~~Confidential~~

Helsinki, 27 May 2024

Addressee
Registrant of as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
23 September 2013

Registered substance subject to this decision ("the Substance")
Substance name: sodium N-chlorobenzenesulphonamide
EC/List number: 204-847-9

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 ***4 December 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 vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: EU B.17./OECD TG 476 or EU B.67./OECD TG 490).

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

2. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C.

3. Identification of degradation products (Annex IX, 9.2.3.; test method: EU C.25./OECD TG 309)

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 of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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)

Reasons related to the information under Annex VIII of REACH

1. *In vitro* gene mutation study in mammalian cells

1 An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII, Section 8.4.3., in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

1.1. Triggering of the information requirement

2 Your dossier contains negative results for both an Ames test and an *in vitro* and *in vivo* cytogenicity studies.

3 Therefore, the information requirement is triggered.

1.2. Information provided

4 You have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following:

(i) an *in vitro* gene mutation study in mammalian cells (according to OECD 476, GLP, 2011) with benzenesulfonamide (Source substance 1);

(ii) an *in vitro* sister chromatid exchange assay in mammalian cells (according to old OECD guideline 479, GLP not specified, 1986) with tosylchloramide sodium (Source substance 2).

1.3. Assessment of the information provided

1.3.1. Weight of evidence adaptation rejected

5 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

6 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

7 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

8 You have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

9 In addition, findings are inconsistent with each other and it is not explained how this is taken into account and how it affects the conclusion.

10 Beside this critical deficiency, ECHA has also assessed the other aspects of your adaptation.

11 Information that can be used to support weight of evidence adaptation for the information requirement of Annex VIII, Section 8.4.3. includes similar information that is produced by

the OECD TGs 476/490. The OECD TGs 476/490 require the study to investigate the following key parameter:

- Detection and quantification of gene mutations (point mutations, frame-shift mutations, small deletions, etc.) including data on the frequency of mutant colonies in cultured mammalian cells (in vitro).

1.3.1.1. Assessment of relevance of the information provided

12 The source of information (i) provides relevant information on detection and quantification of gene mutation in cultured mammalian cells.

13 The source of information (ii) is a sister chromatic exchange assay. The sister chromatid exchange (SCE) assay is a short-term test for the detection of reciprocal exchanges of DNA between two sister chromatids of a duplicating chromosome. SCEs represent the interchange of DNA replication products at apparently homologous loci. While this study detects lesions to DNA in cultured cells, the precise cause of the DNA damage causing the reciprocal exchanges of DNA between two sister chromatids, i.e. gene mutation or structural chromosome aberrations – cannot be established from this study. Due to the uncertainty on the nature of the mechanism of genetic toxicity detected by this test, the relevance of this information is limited.

14 In addition, the reliability of these sources of information is affected by the following deficiencies:

1.3.1.2. Assessment of reliability of the information provided

1.3.1.2.1. Reliability of contribution of the information provided on analogue substances

15 ECHA understands that you use data obtained with analogue substances in a read-across approach as part of your weight of evidence adaptation. For this information to reliably contribute to the weight of evidence approaches, it would have to meet the requirements for grouping of substances and read-across approaches.

16 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

17 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

18 You provide the following reasoning for the prediction of toxicological properties: "*Based on the data from the repeated dose toxicity studies, as well as the comparable molecular structure and similar physicochemical properties, it was concluded that both data from Chloramine B trihydrate as those of Chloramine T and metabolites such as BSA can be used for read-across. Chloramine B trihydrate disintegrates to Benzenesulfonamide during application*".

19 ECHA understands that your read-across hypothesis is based on the (bio)transformation of the Substance to Benzenesulfonamide, thereafter the source substance 1. You predict the properties of your Substance to be quantitatively equal to those of the source substance 1.

20 ECHA understands that your read-across hypothesis for using information from Chloramine T, thereafter the source substance 2, is based on the assumption that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance 2.

21 We have identified the following issues with your predictions:

i. Incomplete characterisation of the source substances

22 Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as group."

