~~Confidential~~

Helsinki,25 May 2023

Addressees
Registrant(s) of JS_2439-35-2 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
20/02/2014

Registered substance subject to this decision ("the Substance")
Substance name: 2-(dimethylamino)ethyl acrylate
EC number: 219-460-0

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 the deadline of ***2 March 2026***.

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

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

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

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

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

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

3. In vivo mammalian alkaline comet assay (test method: OECD TG 489) combined with in vivo mammalian erythrocyte micronucleus test (test method: OECD TG 474) (triggered by Annex IX, Section 8.4., column 2), in rats, or if justified, in mice, oral route. For the comet assay the following tissues shall be analysed: liver, glandular stomach and duodenum.

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

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.

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

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report**, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

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

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

Appendix 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

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

1 Further mutagenicity studies must be considered under Annex VII, Section 8.4., column 2, in case of a positive result.

1.1. Triggering of the information requirement

2 Your dossier contains positive results from an *in vitro* gene mutation study in bacteria (Ames test; 1997).

1.2. The concerns identified and the consideration of the in vitro information

1.2.1. *Gene mutation concern*

1.2.1.1. The information provided

3 Regarding gene mutation, you have provided the following *in vitro* studies:

(i) Ames test with the Substance (2006a), negative, key study;
(ii) Ames test with the Substance (1982, also revieved in a publication from 1987), negative, key study;
(iii) Ames test with the Substance (1997), positive, key study;
(iv) Ames test with the Substance (2006b), negative, supporting study;
(v) *in vitro* gene mutation study in mammalian cells (2006), negative, key study.

4 You state that "*In three Ames tests the test substance was not mutagenic in any bacterial strain tested (2006 a+b, 1987). In one Ames test the test substance did not induce gene mutations in 3 strains of S. typhimurium and in E. coli but did induce gene mutations in S. typhimurium strain TA98 with metabolic activation in one out of two replicates (1997). In mammalian CHO cells, the test substance was not mutagenic in vitro ([redacted] 2006).*"

1.2.1.2. Assessment of the information provided

5 First, regarding the results of the *in vitro* gene mutation studies in bacteria, the study (iii) (1997), performed using the preincubation method, was positive. The assay conducted in *S. typhimurium* TA 98 with S9 metabolic activation was positive at 5000 µg/plate in the main experiment. This positive result was confirmed in a repeat experiment with metabolic activation and using a narrower dose spacing, which showed a dose-dependent increase in *S. typhimurium* TA 98 mutant frequency, with a doubling of the number of mutant colonies at 3400 µg/plate and above in the presence of metabolic activation.

6 Using the same strain *S. typhimurium* TA 98 and the same preincubation method, studies (i) (2006a) and (ii) (1982) were negative but the Substance was only tested up to 2750 and 3333 µg/plate, respectively, i.e. doses lower than those resulting positive in study (i). Therefore, ECHA considers that the concern for gene mutation raised by *in vitro* data cannot be ruled out, because the doses showing a mutagenic effect in the study (iii) (1997) were not tested in the study (i) (2006a). Study (iv) (2006b) was also negative but performed using using the standard plate incorporation method and therefore is not suitable to be compared with study (iii) (1997).

7 Second, the *in vitro* gene mutation study in mammalian cells (v) (2006) was negative. Although the *in vitro* gene mutation test in bacteria and the *in vitro* gene mutation test in mammalian cells both investigate gene mutations, they are considered complementary as they cover different gene mutation mechanisms. Therefore, the negative results obtained in mammalian cells with the Substance (study (v)) cannot be used to superseed the positive results obtained in bacteria in study (i).

8 In the comments to the draft decision, you disagree with the arguments laid down by ECHA in respect to rather artefactual results in one of four bacterial reverse mutation assay in the strain S.typhimurium TA (+S9). According to you, in the study (iii) (Ames Test published by MHW Japan, 1997) the data gave an inconsistent picture across the three experiments for the following reasons:

9 In the first experiment no genotoxicity was described in S.typhimurium TA 98, in the second experiment only at 5000 µg/plate an increase of revertants is observed, whereas in the third experiment a positive response was already seen at 2600 µg/plate.

10 No cytotoxicity was stated in the main experiment – whereas in the pre-study cytotoxicity was stated at 5000 µg/plate. Overall, those data gave no conclusive picture. In addition, the lack of mutagenicity would be supported by the *in vitro* gene mutation study in mammalian cells (iv) and the consistent findings in respect to cytotoxicity and non-genotoxicity in the three further fully reliable bacterial reverse mutation assays, studies (i), (ii) and (iv). In all of them S.typhimurium TA98 was tested and no genotoxicity was observed, whereas cytotoxicity was observed in S.typhimurium TA98 at concentrations > 2750 µg/plate and > 3333 µg/plate, respectively. You provide tables from the study report to support your conclusion.

