Evidence based on model predictions

ECOSAR V1.11 predictions indicate that the transformation products have acute LC/EC_{50}-ecotoxicity values below 0.1 mg/L.

- MME-TBBPA

Fish LC_{50}: 3 µg/L
Daphnid LC_{50}: 3 µg/L
Algae EC_{50}: 20 µg/L

- DME-TBBPA

Fish LC_{50}: 0.98 µg/L
Mysid LC_{50}: 0.013 µg/L
Daphnid LC_{50}: 0.998 µg/L
Algae EC_{50}: 8 µg/L

Conclusion

The available information does not allow concluding on whether the Substance or its transformation products fulfil the T criteria in Annex XIII of REACH. No further information on toxicity is requested in this decision but depending on the outcome of the testing requested in this decision, further toxicity testing may be necessary and may be requested in a follow-up decision.

1.2 Potential exposure

According to the information you submitted in all registration dossiers, the aggregated tonnage of the Substance manufactured or imported in the EU is in the range of 10 000–100 000 tonnes per year.

Furthermore, you reported that among other uses, the Substance is used as:

- Reactive intermediate in the manufacture of polymer resins.
- Manufacture of polymer articles from polymer resins containing additive flame retardant.
- An additive in the manufacture of polymer resins.

Therefore, exposure to consumers, workers, and the environment to the Substance and its transformation products cannot be excluded.

1.3 Identification of the potential risk to be clarified

Based on all information available in the registration dossier and information from the published literature, there is sufficient evidence to justify that the transformation products of the Substance may be PBT/vPvB substances.

The information you provided on manufacture and uses demonstrates a potential for exposure of the environment. Based on this hazard and exposure information the Substance poses a potential risk to the environment.

As explained in Section 1.1 above, the available information is not sufficient to conclude on the potential hazard and in particular the bioaccumulation potential of the transformation products. Consequently, further data is needed to clarify the potential risk related to PBT/vPvB properties.

1.4 Further risk management measures

If a transformation product of the Substance is confirmed as meeting the P, B and T or vP and vB criteria the Substance can be identified as a PBT/vPvB. The evaluating MSCA will analyse the options to manage the risk(s) and will assess the need for:

- Further regulatory risk management in the form of identification as a substance of very high concern (SVHC) under Article 57(d) and/or (e) of REACH;
- A subsequent authorisation or a restriction of the Substance. This would lead to stricter risk management measures than those currently in place, such as minimisation of emissions.

2. How to clarify the potential risk

2.1 Development of the testing strategy

The evaluating MSCA considers that the transformation products of the Substance, MME-TBBPA and DME-TBBPA, meet the criteria for P/vP. If the bioaccumulation potential of the transformation products of the Substance is confirmed in the requested bioaccumulation study, further information on the (eco)toxicity of the transformation products may be requested in a follow-up decision, to clarify the PBT concern.

2.2 Bioaccumulation in fish (Method EU C.13 / OECD TG 305)

a) Aim of the study

Information on bioaccumulation is required in order to enable the evaluating MSCA to assess the properties of the transformation products and to decide whether they are bioaccumulative in relation to the criteria for PBT assessment (REACH, Annex XIII). Without the requested information it will not be possible to verify whether there remains an uncontrolled risk with the Substance that should be subject to further risk management measures.

The OECD TG 305 is a standard information requirement at Annex IX, Section 9.3.2 of REACH. It could also be a requirement for concluding your PBT assessment according to Annex XIII, Section 2.1 of REACH and could be requested in compliance check under Article 41 of REACH. However, since the information request is based on a potential risk identified for the transformation products MME-TBBPA and DME-TBBPA of the Substance the substance evaluation is an appropiate process in the present case.

b) Specification of the requested study

Test material

The study must be conducted with both the transformation products of the Substance, MME-TBBPA and DME-TBBPA.

The transformation products must be ^{14}C radiolabelled with the radiolabel located in the most stable part of the molecule.

Exposure

The low water solubility and the high adsorption potential of the two transformation products indicate significant uncertainty on the feasibility of a study using aqueous exposure. The OECD TG 305 recommends (paragraph 7) dietary exposure for hydrophobic substances (logKow >5 and a water solubility below ~ 0.01-0.1 mg/L).

