~~Confidential~~

Helsinki, 24 October 2022

Addressees
Registrants of 265-049-4/64741-49-7 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
10/12/2021

Registered substance subject to this decision ("the Substance")
Substance name: Condensates (petroleum), vacuum tower
EC number: 265-049-4

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

DECISION ON TESTING PROPOSAL(S)

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit information under request 1-3 below by ***30 July 2025***; and all other requested information listed below by ***30 July 2026***.

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

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

1. In vivo mammalian alkaline comet assay (Annex VIII, Section 8.4. column 2) combined with in vivo mammalian erythrocyte micronucleus test (triggered by Annex I, Section 0.5), also requested below.

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

2. In vivo mammalian alkaline comet assay (Annex IX, Section 8.4. column 2; test method: OECD 489) combined with in vivo mammalian erythrocyte micronucleus test (triggered by Annex I, Section 0.5; test method EU B.12./OECD 474), in rats or if justified, in mice, oral route. For the comet assay, liver, and glandular stomach and duodenum shall be analysed, for the micronucleus test, the bone marrow;

3. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats;

4. 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).

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

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

The reasons for the requests 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 addressees 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 decision
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 decision

Contents

Reasons for the decision(s) related to the information under Annex VIII of REACH

1. In vivo mammalian alkaline comet assay combined with in vivo mammalian erythrocyte micronucleus test

1 Under Annex I, Section 0.5, if the manufacturer or importer considers that further information is necessary for producing his chemical safety report and that this information can only be obtained by performing tests in accordance with Annex IX or X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary.

1.1. Testing proposed to fulfil the information requirement

2 You have submitted a testing proposal for an *in vivo* mammalian alkaline comet assay combined with *in vivo* mammalian erythrocyte micronucleus test to be performed with the Substance.

1.2. Triggering of the information requirement

3 For the reasons explained in request 2, below, ECHA agrees that information on the hazardous properties of the Substance, namely, mutagenicity, is necessary for producing the chemical safety report and that this information can only be obtained by performing an in vivo mutagenicity study (triggered by Annex I, Section 0.5), to address gene mutation and chromosomal aberration.

4 For the specifications of the study to be performed, see the request 2.

Reasons for the decision(s) related to the information under Annex IX of REACH

2. In vivo mammalian alkaline comet assay combined with In vivo mammalian erythrocyte micronucleus test

5 Under Annex I, Section 0.5, if the manufacturer or importer considers that further information is necessary for producing his chemical safety report and that this information can only be obtained by performing tests in accordance with Annex IX or X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary.

2.1. "Information provided to fulfil the information requirement

6 You have submitted a testing proposal for an *in vivo* mammalian alkaline comet assay combined with *in vivo* mammalian erythrocyte micronucleus test to be performed with the Substance.

7 In your dossier, you consider that *in vitro* studies are not appropriate to address the mutagenicity properties of the Substance due to the difficulties with its solubility, and that *in vivo* studies are necessary to confirm the intrinsic properties of the Substance "where there is a clear data gap".

8 In addition, in your dossier you have also provided the following *in vivo* information:

i. Key - chromosome aberration Petroleum Middle Distillate McKee 1994s conducted with the analogue substance Home heating oil (CAS 68476-30-2);
ii. Supporting - chromosome aberration diesel fuel cytogenicity conducted with the analogue substance diesel fuel (CAS 68334-30-5);
iii. Supporting dominant lethal in vivo, diesel conducted with the analogue substance Diesel fuel No 2 (CAS 68476-34-6);
iv. Supporting - SRGO - chromosome aberration CHO 64741-44-2 API 83-11 1985 conducted with the analogue substance Straight run middle distillate (CAS 64741-44-2)

9 We have evaluated the *in vivo* information and identified the following deficiencies:

10 A. For the data from an *in vivo* cytogenicity test to be considered adequate, the study has to meet the requirements of OECD TG 474/475, and the key parameters of the test guidelines include:

a) At least 4000 immature erythrocytes per animal must be scored for the incidence of micronucleated immature erythrocytes. (OECD TG 474)
b) The mitotic index must be determined as a measure of cytotoxicity in at least 1000 cells per animal for all treated animals (including positive controls), untreated or vehicle/solvent negative control animals. (OECD TG 475)
c) At least 200 metaphases must be analysed for each animal for structural chromosomal aberrations including and excluding gaps. (OECD TG 475)
d) the first sampling interval should be the time necessary to complete 1.5 normal cell cycle lengths (the latter being normally 12-18 hours following the treatment period), plus a second 24 hours later. (OECD TG 475)

11 The test guideline reported for the study (i) was indicated as similar to OECD TG 474. The reported data for the study (i) did not include:

a) the analysis of the adequate number of cells. Only 1000 cells were counted.

