~~Confidential~~

Helsinki, 17 May 2023

Addressee(s)
Registrant(s) of Br-epoxy_N=0_3072_84_2 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
29/03/2017

Registered substance subject to this decision ("the Substance")
Substance name: 2,2'-[(1-methylethylidene)bis[(2,6-dibromo-4,1-phenylene)oxymethylene]]bisoxirane
EC number/List number: 221-346-0

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 ***24 November 2025***.

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

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

1. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

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

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. B/C/D/F/OECD TG 301B/C/D/F or EU C.29./OECD TG 310)

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

4. *In vitro* micronucleus study (Annex VIII, Section 8.4.2., test method: OECD TG 487). The aneugenic potential of the Substance must be assessed with an additional control group for aneugenicity on top of the control group for clastogenicity, if the Substance induces an increase in the frequency of micronuclei

5. Only if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. is obtained, *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)

6. Short-term repeated dose toxicity (28 days) (Annex VIII, Section 8.6.1.) by oral route, in rats, to be combined with the screening for reproductive/developmental toxicity requested below

7. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.64/OECD TG 422) by oral route, in rats

8. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: EU C.47./OECD TG 210)

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

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The 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 common to several requests

0.1. Test material not representative of the Substance

1 To comply with the information requirements, the test material in a study must be representative for the Substance; Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.

0.1.1. Information provided

2 In your registration dossier you have provided:

(i) an *in vitro* mammalian chromosome aberration test (2012);

(ii) an *in vitro* mammalian cell gene mutation test (2014);

(iii) a repeated dose (28 Days) toxicity study (2012);

(iv) a growth inhibition study aquatic algae (2012).

3 The studies (i), (iii) and (iv) have been conducted with "*Brominated epoxy having epoxy equivalent of 400gr/eq*", without further information on the identity and composition of the test material.

4 The study (ii) has been conducted with "*Brominated Epoxy*", without further information on the identity and composition of the test material.

0.1.2. Assessment of the information provided

5 In the absence of composition information on the test material, the identity of the test material and its impurities cannot be assessed.

6 You have not demonstrated that the test material is representative for the Substance.

0.2. Read-across adaptations rejected

7 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2);
- Ready biodegradability (Annex VII, Section 9.2.1.1.).

8 You predict the properties of the Substance from information obtained from the source substance "*Brominated epoxy having epoxy equivalent of 400gr/eq.*", EC 500-107-7, and you provide the following reasoning for the prediction of this information requirement: "*Read across was done from "Brominated Epoxy having Epoxy Equivalent of 400 gr/eq" (EC No. 500-107-7/CASRN 40039-93-8 [….] as the target substance F-2200 is a mono-constituent substance (ca. [redacted] % (w/w)), identical to the major constituent of the source substance and the basic structures of the target and source substances are the same. Other experimental data obtained with the source and target substances indicate that both substances have low toxicity. Therefore, their ecotoxicity profile is likely to be favorable.*"

9 ECHA understands that you predict the properties of the Substance (you also refer to it as "F-2200" in your registration dossier) using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

0.2.1. Your justification and documentation does not meet the requirements for adaptation under Annex XI, Section 1.5

10 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.

11 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).

12 We have identified the following issue(s) with the prediction(s) of (eco)toxicological properties:

0.2.1.1. Incomplete information on the identity of the test material

13 Under Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

14 In order to predict the properties of the Substance, the test material used in the study on the source substance must be representative for the source substance (Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.). Therefore, the unambiguous characterisation of the composition of the test material used to generate the source data is required to assess whether the test material is representative for the source substance.

15 You have identified the test material as "*Brominated epoxy having epoxy equivalent of 400gr/eq*", without further information, including composition of the test material.

16 In the absence of the information on the identity and composition of the test material, you have not demonstrated that the test material is representative for the source substance. Therefore, the study is not adequate for the purpose of classification and labelling and/or risk assessment.

0.2.1.2. Missing supporting information to compare the properties of the substances

17 Annex XI, Section 1.5 further 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 (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

18 Supporting information must include supporting information/bridging studies to compare properties of the source substance information.

19 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substance causes the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration with the Substance and the source substance.

