~~Confidential~~

Helsinki, 8 September 2022

Addressees
Registrants of FADMAC10uns as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
27/05/2015

Registered substance subject to this decision ("the Substance")
Substance name: 9-Decenamide, N,N-dimethyl-
EC/List number: 806-919-0

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 ***16 December 2024***.

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

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

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

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

2. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

3. Short-term repeated dose toxicity (28 days; Annex VIII, Section 8.6.1.) to be combined with the Screening for reproductive/developmental toxicity below

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

The reasons for the requests 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 under Annex XI, Section 1.5:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

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:

- Decanamide, N,N-dimethyl-, mixt. with N,N-dimethyloctanamide, List No. 614-052-2.

7 You provide the following reasoning for the prediction of toxicological properties: "[...] *The physico-chemical properties of the target substance and the source substances are very similar for all endpoints where data are available. In terms of toxicity there is also a high concordance between the test results for the target substance and for the source 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 issues with the predictions of toxicological properties:

0.1.1.1. Characterisation of the source substance

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

11 According to the Guidance on IRs and CSA, Section R.6, "the purity and impurity profiles of the substance and the structural analogue need to be assessed", and "the extent to which differences in the purity and impurities are likely to influence the overall toxicity needs to be addressed, and where technically possible, excluded". The purity profile and

composition can influence the overall toxicity/properties of the Substance and of the source substance(s)(Guidance on IRs and CSA, Section R.6.2.3.1). Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) must be provided to allow assessing whether the attempted predictions are compromised by the composition and/or impurities.

12 The Substance is a mono-constituent substance. You do not describe in an exhaustive and comparable manner the composition, including impurities, of the source substance (List No. 614-052-2).

13 Without this information, no qualitative or quantitative information on the compositions of the Substance and of the source substance(s), it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance(s).

0.1.1.2. Inadequate read-across hypothesis

14 A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. Firstly, this hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.). Secondly, it should also explain why the differences in the chemical structures should not influence the toxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

15 Your read-across hypothesis is only based similarities in the physico-chemical properties of the source substance(s) and the Substance. You consider that these elements are a sufficient basis for predicting the (eco)toxicological properties of the Substance.

16 You have not substantiated how physico-chemical similarity alone would explain similarity in the predicted endpoint(s) and thus be sufficient to justify the toxicological predictions.

17 Physico-chemical similarity alone does not necessarily lead to predictable or similar toxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for a toxicological property, explaining why the structural differences do not influence toxicokinetics and toxicodynamics of the substances.

0.1.1.3. Missing supporting information

18 Annex XI, Section 1.5 of the REACH Regulation states that "physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)". For this purpose "it is important to provide supporting information to strengthen the rationale for the read-across" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

19 Supporting information must include information to compare toxicokinetic properties of the category members and bridging studies to compare other properties of the category members.

20 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). 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. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

0.1.1.3.1. Toxicokinetic information

21 You make assumptions on the toxicokinetic characteristics of the Substance, based on its physicochemical properties, but you do not provide experimental evidence with the Substance to support these assumptions. You have provided a study (1971) on "*twelve N-dimethylamides (Hallcomids)*", where a comparison is made between the impact of exposure route and chain length on LD50 in mice. However, you have not provided any comparative toxicokinetic information generated with the source substance in relation to:

- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

0.1.1.3.2. Bridging studies

22 You have not provided bridging studies, using the source substance and the Substance in relation to:

- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

23 In the absence of such information, you have not established that the Substance and the source substance are likely to have similar properties. In particular, you have not addressed the impact of the structural difference (a double bond in the Substance and no double bond in the source substance) on the prediction.

24 Therefore, in relation to these respective information requirements, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

0.1.1.4. Adequacy and reliability of source studies

25 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:

(1) be adequate for the purpose of classification and labelling and/or risk assessment;
(2) have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3);
(3) cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter.

26 Specific reasons why the studies on the source substances do not meet these criteria are explained further below under the applicable information requirement sections 2 and 4. Therefore, no reliable predictions can be made for these information requirements.