23 Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) must be provided to allow assessing whether the attempted predictions are compromised by the composition and/or impurities.

24 In your read-across justification you indicate that you intend to predict the in vitro genotoxicity properties in mammalian cells of the Substance using information from Chloramine T and from metabolites of the Substance such as BSA.

25 You do not further characterise the source substances. No identifiers (EC number, CAS number) as provided. You also do not provide any information on the composition of these source substances.

26 Without this information, no qualitative or quantitative comparative assessment of the compositions of the Substance and of the source substances can be completed. Therefore, it is not possible to assess whether the attempted predictions are compromised by the composition of the source substances.

ii. Missing supporting information on the formation of the source substance 1

27 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

28 As indicated above, ECHA understands that your read-across hypothesis is based on the (bio)transformation of the Substance to the source substance 1. In this context, information characterising the rate and extent of the (bio)transformation of the Substance is necessary to confirm the formation of source substance 1 and to assess the impact of the exposure to the parent compound, i.e. the Substance.

29 You indicate in your CSR in section 5.1.3 that "*Chloramine B trihydrate disintegrates to Benzenesulfonamide during application".* You derive this information from information on the metabolism of the analogue substance Chloramine T: *"the read across substance Chloramine T transforms to p-toluenesulfonamide which has no dangerous effects and is secreted from the body. The same mechanism can be assumed for Chloramine B trihydrate which transforms in the body to benzenesulfonamide*".

30 You have not provided any information to support your assumption that the Substance is biotransformed to the source substance 1, by analogy with the metabolism pathway of the source substance 2.

31 In the absence of this information you have not established that the Substance is biotransformed to the source substance 1 as assumed in your read-across hypothesis.

Therefore, you have not provided sufficient supporting information to scientifically justify your read-across hypothesis.

iii. Missing supporting information for the source substance 2

32 Annex XI, Section 1.5. requires that whenever grouping and read-across is used, adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties.

33 According to the Guidance on IRs and CSA, Section R.6.2.2.1.f., "it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/endpoint being read across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals".

34 In order to support your claim that the Substance and source substance 2 have similar properties for the endpoints under consideration, you refer to similarities in physico-chemical properties and similarities in repeated dose toxicity of the Substance and the source substance 2.

35 However, repeated dose toxicity does not inform on the information requirement that you seek to adapt using grouping and read-across, i.e. in vitro gene mutation in mammalian cells, of the Substance and of the source substance 2. Accordingly, the information provided is not considered relevant to support your read-across hypothesis.

36 In addition, you refer in your read-across justification document to negative results obtained from *in vitro* gene mutation studies in bacteria conducted with the Substance and the source substance 2. This information may constitute relevant supporting information to establish that the Substance and the source substance 2 are likely to have similar genotoxicity properties in mammalian cells. However you have not provided any study record for the *in vitro* gene mutation studies in bacteria conducted with the source substance 2. In the absence of this information, no independent assessment of the reliability of this information on substance 2 and of its adequacy to support the read-across can be completed.

37 For all these reasons, you have not provided supporting information to scientifically justify the read-across hypothesis for prediction of properties.

iv. Methodological issues with the source of information (ii)

38 The evaluation of the reliability of the contribution of each relevant line of information to the weight of evidence approach includes an assessment of source of information against the specifications of the test guideline followed.

39 The source of information (ii) is reported as an *in vitro* sister chromatid exchange assay in mammalian cells. The adequate and reliable coverage of the key specifications foreseen to be investigated in the corresponding test guideline (OECD TG 479) requires that:

a) two separate test conditions are assessed: in absence of metabolic activation and in presence of metabolic activation;
b) the maximum concentration tested induces cytotoxicity compared to the negative control;
c) a positive control is included in the study.

40 In the source of information (ii):

a) the test was performed only in absence of metabolic activation;
b) the maximum tested concentration did not induce cytotoxicity compared to the

negative control;

c) no positive control was included in the study. Although, the results are positive, the validity of the study should be verified with a positive control.