11 On this basis you commented that there would be no scientific and regulatory evidence to request a follow-up animals study (Comet Assay) and you disagree with this requirement.

12 However, your argumentation based on juxtaposition of results omits the fact, as highlighted already in the above, that the doses tested in the presence of metabolic activation with pre-incubation in study (iii) (1997) were not tested in the studies (i) (2006a), (ii) (1982) and (iv) (2006b). These differences in the design of the studies (i), (ii), (iii) and (iv) must be taken into account in the analysis of the data set. Since the test conditions leading to positive results in study (iii) are not replicated in studies (i), (ii) or (iv) the outcome of these studies is not considered to be inconsistent and the studies (i), (ii) or (iv) and cannot be used to dismiss the positive results obtained in study (iii). Furthermore the complementary information from a study in mammalian cells cannot supersede the positive results in the study in bacteria. ECHA considers that the concern for gene mutation raised by the *in vitro* data cannot be ruled out because of the differences in the test conditions across the studies.

1.2.2. *Chromosomal aberration concern*

1.2.2.1. The information provided

13 The dossier contains the following information:

(i) *In vitro* Mammalian Chromosome Aberration Test with the Substance (1991), positive, key study;
(ii) *In vitro* Mammalian Chromosome Aberration Test with the Substance (1997), positive, key study.

1.2.2.2. Assessment of the information provided

14 Both *in vitro* cytogenicity studies (i,ii) show positive results.

1.2.3. *Conclusion based in the in vitro information*

15 Based on above, ECHA considers that an appropriate *in vivo* follow up genetic toxicity study is necessary to address the gene mutation and chromosomal aberration concerns identified *in vitro*.

1.3. Consideration on the available in vivo information, and the study design

16 You have provided an *in vivo* genetic toxicity study (1993).

17 The reasons for why the *in vivo* information provided is not appropriate to follow up the gene mutation concern and for why it does not adequately follow up the concern on chromosomal aberrations, as well as the specifications of the study design, are addressed under request 3.

Reasons related to the information under Annex VIII of REACH

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

18 Appropriate *in vivo* mutagenicity studies must be considered under Annex VIII, Section 8.4., column 2, in case of a positive result in any of the *in vitro* genotoxicity studies under Annex VII or VIII.

2.1. Triggering of the information requirement

19 As presented in sections 1.2.1.2 and 1.2.2.2 above, your dossier contains positive results for the *in vitro* gene mutation study in bacteria (1997) and *in vitro* cytogenicity tests (1991 and 1997) which raise the concerns for gene mutations and chromosomal aberrations.

20 Therefore, the information requirement is triggered.

21 ECHA considers that an appropriate *in vivo* follow up genetic toxicity study is necessary to address the concerns identified *in vitro*.

2.2. Consideration on the available in vivo information, and the study design

22 You have provided an *in vivo* genetic toxicity study (1993). The reasons for why the *in vivo* information provided is not appropriate to follow up the gene mutation concern and for why it does not adequately follow up the concern on chromosomal aberrations, as well as the specifications of the study design are addressed under request 3.

Reasons related to the information under Annex IX of REACH

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

23 Under Annex IX, Section 8.4., column 2, the information requirement for an appropriate *in vivo* somatic cell genotoxicity study is triggered if 1) there is a positive result in any of the *in vitro* genotoxicity studies in Annex VII or VIII and 2) there are no appropriate results already available from an *in vivo* somatic cell genotoxicity study.

3.1. Triggering of the information requirement

24 As presented in sections 1.2.1.2 and 1.2.2.2 above, in relation to the first condition, your dossier contains positive results for the *in vitro* gene mutation study in bacteria (1997) and *in vitro* cytogenicity tests (1991 and 1997) which raise the concerns for gene mutations and chromosomal aberrations.

25 In relation to the second condition, your dossier contains an *in vivo* Mammalian Erythrocyte Micronucleus Test with the Substance (1993) (study i).

26 We have assessed this information with a view to the second condition and identified the following issue(s):

3.1.1. *In vivo cytogenicity study not adequate to follow up gene mutation concern*

27 The Guidance on IRs and CSA, Section R.7.7.6.3. clarifies that in order to justify that an *in vivo* somatic cell genotoxicity study does not need to be performed in accordance with Annex IX, Section 8.4., column 2, the results of the available *in vivo* study must address the specific concern raised by the *in vitro* positive result.