20 For the source substance, you provide the study used in the prediction in the registration dossier. Apart from that study, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of aquatic toxicity or biodegradation data for the Substance that would confirm that both substances cause the same type of effects or have similar fate properties in the environment.

21 Also, you state that the Substance is "*identical to the major constituent of the source substance*" (ca. [redacted]%). You have not included information addressing the impact of the other non-common compounds or of the difference in concentration of the compound of interest in the source substance and Substance on your read-across prediction.

22 In the absence of such information, you have not established that the Substance and the source substance are likely to have similar properties, and you have not established that a reliable prediction of the properties under consideration of the Substance can be derived on the basis of your read-across hypothesis. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

Reasons related to the information under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

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

24 In the provided OECD TG 105 (2012) study, the saturation concentration of the Substance in water was determined to be 26.4 µg/L.

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

1.1. Information provided

26 You have adapted the information on on aquatic invertebrates by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on the following experimental data:

(i) an OECD TG 211 study (2013) with the source substance "*Brominated epoxy having epoxy equivalent of 400gr/eq.*", EC number 500-107-7.

27 You provide the following reasoning for the prediction of this information requirement: "*Read across was done from "Brominated Epoxy having Epoxy Equivalent of 400 gr/eq" (EC No. 500-107-7/CASRN 40039-93-8 [….] as the target substance F-2200 is a mono-constituent substance (ca. [redacted] % (w/w)), identical to the major constituent of the source substance and the basic structures of the target and source substances are the same. Other experimental data obtained with the source and target substances indicate that both substances have low toxicity. Therefore, their ecotoxicity profile is likely to be favorable.*"

28 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

1.2. Assessment of the information provided

29 We have assessed this information and identified the following issue(s):

1.2.1. Read-across adaptation rejected

30 As explained in Section 0.2., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

31 Therefore, the information requirement is not fulfilled.

1.3. Study design and test specifications

32 The Substance is difficult to test due to the low water solubility (26.4 µg/L). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore,

you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

2. Growth inhibition study aquatic plants

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

2.1. Information provided

34 You have provided a growth inhibition study on aquatic algae test (2012) conducted with "*Brominated epoxy having epoxy equivalent of 400gr/eq*".

2.2. Assessment of the information provided

35 As explained in Section 0.1, you have not demonstrated that the test material is representative for the Substance.

36 Therefore, the information requirement is not fulfilled.

2.3. Study design and test specifications

37 OECD TG 201 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under request 1.

3. Ready biodegradability

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

3.1. Information provided

39 You have adapted the ready biodegradability information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on the following experimental data:

(i) an OECD TG 301 B study (2012) with the source substance "*Brominated epoxy having epoxy equivalent of 400gr/eq.*", EC number 500-107-7.

40 You provide the following reasoning for the prediction of this information requirement: "*The study was conducted on the analog named Brominated Epoxy*. As the target substance F-2200 is the main component (Ca [redacted]%) of Brominated Epoxy" (the test item). *Brominated Epoxy having Epoxy Equivalent of 400 gr/eq (EC No. 500-107-7/CASRN 40039-93-8/reaction mass of 2,2'-(((propane-2,2-diylbis(2,6-dibromo-*

4,1phenylene))bis(oxy))bis(methylene))bis(oxirane) and 1,3-bis(2,6-dibromo-4-(2-(3,5-dibromo-4-(oxiran-2-ylmethoxy)phenyl)propan-2-yl)phenoxy)propan-2-ol)."

41 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

3.2. Assessment of the information provided

42 We have assessed this information and identified the following issue(s):

3.2.1. Read-across adaptation rejected

43 As explained in Section 0.2., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

44 Therefore, the information requirement is not fulfilled.

Reasons related to the information under Annex VIII of REACH

4. *In vitro* micronucleus study

45 An *in vitro* mammalian chromosomal aberration study or an *in vitro* mammalian micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

4.1. Information provided

46 You have provided an *in vitro* mammalian chromosome aberration test (2012) conducted with "*Brominated epoxy having epoxy equivalent of 400gr/eq*".

