~~Confidential~~

Helsinki, 09 June 2023

Addressee(s)
Registrant(s) of JS_300-326-6 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
01/10/2020

Registered substance subject to this decision ("the Substance")
Substance name: Phosphonic acid, mixed C12-20-alkyl and C14-18-unsatd. alkyl derivs.
EC number/List number: 300-326-6

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 ***16 March 2026***.

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

Information required from all the Registrants subject to Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1., column 2);

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201);

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. B/C/D /F/OECD TG 301B/C/D/F or EU C.29./OECD TG 310) on relevant constituent(s)/fraction(s) of the Substance, as described under the corresponding appendix on reasons for the request.

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

4. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2).

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

5. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit);

6. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211);

7. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210).

The reasons for the request(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressee(s) of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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 requirements for testing and reporting new tests under REACH, see Appendix 4.

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 Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

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

Appendix 1: Reasons for the request(s)

Contents

Reasons related to the information under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

1 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1. However, under Column 2, long-term toxicity testing on aquatic invertebrates may be required by the Agency if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

1.1. Triggering of the information requirement

2 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required.

3 In the provided OECD TG 105 (2012), the saturation concentration of the Substance in water was determined to be below 0.101 mg/L.

4 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

1.2. Information requirement not fulfilled

5 The information provided, its assessment and the specifications of the study design are addressed under request 6.

6 In the comments to the draft decision you agree with the request.

2. Growth inhibition study aquatic plants

7 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

2.1. Information provided

8 You have provided a Growth inhibition study on aquatic plants/algae (2012) with the Substance.

2.2. Assessment of the information provided

9 To fulfil the information requirement, a study must comply with OECD TG 201 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Characterisation of exposure

a) for volatile, unstable or strongly adsorbing test substances, additional samplings for analysis at 24 hour intervals is required;

Additional requirements applicable to difficult to test substances

10 Preliminary stability study

b) if losses of the test material are expected within the timeframe of the test, a preliminary stability study is conducted, which meets the following requirements, among others:

- the test solutions are prepared under conditions equivalent to those to be used in the test;
- samples are analysed at the beginning and at 24-hour intervals for the duration of the test period;
- the significance of adsorption onto test vessel surfaces may be assessed by a comparative study of concentrations determined in unconditioned closed vessels and in closed vessels conditioned to reduce adsorption.

11 Test solution preparation and exposure systems

c) Modifications to test solution preparation and exposure systems to those described in the test guideline may be required where exposure concentrations of a test chemical are likely to decline ≥20% over the test period:

- for adsorptive substances, pre-conditioning of test vessels using solutions of the test substance must be considered to reduce adsorption (Section 7.4 of OECD GD 23).

12 In the study provided:

Characterisation of exposure

a) the test material is strongly adsorbing (log K_{OC} above 5.6), and no additional sampling for analysis at 24 h interval was conducted.

Additional requirements applicable to difficult to test substances

13 Preliminarty stability study

b) the test material was lost from test solutions within the timeframe of the test (measured concentrations were 0.0692 at test start and below limit of quantification at test end, i.e. below 0.0014 mg/L), and no preliminary stability study was conducted to assess the significance of adsorption onto test vessels.

14 Test solution preparation and exposure systems

c) concentrations of the test substance dropped >20% during the study and test vessels were not pre-conditioned with the test substance.

15 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the test material is difficult to test due to the adsorptive properties (Log Koc above 5.6 as determined in the provided OECD TG 121 study), therefore difficulties in maintaining test concentrations can be expected. In the test, no effects on algae growth inhibition were observed. However, in the absence of sampling for analysis at 24 h intervals (a) and in the absence of a preliminary stability experiment assessing the significance of adsorption into test vessels (b), you have not demonstrated if and to what extent the algae were exposed to the test material during the test. Therefore, considering the losses of the test substance from the test system (c), the results may understimate the hazard.

16 On this basis, the specifications of OECD TG 201 are not met and the information requirement is not fulfilled.

2.3. Study design and test specifications

17 The Substance is difficult to test due to the low water solubility (0.1 mg/L) and/or adsorptive properties (Log Koc above 5.6). The OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in the 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 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 the OECD TG 201. 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.

18 For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

19 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

20 In the comments to the draft decision you agree with the request.

3. Ready biodegradability

21 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

3.1. Information provided

22 You have provided a ready biodegradability study (2011) with the Substance.

3.2. Assessment of the information provided

23 The revised introduction to the OECD Guidelines For Testing Of Chemicals, Section 3 Part I states that ready biodegradability tests are intended for pure substances but may also be relevant, on a case-by-case basis, to mixtures of structurally similar chemicals (i.e. which are composed of constituents expected to show similar degradation kinetics). However, such tests are not generally applicable for complex mixtures or substances (i.e. UVCB or multi-constituent substances) containing different types of constituents. For complex

substances, a single ready biodegradability test does not allow to conclude on the ready biodegradability of all constituents and therefore, does not fulfil the information requirement.

