~~Confidential~~

Helsinki, 12 October 2023

Addressees
Registrant(s) of 271-234-0 Joint Subm. EM Lead as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
11/05/2018

Registered substance subject to this decision ("the Substance")
Substance name: Alcohols, C9-11-iso-, C10-rich
EC/List number: 271-234-0

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 information under request 1. and 2. below by ***19 January 2026*** and all other information listed below by ***19 July 2027***.

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

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

1. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days) requested below (Annex VIII, Section 8.6.1.)

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

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

3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

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

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

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

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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

information requirements.

How to comply with your information requirements

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

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

Appeal

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

Failure to comply

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

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

Appendix 1: Reasons for the 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

0. Reasons common to several requests

0.1. Assessment of the read-across approach

1 You have adapted the following standard information requirements by using grouping and read-across approach as part of a weight of evidence adaptation under Annex XI, Section 1.2 for the first two and under Annex XI, Section 1.5 for the last two information requirements:

- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.)

2 ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following sections.

3 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.

4 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).

0.1.1. Predictions for toxicological properties

5 You provide a read-across justification document in IUCLID Section 13.

6 You predict the properties of the Substance from information obtained from the following source substance(s):

1-dodecanol,	EC 203-982-0, CAS 112-53-8
Tridecanol (mixture of isomers)	EC 607-896-8
Alcohols, C7-9-branched, C8-rich,	EC 295-250-2, CAS 91994-92-2
Branched alcohols, C7-9, C8 rich,	EC 271-231-4, CAS 68526-83-0

7 You provide the following reasoning for the prediction of toxicological properties: ”similar chemical structure, manufacturing process, physicochemical properties and the same type of biological effects or trends among each of these substances”.

8 ECHA understands that your read-across hypothesis assumes 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.

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

0.1.1.1. Missing supporting information to compare properties of the substances

10 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.).

11 Supporting information must include bridging studies to compare properties of the Substance and source substances.

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

13 For the source substances, you provide the studies used in the prediction in the registration dossier. You also provide a supporting study (OECD TG 422, 1992) with a source substance and a dermal repeated dose toxicity study (non-guideline, 1961) with the Substance. Apart from those studies, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that it causes the same type of effects as the source substances, for information requirements (endpoints) that you adapt via grouping and read-across. This is relevant in particular for toxicity to reproduction and development.

14 Specific reasons why the OECD TG 422 and the study with the Substance cannot be considered reliable are explained further below under the relevant information requirement in section 1. Thus the data set reported in the technical dossier does not include relevant, reliable and adequate information for the Substance and of the source substances to support your read-across hypothesis.

15 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.2. Comments to the draft decision

16 In your comment to the draft decision you explain that to substantiate your read-across approach your will apply a phased approach to testing. Reproductive and developmental endpoint studies will first be conducted on Exxal 8 (low end of carbon distribution) and sub-chronic toxicity studies (90-day) will be conducted on the intermediary substances (Exxal 9 and 10). The data from phase 1 will be assessed against the read-across hypothesis to inform actions in phase 2 (i.e., read-across hypothesis is valid or additional data generation is warranted).

17 ECHA agrees that the information intended to be generated are useful information to fulfil information requirements for repeated dose toxicity (90-day) for the Substance. However, there is still no information available with the Substance to compare with the source substance/s important reproductive properties such as reproductive performance and pre- or postnatal development. In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties for the endpoints relevant to this decision. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

18 As this strategy relies on a category approach that has not yet been fully described and justified, as well as on data which is yet to be generated for the proposed category members (including bridging studies and supporting information), no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

0.1.3. Conclusion on the read-across approach

19 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approach under Annex XI, Section 1.5. is rejected.

Reasons related to the information under Annex VIII of REACH

1. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days)

20 Annex VIII, Section 8.6.1., Column 2 provides that an experimental study for this information requirement is not needed if a reliable sub-chronic (90 days) or chronic toxicity study is available.

