~~Confidential~~

Helsinki, 3 May 2023

Addressees
Registrant(s) of EC#202-876-1/CAS#100-66-3 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
17/09/2020

Registered substance subject to this decision ("the Substance")
Substance name: Anisole
EC/ List number: 202-876-1

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

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

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

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: EU C.1./OECD TG 203)

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

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

5. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

6. 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.

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. Information for long-term toxicity testing on aquatic invertebrates and fish

1 This section addresses information provided for the following standard information requirements:

- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

2 For both these information requirements you have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "In accordance with column 2 of REACH Annex IX, long-term toxicity testing on invertebrates/fish, required in section 9.1.5/6, does not need to be conducted as the chemical safety assessment does not indicate the need to investigate further the effects on aquatic organisms.".

3 We have assessed this information and identified the following issue:

4 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

5 Your adaptation is therefore rejected.

6 In the comments to the draft decision, you agree to perform the requested studies.

Reasons related to the information under Annex VII of REACH

1. Growth inhibition study aquatic plants

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

1.1. Information provided

8 You have provided an adaptation under Annex XI, Section 1.2. ('Weight of evidence'). In support of your adaptation, you have provide the following sources of information:

(i) OECD TG 201 study, 2010.

(ii) EU method C.3 study, 1990.

1.2. Assessment of the information provided

9 We have assessed this information and identified the following issues:

10 Annex XI, Section 1.2 states that there may be sufficient weight of evidence weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

11 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 that the Substance has or has not the (dangerous) property investigated by the required study.

12 Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence adaptation.

13 You have provided a justification for the weight of evidence adaptation as follows: "Based on the first data, anisole is considered as harmful to algae, whereas the second data showed that it is not harmful to the tested organisms. As a worst case approach, the results of the first study are considered for the classification and labeling of the substance, and for the chemical safety assessment." However, your justification does not include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

14 Irrespective of the above mentioned deficiency on the documentation, which in itself could lead to the rejection of the adaptation, ECHA has assessed the provided sources of information.

15 Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 9.1.2. at Annex VII includes similar information that is produced by the OECD TG 201. OECD TG 201 requires the study to analyse the following key investigations: the concentrations of the test material leading to a 50 % and 0% (or 10%) inhibition of growth at the end of the test are estimated.

16 The sources of information (i. and ii.) provide relevant information on key investigations, but have the following deficiencies affecting their reliability.

17 For the experimental study relevant for this information requirement the following specifications (OECD TG 201) must be met:

a) Validity criteria

1. exponential growth in the control cultures is observed over the entire duration of the test;

2. at least 16-fold increase in biomass is observed in the control cultures by the end of the test;

3. the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;

4. the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Pseudokirchneriella subcapitata* / *Desmodesmus subspicatus*. For other less frequently tested species, the value is ≤ 10%;

b) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

c) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

18 Your registration dossier provides sources of information (i. and ii.) showing the following:

- for the source of information i. algal biomass was not measured at 48 hours time point;

- analytical monitoring was not conducted and there is no justification provided why the analytical monitoring of exposure concentrations is not technically feasible for the source of information ii.;

- the results of algal biomass determined in each flask at least daily during the test period are not reported for both sources of information.

19 Based on the above, missing measurements of the algal biomass will not allow to confirm that validity criteria 1 and 4 are met for the source of information i.

20 Further, there are critical methodological deficiencies significantly affecting reliability of for the source of information ii. Because the exposure concentration throughout the duration of the test were not analytically verified and therefore it is not possible to assess concentration to which test organisms were exposed which may result in underestimation of ecotoxicity. Furthermore, detailed results of algal biomass are not reported for both sources of information which does not allow further assessment of its reliability.

21 Your sources of information provide information on key investigations but, in the absence of reliable information, no conclusion can be drawn on key investigations as required by the information requirement.

22 Therefore, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 201. Hence, your adaptation is rejected and the information requirement is not fulfilled.