4.2. Assessment of the information provided

47 As explained in Section 0.1, you have not demonstrated that the test material is representative for the Substance.

48 Therefore, the information requirement is not fulfilled.

4.3. Specification of the study design

49 According to the Guidance on IR & CSA, Section R.7.7.6.3., either the *in vitro* mammalian chromosomal aberration ("CA") test (test method OECD TG 473) or the *in vitro* mammalian cell micronucleus ("MN") test (test method OECD TG 487) can be used to investigate chromosomal aberrations *in vitro*. However, while the MN test detects both structural chromosomal aberrations (clastogenicity) and numerical chromosomal aberrations (aneuploidy), the CA test detects only clastogenicity, as OECD TG 473 is not designed to measure aneuploidy (see OECD TG 473, paragraph 2).Therefore, you must perform the MN test (test method OECD TG 487), as it enables a more comprehensive investigation of the chromosome damaging potential *in vitro*.Moreover, in order to demonstrate the ability of the study to identify clastogens and aneugens, you must include two concurrent positive controls, one known clastogen and one known aneugen [1] (OECD TG 487, paragraphs 33 to 35).

4.3.1. Assessment of aneugenicity potential

50 If the result of the MN test is positive, i.e. your Substance induces an increase in the frequency of micronuclei, you must assess the aneugenic potential of the Substance.

51 In line with the OECD TG 487 (paragraph 4), you should use one of the centromere labelling or hybridisation procedures to determine whether the increase in the number of micronuclei is the result of clastogenic events (i.e. micronuclei contain chromosome fragment(s)) and/or aneugenic events (i.e. micronuclei contain whole chromosome(s)).

[1] According to the TG 487 (2016) "At the present time, no aneugens are known that require metabolic activation for their genotoxic activity" (paragraph 34).

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

52 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.

5.1. Triggering of the information requirement

53 Your dossier contains (I) a negative result for *in vitro* gene mutation study in bacteria, and (II) no data or inadequate data for the *in vitro* cytogenicity study in mammalian cells.

54 The *in vitro* cytogenicity study in mammalian cells provided in the dossier is rejected for the reasons provided in request 4.

55 The result of the request 4 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3. is triggered.

56 Consequently, you are required to provide information for this information requirement, if the *in vitro* micronucleus study provides a negative result.

5.2. Information provided

57 You have provided an *in vitro* mammalian cell gene mutation test (2014) conducted with the "*Brominated Epoxy*".

5.3. Assessment of the information provided

58 As explained in Section 0.1, you have not demonstrated that the test material is representative for the Substance.

59 Therefore, the information requirement is not fulfilled.

5.4. Specification of the study design

60 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.

6. Short-term repeated dose toxicity (28 days)

61 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1.

6.1. Information provided

62 You have provided a repeated dose (28 Days) toxicity study (2012) conducted with "*Brominated epoxy having epoxy equivalent of 400gr/eq*".

6.2. Assessment of the information provided

63 As explained in Section 0.1, you have not demonstrated that the test material is representative for the Substance.

64 Therefore, the information requirement is not fulfilled.

6.3. Specification of the study design

65 When there is no information available neither for the 28-day repeated dose toxicity (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

66 The study design is further addressed in request 7.

7. Screening study for reproductive/developmental toxicity

67 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1.

7.1. No information provided

68 You have not submitted any information for this requirement of a screening study for reproductive/developmental toxicity study.

69 Therefore, the information requirement is not fulfilled.

7.2. Specification of the study design

70 When there is no information available neither for the 28-day repeated dose toxicity study (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

71 The information requirement for the 28-day repeated dose toxicity study is not fulfilled for the reasons explained under request 6.

72 Therefore, a study according to the test method EU B.64/OECD TG 422 must be performed in rats.

73 As the Substance is a solid, the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1, Column 1).

74 Therefore, the study must be conducted in rats with oral administration of the Substance

8. Long-term toxicity testing on fish

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

8.1. Triggering of the information requirement

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

8.2. No information provided

77 You have not provided any information on long-term toxicity on fish for the Substance. Therefore, the information requirement is not fulfilled.

8.3. Study design and test specifications

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

79 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under request 1.

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 01 February 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.

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

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

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

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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

- 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

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

- 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 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).