1.1. Information provided

21 You have adapted the following standard information requirements by applying weight of evidence (WoE) adaptation in accordance with Annex XI, section 1.2:

(i) Combined repeated dose toxicity study with the reproductive-developmental toxicity screening test (OECD TG 422) 1992 with the source substance 1-dodecanol (EC 203-982-0)

(ii) 14-day repeated dose toxicity study (similar to OECD TG 407) 1984 with the source substance Tridecanol (mixture of isomers) (EC 607-896-8)

(iii) 15-day repeated dose toxicity study (pre-guideline) 1961 in rabbits with the Substance

22 To support your adaptation according to Annex XI, section 1.2, you have also provided the following statements:

(iv)"A 90 day repeat dose oral toxicity test for Alcohols, C7-9-iso, C8-rich (Isooctanol) CAS number 68526-83-0 and Alcohols, C11-14 iso, C13-rich (Isotridecanol) CAS number 68526-86-3 have been initiated as part of the integrated testing strategy, as agreed upon by ECHA (decision number CCHD-2114342397-45-01/F). A read across justification for use of these test results for members of the Alcohol group will be used to fulfill repeat dose testing data."

23 The statement regarding the studies (iv) cannot be taken into account in the assessment of your weight of evidence adaptation, because the studies they refer to are not actual sources of information in the form of robust study summaries, as required under Article 10(a)(vi) and (vii).

24 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.

25 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.

26 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.

27 Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach. This documentation must include robust study summaries of the studies used as sources of information and a justification explaining why the sources of information together provide a conclusion on the information requirement.

28 You have not included a justification for your weight of evidence adaptation for each of the relevant information requirement, 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.

29 In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation. Your weight of evidence approach has deficiencies that are common to all information requirements under consideration and also deficiencies that are specific for these information requirements individually.

1.2. Assessment of the information provided

30 Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.6.1 at Annex VIII includes, at general level, information on systemic toxicity in intact, non-pregnant and young adult males and females from: 1) in-life observations, 2) blood chemistry, 3) organ and tissue toxicity. Information should address effects on the following physiological systems: circulatory system, digestive/excretory system, endocrine system, immune system, integumentary system, musculoskeletal system, nervous system, renal/urinary system, reproductive system, and respiratory system.

In-life observations

31 In-life observations must include information on survival, body weight development, clinical signs, functional observations, food/water consumption and other potential aspects of in life observations on the relevant physiological systems (circulatory, digestive/ excretory, integumentary, musculoskeletal, nervous, renal/urinary, and respiratory).

32 The piece of information i. provides relevant information on survival, and information on body weight gain and food consumption. It does not provide information on the other in life investigations. The pieces of information ii and iii provide relevant information on surival and no information on the other in life observations.

33 Furthermore, the reliability of these sources of information is significantly affected by the deficiencies described under 1.2.1 and 1.2.2, below.

Blood chemistry

34 Information on blood chemistry must include haematological (full-scale) and clinical chemistry analysis (full-scale), and other potential aspects related to blood chemistry to address relevant physiological systems (circulatory digestive/excretory, endocrine, immune, musculoskeletal, and renal/urinary).

35 The piece of information i. provides limited information on mean white blood cell counts, in free cholesterol and triglycerides. The piece of information ii. provides limited information on catalase and palmitoyl CoA oxidase activity. The pieces of information i, ii and iii provide no further information on blood and clinical chemistry.

36 Furthermore, the reliability of these sources of information is significantly affected by the deficiencies described under 1.2.1 and 1.2.2, below.

Organ and tissue toxicity

37 Organ and tissue toxicity must include information on terminal observations on organ weights, gross pathology and histopathology (full-scale), and other potential aspects related to organ and tissue toxicity to address relevant physiological systems (circulatory, digestive/excretory, endocrine, immune, integumentary, musculoskeletal, nervous, renal/urinary system, reproductive, and respiratory).