12 The test guideline reported for the studies (ii and iv) was indicated as similar to OECD TG 475. The reported data for the *in vivo* studies (ii and iv) you submitted did not include:

b) the analysis of the adequate number of cells for mitotic index (studies ii and iv- numbers are not reported per animal);
c) the analysis of the adequate number of metaphase cells for chromosome aberrations (study ii- numerous groups have less than 200 metaphase cells, e.g. the saline and 0.6 ml/kg 6 hour samples) (study iv- numbers of cells are not reported per animal, and the methodology states that a minimum of 50 metaphase cells from each animal were counted);
d) sampling times at an appropriate time (they are at 6, 24 and 48 hours after dosing).

13 Therefore, the information provided does not cover key parameter(s) required by OECD TG 474 or TG 475.

14 ECHA Guidance on IRs & CSA clarifies that the *in vivo* somatic cell cytogenicity test must be either a micronucleus test or a chromosomal aberration test, performed according to OECD TG 474 or 475, respectively.

15 You have provided an *in vivo* germ cell test, a dominant lethal test, with an analogue substance (iii).

16 The Rodent dominant lethal test (OECD TG 478) (study iii) is an *in vivo* cytogenicity test, however it is performed on germ cells. Therefore, the study does not provide information on somatic cell mutagenicity and the results of such test cannot be used for the first level of classification as germ cell mutagen, i.e. category 2. Indeed *in vivo* data obtained on somatic cells is necessary for this purpose.

17 As a conclusion, there are no are no valid *in vivo* somatic cell mutagenicity studies available for the substance.

18 ECHA requested your considerations for alternative methods to fulfil the information requirement for Genetic toxicity *in vivo*. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

19 In conclusion, ECHA agrees that further information is necessary for producing the chemical safety report and that this information can only be obtained by performing an *in vivo* mutagenicity study (triggered by Annex I, Section 0.5), to address gene mutation and chromosomal aberration.

2.2. Test selection

20 The *in vitro* studies under REACH address both chromosomal aberration and gene mutation, and your proposal is that the corresponding in vitro studies are not appropriate for both those endpoints, and that the *in vivo* study should therefore address both chromosomal aberration and gene mutation. The *in vivo* mammalian erythrocyte micronucleus test ("MN test", OECD TG 474) and the *in vivo* mammalian alkaline comet assay ("comet assay", OECD TG 489) can be combined in a single study (see OECD TG 474 para. 37c; OECD TG 489 para. 33; Guidance on IRs & CSA, Section R.7.7.6.3). While the MN test can detect both structural chromosomal aberrations (clastogenicity) and numerical chromosomal aberrations (aneuploidy), the comet assay can detect primary DNA damage that may lead to gene mutations and/or structural chromosomal aberrations. A combined study will thus address both the identified concerns for chromosomal aberration as well as gene mutation.

21 The combined study, together with the results of the in vitro mutagenicity studies, can be used to make definitive conclusions about the mechanism(s) inducing in vivo mutagenicity and lack thereof. Furthermore, the combined study can help reduce the number of tests performed and the number of animals used while addressing (structural and numerical) chromosomal aberrations as well as gene mutations.

22 Therefore, the comet assay combined with the MN test is the most appropriate study for the Substance.

2.3. Specification of the study design

23 You proposed testing in the rat. According to the test method OECD TG 489, rats are the preferred species. Other rodent species can be used if scientifically justified. According to the test method OECD TG 474, the test may be performed in mice or rats. Therefore, the combined study must be performed in rats, or if justified, in mice.

24 You proposed testing by the oral route. Having considered the anticipated routes of human exposure and adequate exposure of the target tissue(s) performance of the test by the oral route is appropriate.