At pH 7, MME-TBBPA has a logkow of 6.4 and a water solubilty of 35 µg/L, indicating that the aqueous exposure could be technically unfeasible. DME-TBBPA is even more hydrophobic with estimated logkow values up to 8.33. Due to the low water solubility, the simulation testing with DME-TBBPA was not requested in surface water either.

Therefore, you are required to perform the test using dietary exposure.

You must also estimate growth-corrected, lipid-normalised kinetic BMF and BCFs from the dietary test (OECD TG 305-III) data according to Annex 8 of the OECD TG 305 and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO (2017)16).

In the study, the fish must be exposed separately, i.e. you must include a separate exposure group for each of the transformation products. This will allow to avoid any potential conversion between the substances that could complicate proper interpretation of the generated data.

It is important to make sure that the uptake of the applied doses is as complete as possible. For example, potential crystallisation of the test material in the spiked food can reduce its bioavailability and must be avoided. Therefore, when selecting the test concentration and spiking method, you must ensure that a homogenous distribution of the test material in the fish feed is obtained.

Paragraph 119 of OECD TG 305 provides some advice about possible solutions for spiking the test substance to the food. It is also recommended to follow the instructions on spiking included in section 4.2. of the OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (Series on Testing and Assessment No. 264, OECD, 2017).

In your comments to the draft decision, you stated that: "*The setting of the dietary OECD 305 study is complex. Hence, after preparation of the protocol, in consultation with the laboratory, we will appreciate the approval of the protocol by the evaluating MSCA, prior to initiation of the test.".* The evaluating MSCA considered your comment and is willing to informally discuss specific aspects of the test protocol before you initiate the requested study.

Request for the full study report

You must submit the full study report which includes:

- A complete rationale of test design and
- Interpretation of the results
- Access to all information available in the full study report, such as implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.

This will enable the evaluating MSCA to fully and independently assess all the information provided, including the statistical analysis.

c) Alternative approaches and how the request is appropriate to meet its objective

The request for a bioaccumulation study in fish is:

- Appropriate because it will provide information which will clarify the bioaccumulation potential of the transformation products. This will enable the evaluating MSCA to conclude on whether the transformation products fulfil the B/vB criteria for PBT assessment (REACH, Annex XIII).
- The least onerous measure because there is no equally suitable alternative method available to obtain the information that would clarify the potential hazard.

Alternatively, a bioaccumulation study could be requested solely for one of the transformation products, e.g. DME-TBBPA. However, depending on the results and interpretation of such a study, a number of different outcomes are possible.

DME-TBBP could prove to be vPvB, effectively clarifying the concern. However, if DME-TBBPA does not fulfil the criterion for vB, but only for B, further ecotoxicity testing with DME-TBBPA would be needed to clarify the PBT concern (first long term invertebrate testing, then potentially a long term fish test). If as a result DME-TBBPA does not fulfil the

T criterion, the bioaccumulation concern for MME-TBBPA would need to be clarified and a new bioaccumulation test would have to be requested, again, along with potential further ecotoxicity testing. If DME-TBBPA does not fulfll the B criterion, a new bioaccumulation test would similarly have to be requested for MME-TBBPA, along with potential further ecotoxicity testing.

Such a step-wise test strategy, looking at one transformation product at a time, could result in both a substantial delay in clarifying the PBT/vPvB concerns as well as use of more animals. By clarifying the bioaccumulation properties of both transformation products in the same study, duplicate water/solvent controls and positive control (exposure and depuration groups) can be avoided. Testing both transformation products at the same time results in a less complex testing strategy, which also is a logical continuation of clarifying the potential persistency of both transformation products and it is therefore coherent with the overall testing strategy laid out in the first decision.

d) Consideration of time needed to perform the requested studies

In your comments to the draft decision, you agreed to perform the OECD TG 305 study as described. However, you requested an extension to the deadline from 9 months to 24-36 months to allow for the synthesis of radiolabeled (and non-labeled) test substances, study design and protocol preparation, pilot study, review process, dossier update, etc.