38 The piece of information ii. provides information on testis weight, liver weight and the ratios to body weight, as well as histopathology of liver. The pieces of information i, ii and iii provide no further information on organ and tissue toxicity.

39 Furthermore, the reliability of these sources of information is significantly affected by the deficiencies described under 1.2.1 and 1.2.2, below.

1.2.1. Read-across adaptation rejected

40 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

1.2.2. Source study not adequate for the information requirement

41 OECD TG 407/422 include the following:

a. at least three dose levels with concurrent controls are tested, unless the study is conducted at the limit dose;
b. highest dose level should aim to induce toxicity or reach the limit dose.
c. at least 5 animals/sex are included for each dose and control group;
d. an exposure duration of at least 28 days and daily adminstrations;
e. at least weekly body weight and food consumption measurements.

42 The studies (i., ii. and iii.) are described as a repeated dose toxicity study. However, the following specifications are not according to the specifications of the OECD TG 407/422:

a. 2 dose levels (i.e., less than three dose levels) were tested and no concurrent controls were included (study iii);
b. no justification for the dose setting while the highest dose levels tested was 184 mg/kg bw/d, which is below the limit dose of the test guideline, and no adverse effect were observed (ii); the bioavailability via dermal route is unknown and effects were limited to local site of contact (iii);
c. 2 males/females (i.e., less than 5 animals/sex/dose) were included in each dose group (iii);
d. an exposure duration of 14 days (ii); 10 administrations during 15 days duration instead of 28 administrations during 28 days (iii);
e. data on body weights, body weight changes and food consumption are missing (ii, iii).

43 Therefore, the reliability of these studies is significantly affected.

44 Based on the above, the sources of information provide only limited information on in-life observations, blood chemistry, organ and tissue toxicity and that limited information is not reliable.

45 Therefore, it is not possible to conclude, based on any source of information alone or together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 407/422 study.

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

1.3. Comments on the draft decision

47 In your comments to the draft decision you state that an adaption will be included in the updated dossier in accordance with Annex VIII, Section 8.6.1, Column 2.

1.4. Specification of the study design

48 The present decision requests the registrants concerned to generate and submit a reliable sub-chronic toxicity study (90 days) (see request 2). According to Annex VIII, Section 8.6.1., Column 2 and to prevent unnecessary animal testing, a short-term toxicity study (28 days) does not therefore need to be conducted.

49 Because you still must comply with the information requirement in Annex VIII, Section 8.6.1., you are requested to submit a justification for the adaptation provided in Column 2 of that provision.

Reasons related to the information under Annex IX of REACH

2. Sub-chronic toxicity study (90-day)

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

2.1. Information provided

51 You have adapted the following standard information requirements by applying weight of evidence (WoE) adaptation in accordance with Annex XI, section 1.2. You have provided the same information as for request 1, above.

2.2. Assessment of the information provided

52 Relevant information that can be used to support weight of evidence adaptation for the information requirement of Annex IX, Section 8.6.2 includes similar information that is produced by the OECD TG 408 with a design as specified in this decision. OECD TG 408 requires the study to investigate the following key elements: A) in-life observations, B) blood chemistry, C) organ and tissue toxicity.

53 The studies provide only limited information on these key elements and these studies are not reliable for the same reasons already addressed under Section 1, with the difference of the reliability issue of the exposure duration which is 90 days in this case.

54 Therefore, it is not possible to conclude, based on any source of information alone or together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 408 study.

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

2.3. Comments on the draft decision

56 In your comments to the draft decision you agree to perform the requested study.

2.4. Specification of the study design

57 Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance; Guidance on IRs and CSA, Section R.7.5.6.3.2.

58 According to the OECD TG 408, the rat is the preferred species.

59 Therefore, the study must be performed in rats according to the OECD TG 408 with oral administration of the Substance.