25 In line with the test method OECD TG 489, the test must be performed by analysing tissues from liver as primary site of xenobiotic metabolism, glandular stomach and duodenum as sites of contact. There are several expected or possible variables between the glandular stomach and the duodenum (different tissue structure and function, different pH conditions, variable physico-chemical properties and fate of the Substance, and probable different local absorption rates of the Substance and its possible breakdown product(s)). In light of these expected or possible variables, it is necessary to analyse both tissues to ensure a sufficient evaluation of the potential for genotoxicity at the site of contact in the gastro-intestinal tract.

26 The combination of OECD TGs 489 and 474 should not impair the validity of and the results from each individual study. Careful consideration should be given to the dosing, and tissue sampling for the comet analysis alongside the requirements of tissue sampling for the mammalian erythrocyte micronucleus test (see OECD TG 489, e.g. Bowen et al. 2011 [1]).

2.3.1. Germ cells

27 A subsequent germ cell genotoxicity study (TGR/OECD TG 488, or CA on spermatogonia/OECD TG 483) may still be required under Annex IX of REACH, in case 1) an in vivo genotoxicity test on somatic cell is positive, and 2) no clear conclusion can be made on germ cell mutagenicity.

28 Therefore, you may consider collecting the male gonadal cells from the seminiferous tubules in addition to the other tissues in the comet assay, as it would optimise the use of animals. You can prepare the slides for male gonadal cells and store them for up to 2 months, at room temperature, in dry conditions and protected from light. Following the generation and analysis of data on somatic cells in the comet assay, in accordance with Annex IX, Section 8.4., column 2, you should consider analysing the slides prepared with gonadal cells. This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

[1] Bowen D.E. et al. 2011. Evaluation of a multi-endpoint assay in rats, combining the bone-marrow micronucleus test, the comet assay and the flow-cytometric peripheral blood micronucleus test. Mutation Research 722 7–19.

2.4. Outcome

29 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.

3. Sub-chronic toxicity study (90-days)

30 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX to REACH (Section 8.6.2.).

3.1. testing proposal to fulfil the information requirement

31 You have submitted a testing proposal for a Sub-chronic toxicity study (90 day) according to OECD TG 408 with the Substance.

32 ECHA requested your considerations for alternative methods to fulfil the information requirement for Repeated dose toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

33 ECHA agrees that a 90-day study is necessary.

3.2. Specification of the study design

34 You proposed testing in the rat. ECHA agrees with your proposal because the rat is the preferred species according to the OECD TG 408. Therefore, the study must be conducted in the rat.

35 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is appropriate to investigate systemic toxicity; Guidance on IRs and CSA, Section R.7.5.4.3.2.

36 In your comments on the draft decision you indicate that it is your intention to select the dietary route as the test material is poorly soluble and difficult to administer by gavage on a repeated basis, mainly as it forms an aspiration hazard. ECHA notes that you are responsible for ensuring compliance with the Test Guideline.

3.3. Outcome

37 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.

4. Pre-natal developmental toxicity study in a first species

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

4.1. Testing proposal to fulfil the information requirement

39 You have submitted a testing proposal for a PNDT study according to the OECD TG 414 by the oral route with the Substance.

40 ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

41 ECHA received third party information concerning the testing proposal during the third-party consultation.

42 The third party has stated: "[t]here are welfare issues associated with the dermal dosing of pregnant animals with regard to handling/restraint during application, and due to the dressings used to secure the applied test material. We also note that the category of substances to which the testing proposals relate are hydrocarbons (petroleum fractions) and, therefore, may be associated with a risk of toxicity due to reflux and aspiration of the test material."

43 ECHA notes that the test methods for repeated dose toxicity and reproductive toxicity are intended to characterise the repeated dose toxicity and reproductive toxicity, respectively, of the test chemical. Therefore, it is your responsibility to ensure that appropriate dosing is used in the requested studies so that the dosing per se does not cause unnecessary suffering or artefactual toxicity due to the physicochemical properties of the substance.

44 ECHA agrees that a PNDT study in a first species is necessary.

4.2. Specification of the study design

45 You proposed testing in the rat as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

46 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

47 In your comments on the draft decision you indicate that it is your intention to select the dietary route as the test material is poorly soluble and difficult to administer by gavage on a repeated basis, mainly as it forms an aspiration hazard. ECHA notes that you are responsible for ensuring compliance with the Test Guideline. ECHA points out that your current justification is inadequate, as the potential aspiration hazard is not documented and you have not examined alternative methods of reducing aspiration hazard for gavage dosing.

