~~Confidential~~

Helsinki, 24 May 2023

Addressees
Registrant(s) of JS_694-83-7 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
22/06/2022

Registered substance subject to this decision ("the Substance")
Substance name: Cyclohex-1,2-ylenediamine
EC number: 211-776-7

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***31 August 2026***.

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

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

1. Extended one-generation reproductive toxicity study (triggered by Annex IX, Section 8.7.3., column 1; test method: OECD TG 443) by oral route, in rats, specified as follows:

- At least two weeks premating exposure duration for the parental (P0) generation;
- The highest dose level in P0 animals must be determined based on clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals as specified further in Appendix 1, or follow the limit dose concept. The reporting of the study must provide the justification for the setting of the dose levels;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation which shall be followed to weaning;
- Cohorts 2A and 2B (Developmental neurotoxicity); and
- Cohort 3 (Developmental immunotoxicity).

You must report the study performed according to the above specifications. Any expansion of the study must be scientifically justified.

The reasons for the decision(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 addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 IX of REACH

1. Extended one-generation reproductive toxicity study

1 An extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is an information requirement under Annex IX, Section 8.7.3., if the available repeated dose toxicity studies indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity. Furthermore column 2 defines the conditions under which the study design needs to be expanded.

1.1. Triggering of the information requirement

2 The OECD TG 408 study (2022) and OECD TG 422 study (2007) in your dossier indicate adverse effects on reproductive organs or tissues (male reproductive system) and reveal other concerns in relation with reproductive toxicity.

3 More specifically, the OECD TG 408 study reports the following adverse effects on male reproductive system:

- changes in reproductive organ weights: low epididymides and combined seminal vesicles, prostate and coagulating gland weights in males receiving 500 mg/kg/day
- histopathological findings in reproductive organs: e.g. tubular degeneration/atrophy in the testes, reduced luminal sperm and increased cellular debris in males at 500 mg/kg bw/day
- effects in sperm parameters: decrease of motile sperm, progressively motile sperm and epididymal and testicular sperm count in males receiving 500 mg/kg/day, which were below the historical control data; increase of abnormal sperm (head, neck, midpiece and tail abnormalities), an associated decrease of normal sperm and an increase of decapitate sperm which were also outside of the historical control data. There was also a reduction of epididymal sperm count in males receiving 150 mg/kg/day and although statistical significance was not attained and this did not associate with any alteration of sperm morphology or motility, values were below the historical control data.

4 Based on the OECD TG 408 study, you consider that the male reproductive system is a target system for the Substance (IUCLID section 7.5.1).

5 Furthermore, the OECD TG 422 study reports the following concerns in relation with reproductive toxicity:

- decreased gestation index (77.8% at 500 mg/kg bw/day vs. 100% in controls)
- a statistically significantly reduced number of living pups per litter during the first litter check (6.9 pups per litter at 500 mg/kg bw/day vs. 16.0 pups per litter in controls)
- an increased incidence of postnatal loss in all treated groups was reported, resulting in a reduced viability index.

6 In IUCLID section 7.8.1, you considered that "There was an increased incidence in missing and cannibalized pups, correlating with the increased post natal loss noted at 50, 150 and 500 mg/kg when compared to the concurrent controls. The increased incidence in postnatal loss might be caused by possible developmental effects".

7 In your comments, you consider that the decreased gestation index is most certainly due to the impaired male reproductive function.

8 Furthermore, you consider that the concern on developmental toxicity of the Substance was not confirmed in a newly performed OECD TG 414 study. ECHA notes that an OECD TG 414 study does not investigate pup survival and viability post-natally, and consequently it does not inform on viability index. Therefore, an OECD TG 414 study does not negate a concern on pup post-natal survival observed in an OECD TG 422 study.

9 Therefore, the information requirement is triggered.

1.2. Information provided

10 You have not provided any source of information to fulfil this information requirement.

11 In IUCLID section 7.8.1, you have provided a reference to an earlier decision[2] initially requesting the EOGRT study, stating that 'This information will be submitted later based on ECHA decision number CCH-D-2114448614-46-01/F. Feedback from ECHA on the newly presented OECD TG 408 study results needs to be awaited.'

12 Based on the newly-submitted OECD TG 408 study, ECHA considers that the design of EOGRT study as initially requested in the previous decision referred to by you[2] requires modifications to fulfil the information requirement. Therefore, on 8 July 2022, ECHA withdrew the request for the EOGRT study in the aforementioned decision with the number CCH-D-2114448614-46-01/F.