28 You have provided an *in vivo* Mammalian Erythrocyte Micronucleus Test (i). However, this study is not addressing the gene mutation concern raised by the *in vitro* data.

3.1.2. *In vivo cytogenicity study is not adequate to investigate cytogenicity concern*

29 To be considered adequate, the study has to meet the requirements of the OECD TG 474. Therefore, the following specifications must be met:

a) the study includes a minimum of three dose level groups of treated animals

30 In study (i) described as an *in vivo* mammalian erythrocyte micronucleus study:

a) the study included only one group of treated animals (i.e. less than three groups) at the dose of 75 mg/kg bw/d which is not the limit dose according to the OECD TG 474.

31 The information provided does not cover the specifications required by the OECD TG 474.

3.1.3. *Conclusion*

32 Based on above, the conditions set out in Annex IX, Section 8.4., column 2 are met and the information requirement for an appropriate *in vivo* somatic cell genotoxicity study is triggered.

3.2. Information provided and its assessment

33 You have provided an *in vivo* Mammalian Erythrocyte Micronucleus Test with the Substance (1993) (study i).

34 The information provided does not fulfil the information requirement for the reasons described under the sections 3.1.1. and 3.1.2. above.

35 Therefore, the information requirement is not fulfilled.

36 In the comments to the draft decision, you agree with ECHA that study (i) does not meet the requirements of the current version of the OECD TG 474. Nevertheless, according to you, within this study the maximum tolerated dose was tested and it was also confirmed by the PCE/NCE ratio that the substance reached the bone marrow. You stated that no indication of an induction of micronuclei was observed and the result was clearly negative.

37 The study was performed as limit test applying 75 mg/kg bw and induced toxicity including mortality. You report that the test dose of 75 mg/kg bw was based on the results from a pre-study, in which mortality was observed at 100 mg/kg bw. You have also mentioned, that the Substance was tested twice in an chromosomal aberration study according to the OECD TG 473 and was positive at cytotoxic concentrations.

38 In your opinion this study is still fully reliable and no repetition of this *in vivo* test is needed.

39 However, the OECD TG 474 in the versions since 1997, and equivalently test method B.12 in the EU Test methods Regulation No 440/2008, set out conditions with regard to the number of test doses to be used in the study. Specifically, it states that: "*a full study using three dose levels may not be considered necessary*" (and "a single dose level, at the limit dose, may be sufficient"), i.e. if a test at one dose level of at least 2000mg/kg body weight using a single treatment […]produces no observable toxic effects.

40 Considering that mortality was induced by the dose 100 mg/kg bw in the pre-study, it is demonstrated that the substance induced toxicity. This observation of toxicity at a dose level lower than the identified limit dose of 2000 mg/kg/d dismisses the possibility for a limit test and requires the use of three dose levels in the micronucleus test.

41 Therefore the study (i) is not adequate to fulfil the information requirement and the data gap remains.

3.3. Test selection

42 The positive *in vitro* results available in the dossier indicate a concern for both chromosomal aberration and gene mutation.

43 The *in vivo* mammalian erythrocyte micronucleus test ("MN test", OECD TG 474) and the *in vivo* mammalian alkaline comet assay ("comet assay", OECD TG 489) can be combined in a single study (see OECD TG 474 paragraph 37c; OECD TG 489 paragraph 33; Guidance on IRs & CSA, Section R.7.7.6.3). While the MN test can detect both structural chromosomal aberrations (clastogenicity) and numerical chromosomal aberrations (aneuploidy), the comet assay can detect primary DNA damage that may lead to gene mutations and/or structural chromosomal aberrations. A combined study will thus address both the identified concerns for chromosomal aberration as well as gene mutation.

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

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

3.4. Specification of the study design

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

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

3.4.1. *Germ cells*

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

49 You may consider collecting the male gonadal cells from the seminiferous tubules in addition to the other aforementioned tissues in the comet assay, as it would optimise the use of animals. You can prepare the slides for male gonadal cells and store them for up to 2 months, at room temperature, in dry conditions and protected from light. Following the generation and analysis of data on somatic cells in the comet assay, you should consider analysing the slides prepared with gonadal cells.

50 This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

[1] Bowen DE et al. (2011) Evaluation of a multi-endpoint assay in rats, combining the bone-marrow micronucleus test, the comet assay and the flow-cytometric peripheral blood micronucleus test. *Muta Res.*;722:7–19.