4.3. Outcome

48 Your testing proposal is accepted under Article 40(3)(b) and you are requested to conduct the test, as specified above.

Reasons for the decision(s) related to the information under Annex X of REACH

5. Pre-natal developmental toxicity study in a second species

49 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in two species is a standard information requirement under Annex X, Section 8.7.2. to REACH.

5.1. Testing proposed to fulfil the information requirement

50 You have submitted a testing proposal for a PNDT study according to the OECD TG 414 by the oral route with the Substance.

51 You consider there is no data available in a second species.

52 ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

53 ECHA received third party information concerning the testing proposal during the third-party consultation.

54 The third party has stated: "[t]here are welfare issues associated with the dermal dosing of pregnant animals with regard to handling/restraint during application, and due to the dressings used to secure the applied test material. We also note that the category of substances to which the testing proposals relate are hydrocarbons (petroleum fractions) and, therefore, may be associated with a risk of toxicity due to reflux and aspiration of the test material."

55 ECHA notes that the test methods for repeated dose toxicity and reproductive toxicity specify that the highest dose level should induce "toxicity but not death or severe suffering". Therefore, it is your responsibility to ensure that appropriate dose/ exposure levels are used in the requested studies.

56 ECHA agrees that a PNDT study in a second species is necessary.

5.2. Specification of the study design

57 You proposed testing in the rabbit as a second species. The rat or the rabbit are the preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.). A PNDT study according to the OECD TG 414 study should be performed in the rabbit or rat as the preferred second species, depending on the species tested in the first PNDT study.

58 If studies in the preferred rodent or non-rodent species will not provide information that is relevant for human health hazard assessment, another rodent or non-rodent species should be used and the choice should be justified.

59 In "VHGO strategy and read-across justification Nov 2021", you state that "oral administration of oily substances causes gastro-intestinal disturbances in the rabbit", with the inference that the Substance being oily will cause such effects, but you have not provided substance-specific data to substantiate this claim.

60 In respect of your argument that "oral administration of oily substances causes gastro-intestinal disturbances in the rabbit", ECHA considers that if there were substance-specific data to show that the Substance causes gastro-intestinal disturbance in the rabbit; that the

resulting toxicity is not relevant for humans; and would limit the hazard assessment of the Substance for pre-natal developmental toxicity; this would indicate that the rabbit is not an appropriate non-rodent species to test the Substance and the Registrant should evaluate other non-rodent species. You have not demonstrated that the Substance causes gastro-intestinal disturbance in the rabbit, that the resulting toxicity is not relevant for humans, and would limit the hazard assessment of the Substance for pre-natal developmental toxicity, and nor have you provided considerations on other non-rodent species for testing.

61 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

5.3. Outcome

62 Your testing proposal is accepted under Article 40(3)(b) and you are requested to conduct the test, as specified above.

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).

All Guidance on REACH is 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

The testing proposal submitted to fulfil the information requirement for an Extended one-generation reproductive toxicity study (EOGRTS; Annexes IX or X, Section 8.7.3.) is not addressed in this decision. This may be addressed in a separate decision once the information from the Sub-chronic toxicity study (90-day) requested in the present decision is provided; due to the fact that the results from the 90-day study is needed for the design of the EOGRTS.

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 30 January 2020.

ECHA held a third party consultation for the testing proposal(s) from 7 July 2020 until 21 August 2020. ECHA received information from third parties (see corresponding Appendix/Appendices

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

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

ECHA took into account your comments and did not amend the requests.

Deadline to provide the information

In your comments on the draft decision, you requested an extension of the deadline to provide the information from 18 months to 30 months for items 1-3 in the decision letter from the date of adoption of the decision. You refer to limited laboratory capacity and extended lead times for the requested tests.

ECHA took into account this information and the provided documentary evidence. The deadlines of the decision are set based on standard practice for carrying out OECD TG tests. They have 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 took into account your comments and amended the deadlines.

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: Addressees 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]
[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:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) 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.
b) 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 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,

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

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).