0.1.2. Conclusion on the read-across approach

27 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.

28 In your comments to the draft decision, you state that for all endpoints listed above where you used a grouping and read-across approach under Annex XI, Section 1.5: "*We agree that there is insufficient information to support the use of the study performed on the read-across substance to fill this endpoint.*"

Reasons related to the information under Annex VII of REACH

1. Ready biodegradability

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

1.1. Information provided

30 An OECD TG 301B study on the Substance (2015)

1.2. Assessment of information provided

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 Technical specifications impacting the sensitivity/reliability of the test

a) The concentration of the inoculum is set to reach a bacterial cell density of 10^7 to 10^8 cells/L in the test vessel. The suspended solid concentration is ≤ 30 mg/L

33 Reporting of the methodology and results

b) The inoculum concentration in the test is adequately reported to verify that the specifications of OECD TG 301B are met;
c) The results of measurements at each sampling point in each replicate is reported in a tabular form;
d) The inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is reported.

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

35 Technical specifications impacting the sensitivity/reliability of the test

a) You described the inoculum density as follow: "*The test substance flasks, the blank flasks, the procedural control flask, and the toxicity control flasks all received 6.0 mL of the inoculum to produce an activated sludge concentration of 30 mg solids/L.* [In addition], *a 3.0-mL aliquot of the soil/sediment filtrate was added to each test vessel containing 2991 mL of mineral medium and 6.0 mL of activated sludge*". Therefore, it can be expected that the suspended solid concentration exceeded the maximum tolerable value of 30 mg/L.

In your comments to the draft decision, you provide a letter from the laboratory who conducted the study. In this letter, it is stated that the soil/sediment filtrate only contained 0.6 mg of solids in 3 mL and the bacterial density was c.a. 1000 cells/mL.

36 Reporting of the methodology and results

b) The concentration of the inoculum is not reported based on cell density (in cells/mL) in the test bottles. Further you have not provided information on the suspended solid content of the soil/sediment filtrate added in addition to the activated sludge inoculum

In your comments to the draft decision, you provide a letter from the laboratory who conducted the study. In this letter, it is stated that "*the cell density in [the] inoculum control vessels has been confirmed to be 1 x 10^7 cells per liter*".

c) The results of measurements at each sampling point in each replicate is not reported.

In your comments to the draft decision, you provide a letter from the laboratory who conducted the study. In this letter, it is stated that "*Replicate A and B values are included in the report in Table 4, 5 and 6 in the top rows*". However, you have not provided these tables as part of your comments to the draft decision.

d) The inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is not reported.

In your comments to the draft decision, you provide a letter from the laboratory who conducted the study. In this letter, it is stated that "*the IC concentration in the mineral media was "just under 0.5 mg/L and the ttal carbon was approximately 21 pp C (with 10 ppm C from the Test Substance and 11 mg/L C came from the sludge)" and that "the IC content of the test suspensions is most likely similar to what was measured in the mineral media*".

37 The information you have provided in your comments addresses a number of incompliances identified in this decision for this information requirement (namely points a), b) and d) above). However, you have still not provided adequate reporting of the study results. Therefore, it remains not possible to conduct an independent assessment of whether all validity criteria of the test guideline were met.

38 Therefore, the requirements of OECD 301B are not met.

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

Reasons related to the information under Annex VIII of REACH

2. In vitro gene mutation study in mammalian cells

40 An in vitro gene mutation study in mammalian cells is an information requirement under Annex VIII to REACH (Section 8.4.3.) in case of a negative result in the in vitro gene mutation test in bacteria and the in vitro cytogenicity test.

2.1. Triggering of in vitro gene mutation study in mammalian cells

41 Your dossier contains negative results for both an Ames test and an in vitro cytogenicity study. Therefore, the information requirement is triggered.

2.2. Information provided

42 You have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substances:

(i) *in vitro* gene mutation study in mammalian cells according to OECD TG 476 (1994) with Decanamide, N,N-dimethyl-, mixt. with N,N-dimethyloctanamide, List No. 614-052-2.