23 In your comments to the draft decision you agree that in your dossier there is missing information in the reporting of study (i). You have now received the full study report for study (i) and provided this information in an attachment to the comments to the draft decision. ECHA has assessed this information and concludes that the data gaps for OECD TG 201 study are filled.

24 Furthermore in your initial comments to the draft decision you agree that there are methodological deficiencies significantly affecting the reliability of study (ii), namely that the test is not carried out in a closed system and the exposure concentration has not been checked despite the fact that the substance is volatile. You suggest to score the study as 3 (not reliable).

25 Overall you consider the OECD TG 201 study (study (i)) valid and propose to update the IUCLID dossier with the additional data while modifying the strategy presented in the dossier as follows:

- removal of the weight of evidence approach and addition of the OECD TG 201 study as the Key study with a reliability score of 2 (Klimisch);
- Consider the EU method C3 study (1990) with a reliability score of 3 (Klimisch) as a supporting study (as mentioned in the initial comments to the draft decision);
- Discard the provided QSAR information in the initial response in the comments to this draft decision.

26 The information provided as part of your comments addresses the incompliances identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

1.3. Study design and test specifications

27 The Substance is difficult to test due to its potential volatility (Henry's Law Constant of 27.77 Pa.m^3/mol at 25 ^{o}C). OECD TG 201 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 201. 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.

2. Ready biodegradability

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

2.1. Information provided

29 You have provided:

i. OECD TG 301C key study from 1992 performed by a Japanese Competent Authority

analysing the ready biodedegradability of anisole (CAS 100-66-3)

ii. an adaptation under Annex XI, Section 1.3. ('(Q)SAR'). In support of your adaptation, you provide the following information: a ready biodegradability prediction derived from BIOWIN 1-7 models using methoxybenzene (EC No 202-876-1) as an input structure.

2.2. Assessment of information provided

30 We have assessed this information and identified the following issues:

2.2.1. The provided key study does not meet the information requirement

31 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following requirements must be met:

32 Validity criteria

- The difference of extremes of replicate values of the removal of the test material at the plateau, at the end of the test or, if appropriate, at the end of the 10-d window is ≤ 20%;
- In the toxicity control, the degradation of the reference substance has reached ≥ 35% (based on DOC) or ≥ 25% (based on ThOD or $ThCO_2$) by day 14;
- The oxygen uptake of the inoculum blank does normally not exceed 20-30 mg O_2/L;
- The percentage degradation of the reference compound calculated from the oxygen consumption is ≥ 65% by day 14;

33 Technical specifications impacting the sensitivity/reliability of the test

- The test duration is normally 28 days. The duration of the test may only be shortened if the biodegradation curve has reached a plateau for at least three consecutive determinations;
- The inoculum is not be pre-adapted to the test material;
- The results of measurements at each sampling point in each replicate is reported in a tabular form;
- The determination of the biodegradation using a specific chemical analytical method is reported.

34 Your registration dossier provides an OECD TG 301 C showing the following:

- Fulfilment of listed above validity criteria is not reported;
- The test duration was 2 weeks and it is reported that "*At the end of the 2-week period there was an upward trend in BOD consumption*", i.e. the biodegradation curve has not reached a plateau;
- The pre-adaptation of the inoculum is not specified while it is noted that mixture of ten samples from different locations, including '*industrial sewage plants*' was used; the substance has a number of uses at industrial sites identified;
- The results of measurements at each sampling point in each replicate is not reported;
- The determination of the biodegradation using a specific chemical analytical method is not reported.

35 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the test duration was too short while the biodegradation curve has not reached a plateau and the pre-adaptation of inoculum is not specified while the Substance is used at industrial sites and inoculum taken from the industrial sewage plants could be pre-adapted to the Substance. Furthermore, the reporting of the study is not sufficient to conduct an independent assessment of its reliability specifically because information on validity criteria and results is missing.