1.3. Specification of the study design

1.3.1. Species and route selection

13 A study according to the test method OECD TG 443 must be performed in rats with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

1.3.2. Pre-mating exposure duration

14 The length of pre-mating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

15 A two-week pre-mating exposure duration for P0 animals is sufficient for your Substance because the F1 animals of Cohort 1B are mated to produce the F2 generation and, thus, the premating exposure duration will be ten weeks for these Cohort 1B animals.

16 Therefore, the requested pre-mating exposure duration for the P0 animals is two weeks.

1.3.3. Dose-level setting

17 The aim of the requested test must be to demonstrate whether the classification criteria of the most severe hazard category for sexual function and fertility (Repr. 1B; H360F) and developmental toxicity (Repr. 1B; H360D) under the CLP Regulation apply for the Substance (OECD TG 443, paragraph 22; OECD GD 151, paragraph 28; Annex I Section 1.0.1. of REACH and Recital 7, Regulation 2015/282), and whether the Substance meets the criteria for a Substance of very high concern regarding endocrine disruption according to Art.57(f) of REACH as well as supporting the identification of appropriate risk management measures in the chemical safety assessment.

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[2] ECHA decision number CCH-D-2114448614-46-01/F issued on 31 October 2018: https://echa.europa.eu/documents/10162/e1ebaed4-ace0-dfea-178a-c7479fc1851b

18 To investigate the properties of the Substance for these purposes, the highest dose level must be set on the basis of clear evidence of an adverse effect on sexual function and fertility, but no deaths (i.e., no more than 10% mortality; Section 3.7.2.4.4 of Annex I to the CLP Regulation) or severe suffering such as persistent pain and distress (OECD GD 19, paragraph 18) in the P0 animals.

19 In case there are no clear evidence of an adverse effect on sexual function and fertility, the limit dose of at least 1000 mg/kg bw/day or the highest possible dose level not causing severe suffering or deaths in P0 must be used as the highest dose level. A descending sequence of dose levels should be selected to demonstrate any dose-related effect and aiming to establish the lowest dose level as a NOAEL.

20 In summary: Unless limited by the physical/chemical nature of the Substance, the highest dose level in P0 animals must be as follows:

(1) in case of clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals, the highest dose level in P0 animals must be determined based on such clear evidence, or
(2) in the absence of such clear evidence, the highest dose level in P0 animals must be set to be the highest possible dose not causing severe suffering or death, or
(3) if there is such clear evidence but the highest dose level set on that basis would cause severe suffering or death, the highest dose level in P0 animals must be set to be the highest possible dose not causing severe suffering or death, or
(4) the highest dose level in P0 animals must follow the limit dose concept.

21 You have to provide a justification with your study results demonstrating that the dose level selection meets the conditions described above.

22 Numerical results (i.e. incidences and magnitudes) and description of the severity of effects at all dose levels from the dose range-finding study/ies must be reported to facilitate the assessment of the dose level section and interpretation of the results of the main study.

1.3.4. Cohorts 1A and 1B

23 Cohorts 1A and 1B belong to the basic study design and must be included.

1.3.4.1. Splenic lymphocyte subpopulation analysis

24 Splenic lymphocyte subpopulation analysis must be conducted in Cohort 1A (OECD TG 443, paragraph 66; OECD GD 151, Annex Table 1.3).

1.3.4.2. Investigations of sexual maturation

25 To improve the ability to detect rare or low-incidence effects, all F1 animals must be maintained until sexual maturation to ensure that sufficient animals (3/sex/litter/dose) are available for evaluation of balano-preputial separation or vaginal patency (OECD GD 151, paragraph 12 in conjunction with OECD TG 443, paragraph 47). For statistical analyses, data on sexual maturation from all evaluated animals/sex/dose must be combined to maximise the statistical power of the study.

1.3.5. Extension of Cohort 1B

26 If the Column 2 conditions of 8.7.3. are met, Cohort 1B must be extended by mating the Cohort 1B animals to produce the F2 generation.

27 The extension is required, among others, if the use of the Substance is leading to significant exposure of consumers and professionals (column 2, first paragraph, point (a) of Section 8.7.3.) and there are indications of one or more relevant modes of action related to endocrine disruption from available in vivo studies or non-animal approaches (column 2, first paragraph, point (b), third indent of Section 8.7.3.).