4. Long-term toxicity testing on fish

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

4.1. Information provided

52 You have adapted this information requirement with reference to the wording of Column 2 of Annex IX, Section 9.1. To support the adaptation of the standard information requirement under Column 1, you have provided following information:

(i) A justification mentioning that "*the acute toxicity studies on freshwater organisms available for all three trophic levels showed that algae is the most sensitive organisms with an ErC50 value of 0.88 mg/L. Fish and daphnids were far less sensitive as demonstrated by LC50 and EC50 values of 8.49 and 9.92 mg/L or higher*." You also added that "*this higher sensitivity of algae is also reflected in the results of long-term testing for algae i.e. NOEC of 0.039 mg/L and 3 mg/L for Daphni magna (OECD 211). On this basis and for reasons of animal welfare, a long-term toxicity test in fish is not provided*";
(ii) an OECD 204 study (2003) with the Substance.

53 In your comments you clarify that you intend to fulfil the information requirement by using a weight of evidence approach based on available aquatic toxicity data on the Substance

and on it hydrolysis products i.e. acrylic acid and 2-dimethylaminoethanol. Your justification is that in line with the nature of the Substance that hydrolyses at ph 7 (and higher) to acrylic acid and 2-dimethylaminoethanol. Whereas 2-dimethylaminoethanol has a low toxicity to aquatic organisms, acrylic acid is highly toxic to algae with a lower toxic potential to fish and aquatic invertebrate. You indicate your intention to include aquatic toxicity data on both hydrolysis products including a chronic fish test according to the OECD TG 210 with acrylic acid.

4.2. Assessment of the information provided

4.2.1. *Your justification to omit the study has no legal basis*

54 However, it is noted that Column 2 of Annex IX, Section 9.1, does not allow omitting the need to submit information on long-term toxicity to fish under Column 1 (Decision of the Board of Appeal in case A-011-2018). A registrant may only adapt this standard information requirement based on the general rules set out in Annex XI.

55 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

56 Therefore, you have not demonstrated that this information can be omitted. Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

57 In your comment to the draft decision you reiterate your justification related to species sensitivity indicating that the algae is the most sensitive species, and therefore the effect value obtained from the algae study was used to derive the PNEC for the risk assessment. However, as already explained above the species sensitivity does not refer to any legal ground for adaptation under Annex XI to REACH. Furthermore, this column 1 info requirement cannot be adapted based on the the provisions ofAnnex IX Column 2 referring to the Chemical Safety Assessment.

4.2.2. *The OECD TG 204 is not a valid test guideline to meet this information requirement*

58 To fulfil the information requirement, a study must be a long-term fish test. Guidance on IRs and CSA, Section R.7.8.4.1. specifies that only studies in which sensitive life-stages (juveniles, eggs and larvae) are exposed can be regarded as long-term fish tests.

59 Your registration dossier provides an OECD TG 204 study in which only adults were exposed to the test material.

60 This study does not provide information on the toxicity of the test material to relevant sensitive life-stages (i.e. juveniles, eggs and larvae). OECD TG 204 only provides information on prolonged acute toxicity and, based on the above, it does not qualify as a long-term fish test.

4.2.3. *WoE adaptation in accordance with Annex XI, section 1.2.*

61 In your comment to the draft decision you indicate your intention to use the WoE adaptation to fulfill the the information requiremen. Your justification is that in line with the nature of the Substance that hydrolyses at ph 7 (and higher) to acrylic acid and 2-dimethylaminoethanol. Whereas 2-dimethylaminoethanol has a low toxicity to aquatic organisms, acrylic acid is highly toxic to algae with a lower toxic potential to fish and aquatic invertebrate. You indicate your intention to include aquatic toxicity data on both hydrolysis products including a chronic fish test according to OECD 210 with acrylic acid.

62 ECHA acknowledges your intention to adapt this information requirement according to Annex XI, Section 1.2 of REACH (Weight of Evidence) and to include new studies in the registration dossier. However, as indicated in your comments, your justification relies essentially on data which is not yet included in the dossier, therefore no conclusion on the compliance of your adaptation can currently be made. A Weight of evidence adaptation will need to meet the requirements set out in Annex XI, Section 1.2 of REACH.

63 On this basis, the information requirement is not fulfilled.

4.3. Study design and test specifications

64 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.).

65 The Substance is difficult to test due to its fast Hydrolysis half-life at 25°C within a pH range of 7-9 < 24 hour. OECD TG 210 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 210. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

References

The following documents may have been cited in the decision.

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

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

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

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 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.

The compliance check was initiated on 04 October 2021.

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

ECHA took into account your comments and did not amend the request(s).

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

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

Appendix 3: Addressees of this decision and their corresponding information requirements

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

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

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

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

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

1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

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

1.2. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)
The Test Material used to generate the new data must be selected taking into account the following:
- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

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[3].

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