24 You have provided a study conducted on the Substance as a whole. In Section 1.1. of your dossier you describe the Substance as UVCB. In Section 1.2, you describe the substance as UVCB substance with the following main constituents: [redacted] The alkyl constituents C14, C16 and C18 have different degree of saturation which make them significantly different with regards to biodegradation rates.

25 The Substance is a complex substance and contains constituents with significant structural differences described above. Therefore the submitted study on the Substance as a whole does not fulfil the information requirement.

26 In your comments to the draft decision, you disagree with ECHA assessment stating the following:" *The substance is an UVCB and includes the following constituents:* [redacted] *Based on a worst-case assessment for the substance, the* [redacted] *was considered to be completely biodegradable (100%). The minor constituent* [redacted] *is not readily biodegradable. According to the principle of biodegradation in which the rate is derived from the ratio of BOD to ThOD, the biodegradation of alkyl phosphonate can be predicted with confidence based on the constituent content and biodegradation*."

27 In addition of that, you have provided a table with calculation in which the biodegradation rate of the whole Substance was calculated based on the worst case scenario (described in your justification above) in which the [redacted] was considered to be completely biodegradable (100%) and [redacted] as not readily biodegradable (50% degradation). The biodegradation of the Substance was calculated based on the constituent content and their "assumed" biodegradations rate. Based on the above you conclude that "*it can be predicted with confidence that the* [redacted] *can attain a pass level of 60% and can be regarded as readily biodegradable, not persistent and supporting the overall result of 68% for the substance".*

28 Further, you also add that "*it is considered infeasible to conduct multiple tests on the individual constituents due to likely significant technical challenges to separation of the homologues*"

29 Based on your comments, ECHA would like to highlight the following:

30 First, regarding the constituents of the Substance, you indicate that [redacted] are homologues and have similar kinetics. However, based on the structural information provided in your registration dossier (i.e. IUCLID dossier Section 1.2) [redacted] have structural and molecular weight differences. While the [redacted] have two alkyl substituents, the methyl/alkyl phosphonates have two different substituents (i.e. [redacted]). Considering those structural differences these constituents cannot be considered as homologues and you have not provided any evidence to support your argument claiming similar degradation kinetics. Furthermore, as described above, alkyl constituents C14, C16 and C18 have different degree of saturation which can make them significantly different with regards to biodegradation rates.

31 Furthermore, you assume in your comments that the [redacted] was completely biodegradable and [redacted] is not readily biodegrdable. However, you you do not provide any specific information and/or studies to demonstrate the validity of these assumptions. Therefore, ECHA is not in a position to assess the biodegradability of these constituents and you have not demonstrated their biodegradability.

32 For all these reasons, the provided study does not provide unequivocal conclusion that all constituents can safely be regarded as readily biodegradable.

33 Second, you indicate in your comments that you consider it infeasible to conduct multiple tests on the individual constituents due to significant technical challenges to separate the homologues.

ECHA understands that you intend to adapt this information requirement according to Annex XI, Section 2 of REACH regulation (i.e. technically not feasible).

34 Under Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance.

35 However, you have not demonstrated in your comments that conducting the test is technically not feasible, because of the properties of the Substance. For the reasons explained above, your argument that the constituents cannot be separated because they are considered as homologues, is rejected. You have not provided any further experimental evidence in support of your claim that testing would be technically not feasible.

Therefore, your adaptation provided in your comments is rejected.

36 For all these reasons, the information requirement is not fulfilled.

3.3. Study design and test specifications

37 For the reasons provided above, testing on the Substance as a whole does not fulfil the information requirement. For the generation of information on ready biodegradability, you must consider the level of information required for the purposes of classification and labelling and, if applicable to your registration, the PBT/vPvB assessment and the exposure assessment/risk characterisation. In order to conclude on which of constituents of the Substance are and which are not readily biodegradable, you may have to consider conducting more than one study using selected individual constituents and/or fractions. If you choose to test one (or more) fraction(s) of the Substance, you must provide a justification that their constituents within chosen fraction(s) are similar enough so that similar degradation kinetics can be assumed. If you decide to conduct a single study in order to prove that all constituents of the Substance are readily biodegradable, you must provide a justification that the selected constituent/fraction can be considered a reasonable worst-case for the Substance as a whole in terms of degradation kinetics.