28 The use of the Substance reported in the joint submission is leading to significant exposure of professionals because the Substance is used by professionals as curing agent in composite and coating materials (PROCs 4, 5, 8a, 10, 11, 13, 14, 19).

29 Furthermore, there are indications of one or more modes of action related to endocrine disruption because changes in reproductive organs were reported in the OECD TG 408 study, as explained under section 1.1.

30 For the reasons stated above, Cohort 1B must be extended.

31 Organs and tissues of Cohort 1B animals processed to block stage, including those of identified target organs, must be subjected to histopathological investigations (according to OECD TG 443, paragraph 67 and 72) because there is a concern for reproductive toxicity/endocrine activity indicated by the toxicity-triggers to extend the Cohort 1B.

32 The F2 generation must be followed to weaning allowing assessment of nursing and lactation of the F1 parents and postnatal development of F2 offspring. Investigations for F2 pups must be similar to those requested for F1 pups in OECD TG 443 and described in OECD GD 151.

1.3.6. Cohorts 2A and 2B

33 The developmental neurotoxicity Cohorts 2A and 2B must be conducted in case of a particular concern on (developmental) neurotoxicity.

34 In the OECD TG 408 study with the Substance, changes in reproductive organ weights were observed. More specifically, these findings include reduced epididymides weight and reduced combined seminal vesicles, prostate and coagulating gland weights in males receiving 500 mg/kg/day. In addition, histopathological findings in reproductive organs were observed, such as tubular degeneration/atrophy in the testes, reduced luminal sperm and increased cellular debris in epididymides as well as acinar atrophy of the accessory sex glands (prostate, seminal vesicles and coagulating glands) in males at 500 mg/kg bw/day. Several effects were also observed in sperm parameters including decreased count, decreased motility and increased number of abnormalities.

35 These effects are consistent with estrogenic or anti-androgenic-mediated activity (OECD GD 150). According to ECHA Guidance R.7a, Appendix R.7.6-2, estrogenicity and anti-androgenicity are specific mechanisms/modes of action which have an association with the developing nervous system. Therefore, there is a particular concern on developmental neurotoxicity.

36 In your comments, you consider the specific mode of action of the substance, and you further consider the endocrine mode of action as part of assessment of endocrine disrupting activity. You consider that the endocrine mode of action still needs further clarification because there are contradictory results. The results from the OECD TG 408 study are consistent with estrogenic or anti-androgenic activity. However, such activities are not shown in the respective androgen receptor (AR) and estrogen receptor (ER) models[3,4], and you also note that in females no relevant changes in estrous cyclicity or reproductive organs

[3] Danish (Q)SAR Database: Division of Diet, Disease Prevention and Toxicology, Technical University of Denmark. http://qsar.food.dtu.dk, accessed on 24-Mar-2023
[4] ToxCast/Tox21, Integrated Chemical Environment: https://ice.ntp.niehs.nih.gov/Search

were observed. You propose to discuss further *in vitro* and/or *in vivo* mechanistic testing rather than extension of the EOGRTS testing.

37 This decision requires compliance with Annex IX, 8.7.3, and not information to complete an assessment of endocrine disruption. ECHA considers that even if predictive models for AR and ER activity were negative, there is reliable *in vivo* information from the OECD TG 408 study showing effects which are consistent with estrogenic or anti-androgenic-mediated activity, and the data in female do not negate that.

38 As supporting evidence, in the OECD TG 422 study with the Substance, decreased gestation index, reduced number of living pups per litter and increased incidence of postnatal loss in all treated groups resulting in reduced viability index was observed. Changes in the number of live births, litter size and viability index are potentially sensitive to, but not diagnostic of, E, A, T or S modalities (OECD GD 150).

39 In your comments, you consider that the findings from OECD TG 422 study are not definitive but only indicative of estrogenic or anti-androgenic-mediated activity, as the study design provides only limited evidence. ECHA agrees and notes that the findings of the OECD TG 422 study provide supporting evidence to the findings of the OECD TG 408 study.

40 In your comments, you further consider that based on the available data set (OECD TG 408, 414 and 422 studies), there is no evidence that the Substance could be a developmental neurotoxicant based on adverse effects on the nervous system.