ECHA notes that (i) the standard 9 month deadline already includes time for the dossier update; (ii) several aspects you described can be undertaken simultaneously (e.g synthesis of test substance and protocol preparation). Therefore, ECHA has only partially granted the request and extended the deadline by 9 months.

Moreover, an additional extension of 6 months from the standard deadline has been exceptionally granted by ECHA to take into account the current longer lead times in contract research organisations.

Therefore, ECHA has amended the deadline of the decision to 24 months.

2.3 References relevant to the requests (which are not included in the registration dossier)

ECHA PBT Guidance R.11, Version 3, June 2017. https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

George and Häggblom (2008). Microbial 0-Methylation of the Flame Retardant - Tetrabromobisphenol-A. Environ. Sci. Technol., 42, 5555-5561.

OECD Test guideline 305. October 2012. Bioaccumulation in Fish: Aqueous and Dietary Exposure. https://www.oecd-ilibrary.org/environment/test-no-305-bioaccumulation-in-fish-aqueous-and-dietary-exposure_9789264185296-en

OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO (2017)16). July 2017. https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2017)16&doclanguage=en

Li F, Wang J, Jiang B, Yang X, Nastold P, Kolvenbach B, Wang L, Ma Y, Corvini PF, Ji R. - Fate of Tetrabromobisphenol A (TBBPA) and Formation of Ester- and Ether-Linked Bound Residues in an Oxic Sandy Soil (2015). Environ Sci Technol. 3;49(21):12758-65. doi: 10.1021/acs.est.5b01900.

Sun F, Kolvenbach BA, Nastold P, Jiang B, Ji R, Corvini PFX (2014). Degradation and Metabolism of Tetrabromobisphenol A (TBBPA) in Submerged Soil and Soil-Plant Systems. Environ. Sc!. Technol., 2014, 48 (24), pp 14291-14299

Appendix B: Procedure

This decision does not imply that the information you submitted in your registration dossier(s) is in compliance with the REACH requirements. ECHA may still initiate a compliance check on your dossiers.

12-month follow-up evaluation

Due to initial grounds of concern relating to human health (suspected reprotoxic), potential endocrine disruptor in the environment and human health, exposure of the environment and workers, and suspected PBT/vPvB properties, the Member State Committee agreed to include the Substance in the Community rolling action plan (CoRAP) to be evaluated in 2015. Denmark is the competent authority ('the evaluating MSCA') appointed to carry out the evaluation.

In accordance with Article 46(3) of REACH, the evaluating MSCA carried out its evaluation based on the information in the registration dossier(s) you submitted on the Substance subsequent to a decision dated 22 March 2017 and on other relevant and available information.

The evaluating MSCA completed its 'follow-up' evaluation considering that further information is required to clarify potential risk on PBT/vPvB.

Therefore, it submitted a draft decision (Article 46(3) of REACH) to ECHA on 17 March 2022.

Decision-making

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

(i) Registrant(s)' commenting phase

ECHA received your comments and forwarded them to the evaluating MSCA. The evaluating MSCA took your comments into account (see Appendix A) and the deadline (as explained in Section 2.2.d) was amended.

(ii) Proposals for amendment by other MSCAs and ECHA and referral to the Member State Committee

The evaluating MSCA notified the draft decision to the competent authorities of the other Member States and ECHA for proposal(s) for amendment.

As no amendments were proposed, ECHA took the decision according to Articles 52(2) and 51(3) of REACH.

(iii.) Follow-up evaluation

After the deadline set in this decision has passed, the evaluating MSCA will review the information you will have submitted and will evaluate whether further information is still needed to clarify the potential risk, according to Article 46(3) of REACH. Therefore, a subsequent evaluation of the Substance may still be initiated after the present substance evaluation is concluded.

Appendix C: Technical Guidance to follow when conducting new tests for REACH purposes

Test methods, GLP requirements and reporting

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.

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.

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[2].

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*

   a) 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.

Technical instructions on how to report the above is available in the manual "How to prepare registration and PPORD dossiers"[3].

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