36 Therefore, the requirements of OECD 301C are not met.

37 In your comments to the draft decision you agree that there is missing or wrong information in the dossier for the OECD TG 301 C study. You contacted the Japanese authority and obtained the study report with the following additional information (i) there is no pre-adaptation of the sludge used as an inoculum as it does not come from industrial sewage plant sources (ii) Test duration was shortened to 14 days because the curve reached a plateau and biodegradation was confirmed by GC analysis (100 %) and TOC analysis (86%) (iii) the difference between extremes of replicate values of the test material removal at the end of the test is ≤ 20% (iv) the degradation percentage of the reference compound (aniline) calculated from the oxygen consumption is > 40% by day 7 (58% of degradation) and should be approaching the 65% level by day 14.

38 ECHA has assessed this information and notes that the information provided as part of your comments addresses the incompliances identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

2.2.2. Adaptation according to Annex XI, 1.3

39 Under Annex XI, Section 1.3., the following conditions must be fulfilled whenever a (Q)SAR approach is used:

i. the prediction needs to be derived from a scientifically valid model,

ii. the substance must fall within the applicability domain of the model,

iii. results need to be adequate for the purpose of risk assessment or classification and labelling, and

iv. adequate and reliable documentation of the method must be provided.

40 With regard to these conditions, for the information provided by you in the registration dossier (a ready biodegradability prediction derived from BIOWIN 1-7 models) we have identified the following issue:

41 ECHA Guidance R.6.1.6.3 states that the information specified in or equivalent to the (Q)SAR Prediction Reporting Format document (QPRF) must be provided to have adequate and reliable documentation of the applied method. For a QPRF this includes, among others:

- the model prediction(s), including the endpoint,
- a precise identification of the substance modelled,
- the relationship between the modelled substance and the defined applicability domain,
- the identities of close analogues, including considerations on how predicted and experimental data for analogues support the prediction.

42 You have not provided information about the prediction.

43 In absence of such information, ECHA cannot establish that the prediction can be used to meet this information requirement.

44 On this basis, the information requirement is not fulfilled on the basis of the information in the registration dossier.

45 In your comments to the draft decision you agree that the QPRF is missing and that you will include this in the registration dossier. You provide the missing QPRF information in an Appendix of the comments to this draft decision. The provided QPRF addresses the identified deficiencies. Therefore the QSAR prediction is considered to be reliable, the Ssubstance is in the domain of applicability.

46 With a view to your obligation to update the registration dossier with all available and relevant information, ECHA further welcomes the suggestion in your comments to the draft decision to include data from another valid QSAR. You identified the Substance to be readily biodegradable through predictions with ISIDA Predictor. ECHA observes that the Substance's molecular weight (MW=108.14 g/mol) falls within the range of molecular weights of the training set compounds: 28 to 1231 g/mol. All fragments are present in the training set of the individual model. The Substance is within the known boundaries of the applicability domain.

47 Furthermore, in your comments to the draft decision you indicate that you will correct the results to 'readily biodegradable' from 'biodegrades fast' – an error you identified in the dossier yourself.

48 The information provided as part of your comments addresses the incompliances identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

Reasons related to the information under Annex VIII of REACH

3. Short-term toxicity testing on fish

49 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

3.1. Information provided

50 You have provided an adaptation under Annex XI, Section 1.2. ('Weight of evidence'). In support of your adaptation, you have provide a study equivalent or similar to OECD 203 (1982), published data, identified by you being 'not reliable' (with Klimish Score of 3).

3.2. Assessment of the information provided

51 We have assessed this information and identified the following issues:

52 Annex XI, Section 1.2 states that there may be sufficient weight of evidence weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

53 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 that the Substance has or has not the (dangerous) property investigated by the required study.

54 Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence adaptation.