41 The methodological deficienicies identified above negatively impact the reliability of the contribution of the information from this study to the weight of evidence adaptation.

1.3.2. Conclusion on the weight of evidence

42 While the studies provide relevant information (or, of limited relevance, as regards the source of information (ii)) on the detection and quantification of gene mutation in cultured mammalian cells, they have significant reliability issues affecting the reliability of their contribution to the conclusion on the the detection and quantification of gene mutation in cultured mammalian cells as investigated by the required study.

43 Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for *in vitro* gene mutation study in mammalian cells.

44 Based on the above, your weight of evidence adaptation under Annex XI, Section 1.2. is rejected and the information requirement is not fulfilled.

1.4. Study design

45 To fulfil the information requirement for the Substance, either the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

Reasons related to the information under Annex IX of REACH

2. Simulation testing on ultimate degradation in surface water

46 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

2.1. Information provided

47 You have adapted this information requirement by providing the following justification: "*According to the TNsG on data requirements a water simulation test is always required where a biocide is directly emitted to water. Chloramine B trihydrate is not inteded for direct use in surface waters, but it is used in industrial, professional and private facilities. Hence a direct contamination of surface waters is unlikely*".

48 In addition, you claim that the Substance is fast dechlorinating to its metabolite BSA, which is readily biodegradable. ECHA understands that, with this claim, you would like to adapt this information requirement based on Annex IX, Section 9.2., Column 2.

2.2. Assessment of information provided

2.2.1. Your justification to omit the study has no legal basis

49 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 9.2.1.2., Column 2.

50 It is noted that Column 2 of Annex IX, Section 9.2, does not allow omitting the need to submit information on simulation on ultimate degradation in surface water under Column 1.

51 In the justification provided in your dossier you refer to the Technical Notes for Guidance (TNsG) of the Biocidal Product Directive indicating that simulation study in water is not needed in case there is no direct contamination water.

52 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex IX, Section 9.2.1.2., Column 2

53 Therefore, you have not demonstrated that this information can be omitted.

2.2.2. Annex IX, Section 9.2., Column 2 is not a valid basis to omit the study

54 Under Annex IX, Section 9.2.1.2., Column 2, the study may be omitted if the substance is readily biodegradable.

55 In your dossier, you have provided the following justification: "*Chloramine B trihydrate is not biodegradable (see [redacted]). However, during its application and its discharge in wastewaters, complete degradation occurs by fast dechlorination (see [redacted]. The dechlorinated form of Chloramine B, benzenesulphonamide (BSA), is readily biodegradable (see [redacted]). Hence at the proposed use concentrations, chloramine B trihydrate degrades completely and does not enter the environment. As the substance – via fast dechlorination to its metabolite BSA – is readily biodegradable, further investigations with respect to its fate in aquatic ecosystems are obsolete*".

56 You claim that the Substance has a fast dechlorination and the dechlorinated form (i.e. BSA) is readily biodegradable. While you refer to documents (i.e. [redacted] and [redacted]) to prove fast dechlorination of the Substance and its complete degradation, you have not provided any of these documents. Therefore, you did not provide

any evidence to demonstrate your claims. To the contrary, based on the information provided, the Substance is regarded as not readily biodegradable.

57 Therefore, your adaption is rejected.

58 Based on the above, the information requirement is not fulfilled.

2.3. Study design

59 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

60 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

61 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

62 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Paragraph 52 of the OECD TG 309 provides that the "total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

63 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website (NER - summary 2019 (europa.eu) [1]).

[1] https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342

64 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

3. Identification of degradation products

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

3.1. Information provided

66 You have provided no information on the identity of transformation/degradation products for the Substance. Therefore, the information requirement is not fulfilled.

3.2. Study design

67 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

68 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

69 You must obtain this information from the degradation study requested in request 2.

70 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 2 must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).

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 (2023).
***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 27 March 2023.

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.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Addressee 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]

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 (https://echa.europa.eu/practical-guides).
(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

(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 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.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

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).