3. Pre-natal developmental toxicity study in one species

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

3.1. Information provided

61 You have adapted this information requirement by using Annex XI, Section 1.5 grouping and read-across. To support the adaptation, you have provided following information:

i. Developmental toxicity study (similar to OECD TG 414), 1995, with the source substance Alcohols, C7-9-branched, C8-rich (EC 295-250-2)

ii. Developmental toxicity study (similar to OECD TG 414), 1994, with the source substance Branched alcohols, C7-9, C8 rich (EC 271-231-4)

3.2. Assessment of the information provided

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

3.2.1. Read-across adaptation rejected

63 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

3.3. Comments on the draft decision

64 In your comments to the draft decision you propose to delay the initiation of this study until more data on Exxal 9 and 10 are available and the validity of your read-across approach can be assessed. ECHA has addressed the comment related to read-across in Section 0.1 above. Regarding your proposal to delay the initiation of the OECD TG 414 study in a first species, ECHA notes that for the reasons explained above your dossier is currently not compliant with the information requirement and therefore, you remain responsible for complying with this decision by the set deadline.

3.4. Specification of the study design

65 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species.

66 The study must be performed with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

67 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

Reasons related to the information under Annex X of REACH

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

68 Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is an information requirement under Annex X, Section 8.7.2.

4.1. Information provided

69 You have adapted this information requirement by using Annex XI, Section 1.5 grouping and read-across. To support the adaptation, you have provided following information:

i. "*Members of the Exxal group of alcohols are currently undergoing testing as part of an integrated testing strategy as agreed upon by ECHA (decision number CCH-D-2114342397-45-01/F) and we are awaiting the results to inform further testing.*"

4.2. Assessment of the information provided

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

4.2.1. Read-across adaptation rejected

71 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

72 In any case, the registration dossier mentions only an intent to adapt on the basis of future data; which, in the absence of current data, is insufficient to fulfil the requirements of Annex XI, Section 1.5.

73 Therefore, the information requirement is not fulfilled.

4.3. Comments on the draft decision

74 In your comments to the draft decision you propose to delay the initiation of this study until more data on Exxal 9 and 10 are available and the validity of your read-across approach can be assessed. ECHA has addressed the comment related to read-across in Section 0.1 above. Regarding your proposal to delay the initiation of the OECD TG 414 study in a second species ECHA notes that for the reasons explained above your dossier is currently not compliant with the information requirement and therefore, you remain responsible for complying with this decision by the set deadline.

4.4. Specification of the study design

75 A PNDT study according to the test method OECD TG 414 should be performed in rabbit or rat as preferred second species, depending on the species tested in the first PNDT study (request 3 in this decision).

76 The study must be performed with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

77 Based on the above, the study must be conducted in rabbit or rat with oral administration of the Substance.

References

The following documents may have been cited in the decision.

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

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

Guidance on data-sharing; ECHA (2017).

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

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

The information requirement for an Extended one-generation reproductive toxicity study (EOGRTS; Annexes IX or X, Section 8.7.3.) is not addressed in this decision. This may be addressed in a separate decision once the information from the Sub-chronic toxicity study (90-day) requested in the present decision is provided; due to the fact that the results from the 90-day study is needed for the design of the EOGRTS. Similarly the information requirement for a Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) is not addressed in this decision; as the EOGRTS will cover the same parameters.

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 17 January 2022.

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) but extended the deadline.

In your comments on the draft decision, you requested an extension of the deadlines to provide the requested information. The deadlines of the draft decision was set based on standard practice for carrying out OECD TG tests. They have been exceptionally extended by 12 months from the standard deadlines granted by ECHA to take into account currently longer lead times in contract research organisations and aligning with the category members.

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.

Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

Information on the Test Material needed in the updated dossier

a) You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note,

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

Annex) and Annex XI Section 1.5 of REACH; namely all the constituents must be identified as far as possible as well as their concentration and the variability in these concentrations. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

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).