55 You have provided a justification for the weight of evidence adaptation as follows: "Two data are available for this endpoint. Due to lack of information, these data are scored 3 in the endpoint study summary. However, both studies are consistent in their results, concluding that anisole is not harmful to fish. Therefore, a weight of evidence approach is performed to document this endpoint." However, your justification does not include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

56 Furthermore, relevant information that can be used to support weight of evidence adaptation for information requirement of Section 9.1.3. at Annex VIII includes similar information that is produced by the OECD TG 203 and reliability of the provided sources of information should not be significantly affected. ECHA agrees with your assessment that both studies provided in support of the adaptation are not reliable.

57 Thus, your adaptation is rejected because lack of adequate and reliable (concise) documentation for justification and the information requirement is not fulfilled and because there is no reliable sources of information provided to conclude whether your Substance has or has not the particular dangerous property foreseen to be investigated in an OECD TG 203 study.

58 In your comments to the draft decision you agree with the assessment. However, you rightfully point out that according to the board of appeal A-011-2018 (2020) that in

accordance with column 2 of REACH, Annex VIII section 9.1.3 Short-term toxicity testing on fish does not need to be conducted if a long-term aquatic toxicity study on fish is available. In your comments you agree on the basis of the board of appeal conclusions to carry out the requested long-term study according to OECD TG 210. If you update your dossier with that study, the short-term study can be omitted, to avoid carrying out two additional tests on vertebrate animals but limit it to one.

Reasons related to the information under Annex IX of REACH

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

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

4.1. Information provided

60 You have adapted this information requirement by, as we understand, using Column 2 of Annex IX, Section 8.6.2, fourth indent. To support the adaptation, you have provided following information:

(i) A sub-acute inhalation study (OECD TG 412) with the Substance

(ii) A justification for your adaptation, in which you refer to study (i): " *Based on this study only reversible non adverse effects with no histopathological findings were noted at the higher tested concentration (3000 mg/m3). Since no target organ and no significant biological symptoms were identified at a very high concentration such as 3000 mg/m3, anisole can be considered to have a low toxicity after repeated exposure and no more effect or no more sever effect can be expected after longer exposures. Based on these elements a 90 day inhalation study is not needed"*

4.2. Assessment of the information provided

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

4.2.1. Column 2 criteria not met

62 Under Section 8.6.2, Column 2, fourth indent, of Annex IX to REACH, the study may be omitted if the following cumulative conditions are met:

(1) the substance is unreactive, insoluble and not inhalable;

(2) there is no evidence of absorption.

63 Your adaptation justification does not provide any supporting data showing that the Substance is unreactive, insoluble, not inhalable, and it is not absorbed.

64 In your registration dossier:

- the solubility of the Substance is reported as 1.71 g/L at 20°C and pH 7 (experimental result), and the Substance is, thus, not insoluble;
- a sub-acute 29-day toxicity study (2012) was performed via inhalation, which does not exclude that the Substance is inhalable;
- systemic effects (maternal toxicity) are reported in the provided PNDT study (OECD TG 414, 2015) which indicates that the Substance is absorbed.

65 You have not demonstrated that the Substance is unreactive, insoluble, not inhalable, and not absorbed.

66 Therefore, your adaptation is rejected.

67 In the comments to the draft decision, you agree to perform the requested study.

4.3. Specification of the study design

68 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.

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

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

5. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

71 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

5.1. Information provided

72 You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.

5.2. Assessment of the information provided

73 We have assessed this information and identified the following issue:

74 As explained under Section 0.1 of this Appendix above your adaptation is rejected.

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

5.3. Study design and test specifications

76 OECD TG 211 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' under Section 1.3 of this Appendix.

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

6.1. Information provided

77 You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2.

6.2. Assessment of the information provided

78 We have assessed this information and identified the following issue:

79 As explained under Section 0.1 of this Appendix above your adaptation is rejected.

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

6.3. Study design and test specifications

81 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.).

82 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' under Section 1.3 of this Appendix.

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 compliance check was initiated on 08 July 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 requests.

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 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]
[redacted]	[redacted]	[redacted]
[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].

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