41 As stated above, the trigger for the DNT cohort is a mode of action associated with developmental neurotoxicity, and the evidence on adversity to which you refer does not demonstrate that mode of action is not producing a developmental neurotoxic effect. Classification for developmental toxicity is not limited to effects induced during pregnancy or due to parental exposure but includes also any effect interfering with normal development of the offspring resulting from exposure of the developing offspring to the time of sexual maturation[5]. Furthermore, these effects can be manifested at any point in the life span of the organism[5]. In this context, ECHA notes that the OECD TG 408 study investigates adult (non-pregnant) animals and hence it does not inform on developmental toxicity. OECD TG 414 study informs only on foetal development, i.e. effects manifested during pre-natal development. OECD TG 422 study provides limited information on pre- and post-natal development, as it continues until post-natal day (PND) 4. However, development of the nervous system continues after birth, and none of the available studies has investigated developmental neurotoxicity of the F1 generation up to adulthood.

42 For the reasons stated above, the developmental neurotoxicity Cohorts 2A and 2B must be conducted.

1.3.7. Cohort 3

43 The developmental immunotoxicity Cohort 3 needs to be conducted in case of a particular concern on (developmental) immunotoxicity.

44 Existing information on the Substance itself derived from the available OECD TG 408 study shows

[5] CLP 3.7.1.4. Developmental toxicity includes, in its widest sense, any effect which interferes with normal development of the conceptus, either before or after birth, and resulting from exposure of either parent prior to conception, or exposure of the developing offspring during prenatal development, or postnatally, to the time of sexual maturation. However, it is considered that classification under the heading of developmental toxicity is primarily intended to provide a hazard warning for pregnant women, and for men and women of reproductive capacity. Therefore, for pragmatic purposes of classification, developmental toxicity essentially means adverse effects induced during pregnancy, or as a result of parental exposure. These effects can be manifested at any point in the life span of the organism. The major manifestations of developmental toxicity include (1) death of the developing organism, (2) structural abnormality, (3) altered growth, and (4) functional deficiency.

- reduced leucocyte counts in both sexes at 500 mg/kg bw/day (below historical control data in males)
- reduced thymus weights in both sexes at 500 and 150 mg/kg bw/day, and in males receiving 50 mg/kg bw/day, with the extent of the decrease being broadly dose-related and statistically significant.
- decreased cellularity was observed in the mesenteric and axillary lymph nodes, as well as in the Peyer's patches and splenic periarteriolar lymphoid sheaths, in both sexes receiving 500 mg/kg/day.

45 Based on the OECD TG 408 study, you note that changes in the hemolymphoreticular system occurred in both sexes, and consider that the hemolymphoreticular system is a target system for the Substance (IUCLID section 7.5.1). Therefore, ECHA considers that there is a particular concern on (developmental) immunotoxicity.

46 For the reasons stated above, the developmental immunotoxicity Cohort 3 must be conducted.

1.3.8. Need to perform an EOGRT study

47 In your comments, you question the need for conducting an EOGRT study. You refer to new information, namely an ongoing dose range finding (DRF) study whose interim results are available and included in your comments. These results show that cauda epididymis weight, sperm count, and sperm motility are affected in a dose-dependent way. Despite successful mating, no/only some pregnancies were achieved in the treatment groups. Therefore, you consider that the effects observed on male fertility parameters in the OECD TG 408 study together with the interim findings in the DRF of the OECD TG 443 study warrant a classification for reproductive toxicity, category 1B (H360F). With classification in the hazard class reproductive toxicity (category 1B: May damage fertility (H360F)), and adequate data to support a robust risk assessment, you consider that REACH Annex IX, section 8.7 column 2 adaptation applies, and further testing may not be needed.

48 The information you have provided in your comments reflects only preliminary results of the DRF study, some investigations from the DRF study are still not available (e.g. histopathological investigations are missing, characterisation of toxicity), and so ECHA is unable to evaluate this information. Moreover, this information is currently not available in your registration dossier. Thus the data gap remains. If the final results fulfil the criteria for classification for reproductive toxicity, category 1B (H360F), you should revise the hazard classification of the Substance, and update your registration, accordingly. You should submit this information, together with a revised hazard classification and where necessary safety assessment, in an updated registration dossier. You should consider whether submission of an adaptation of the information requirement according to the specific rules for adaptation in column 2 of Section 8.7 in Annex IX rules is possible.

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 7 July 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 did not receive any comments within the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s) and referred the modified draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee unanimously agreed on the draft decision in its MSC-82 written procedure. ECHA adopted the decision under Article 51(6) 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 Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[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[6].

(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 all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

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

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[7].

2. General recommendations for conducting and reporting new tests

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

[7] https://echa.europa.eu/manuals