38 Justification for selection of relevant constituent and/or fractions for the testing, must consider degradation kinetics of constituents of the Substance based, as minimum, on the similarity/differences of the chemical structures and the physico-chemical properties of constituents of the Substance. For that purpose, tools and approaches mentioned in Guidance on IRs and CSA, Sections R.7b and R.11 should be considered.

Reasons related to the information under Annex VIII of REACH

4. Long-term toxicity testing on fish

39 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, Section 9.1.3.. However, long-term toxicity testing on fish may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

4.1. Triggering of the information requirement

40 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required.

41 As already explained in request 1, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

4.2. Information requirement not fulfilled

42 The information provided, its assessment and the specifications of the study design are addressed under request 7.

43 In the comments to the draft decision you agree with the request.

Reasons related to the information under Annex IX of REACH

5. Pre-natal developmental toxicity study in one species

44 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX, Section 8.7.2.

5.1. Information provided

45 You have adapted this information requirement by using Annex IX, Section 8.7., Column 2. To support the adaptation, you have provided the following justification: "The submission item is in accordance with this characterisation. In all toxicity studies including the screening test according to OECD TG 421 (1995 required in REACH Annex VIII, 8.7.1.) the test systems gave clear negative, non-toxic responses. The chemical structure of the submission item does not feature any element associated with any specific toxic effects. No critical information is available from structurally related compounds. Therefore no further experimental evaluation of developmental toxicity / teratogenicity as required in Annex IX, 8.7.1. is necessary and baseline toxicity can be assumed."

5.2. Assessment of the information provided

46 Under Annex IX, Section 8.7., Column 2, the study does not need to be conducted if the following criteria are met:

- the substance is of low toxicological activity, demonstrated by a comprehensive and informative dataset showing no toxicity in any of the tests available; and
- that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and
- that there is no or no significant human exposure.

47 No evidence of toxicity is observed in the study reproduction/developmental toxicity screening test performed on the Substance included in your dossier and referred to in your justification for the adaptation up to the limit dose of 1000 mg/kg/d. Similarly no evidence of toxicity is identified in the 28-day study conducted with the Substance included in your dossier up to the dose of 1000 mg/kg/d.

48 No toxicokinetic data is provided to show that there is no systemic absorption.

49 The uses of the Substance include professional and consumer uses as lubricating agent.

50 Based on the information in the dossier, two of the cumulative conditions, as noted above, are not met.

51 In particular, there is no toxicokinetic data to demonstrate no systemic absorption and there are above indicated uses of the Substance and no information to demonstrate that there is "no or no significant human exposure" (as no exposure assessment and risk characterisation are provided).

52 On this basis, you have not demonstrated that all the criteria for this adaptation are fulfilled.

53 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

5.3. Specification of the study design

54 A PNDT study according to the test method OECD TG 414 should be performed in rats or rabbits as preferred species.

55 As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex IX, Section 8.7.2., Column 1).

56 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

57 In the comments to the draft decision you agree with the request.

6. Long-term toxicity testing on aquatic invertebrates

58 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

6.1. Information provided

59 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information: "No experimental data on long-term toxicity to aquatic invertebrates are available. Testing, required in Annex IX, 9.1.5., has been waived in accordance with column 2 restrictions. The chemical safety assessment according to Annex I indicates no need to investigate further the effects on aquatic organisms, as no hazard of the submission item was identified"

6.2. Assessment of the information provided

60 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to aquatic invertebrates referred to under Column 1, Section 9.1.5.

61 Your adaptation is therefore rejected and the information requirement is not fulfilled.

6.3. Study design and test specifications

62 The OECD TG 211 specifies that, for difficult to test substances, the OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design and test specifications" under request 2.

63 In the comments to the draft decision you agree with the request.

7. Long-term toxicity testing on fish

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

7.1. Information provided

65 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information: "No experimental data on long-term toxicity to fish are available. Testing, required in Annex IX, 9.1.6. has been waived in accordance with column 2 restrictions. The chemical safety assessment

according to Annex I indicates no need to investigate further the effects on aquatic organisms, as no hazard of the submission item was identified".

7.2. Assessment of the information provided

66 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to fish referred to under Column 1, Section 9.1.6.

67 Your adaptation is therefore rejected and the information requirement is not fulfilled.

7.3. Study design and test specifications

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

69 The OECD TG 210 specifies that, for difficult to test substances, the OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design and test specifications" under request 2.

70 In the comments to the draft decision you agree with the request.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: 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 02 May 2022.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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 3: Addressee(s) of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- 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;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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[2].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. 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

- 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 the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as

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

far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

With that detailed information, ECHA can confirm 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 (https://echa.europa.eu/manuals).