2.3. Assessment of the information provided

2.3.1. Read-across adaptation rejected

43 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. In addition, ECHA identified endpoint specific issue(s) addressed below.

2.3.2. Source study not adequate for the information requirement

44 Under Annex XI, Section 1.5., the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 476. Therefore, the following specifications must be met:

a) the maximum concentration tested must induce 80-90% of cytotoxicity compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test concentration must correspond to 10 mM, 2 mg/mL or 2 µl/mL, whichever is the lowest;

b) data on the cytotoxicity and the mutation frequency for the treated and control cultures must be reported.

45 The study is described as according to OECD TG 476. However, the following specifications are not according to the requirements of OECD TG 476:

a) you claim that cytotoxicity was observed in the submitted study, but you do not clarify whether this was 80-90% as compared to the negative control;

b) data on the cytotoxicity and the mutation frequency for the treated and control cultures is not reported.

46 Based on the above, the study does not provide an adequate and reliable coverage of the key parameter(s) addressed by the OECD TG 476 and this study is not an adequate basis for your read-across predictions.

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

In your comments to the draft decision, you state: "*We agree that there is insufficient information to support the use of the study performed on the read-across substance to fill this endpoint*," and you agree to perform the requested study. You specify that you intend to conduct a study according to OECD TG 490.

2.4. Specification of the study design

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

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

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

3.1. Information provided

50 You have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substances:

(i) sub-chronic toxicity study (90 day) (2000) with Decanamide, N,N-dimethyl-, mixt. with N,N-dimethyloctanamide, List No. 614-052-2.

3.2. Assessment of the information provided

3.2.1. Read-across adaptation rejected

51 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.

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

53 In your comments to the draft decision, you state: "*We agree that there is insufficient information to support the use of the study performed on the read-across substance to fill this endpoint*," and you agree to perform the requested study. You specify that you intend to conduct a study according to OECD TG 422.

3.3. Specification of the study design

54 When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided. Such an approach offers the possibility to avoid carrying out a 28-day study according to OECD TG 407, because the OECD TG 422 can at the same time fulfil the information requirement of REACH Annex VIII, 8.6.1 and that of REACH Annex VIII, 8.7.1. (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

55 For more information on the study design see request for OECD TG 422 below.

4. Screening for reproductive/developmental toxicity

56 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII to REACH (Section 8.7.1.), if there is no evidence from analogue substances, QSAR or in vitro methods that the substance may be a developmental toxicant.

4.1. Triggering of a screening for reproductive/developmental toxicity study

57 Under Section 8.7., Column 2 of Annex VIII to REACH, the study does not need to be conducted if a pre-natal developmental toxicity study (OECD TG 414) is already available.

58 In your dossier, you have provided following information:

(i) a pre-natal developmental toxicity study (1991) with Decanamide, N,N-dimethyl-, mixt. with N,N-dimethyloctanamide, List No. 614-052-2

(ii) a statement that a reproductive screening study does not need to be conducted as results from a "*developmental toxicity study and a subchronic toxicity study*" did not reveal any adverse effects regarding developmental or fertility.

59 However, for the reasons explained below, the information on pre-natal developmental toxicity in your dossier does not meet the information requirement. Consequently, a screening for reproductive/developmental toxicity study must be submitted.

4.2. Assessment of the information provided

4.2.1. Read-across adaptation rejected

60 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. In addition, ECHA identified endpoint specific issue(s) addressed below.

4.2.2. Source study not adequate for the information requirement

61 Under Annex XI, Section 1.5., the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 414. Therefore, the following specifications must be met:

a) an exposure duration at least from implantation until one day prior to scheduled caesarean section;

b) examination of the dams for any structural abnormalities, weight and histopathology of the thyroid gland, thyroid hormone measurements, gravid uterus weight, and uterine content.

c) examination of the foetuses for body weight, number and percent of live and dead foetuses and resorptions, sex ratio, external, skeletal and soft tissue alterations (variations and malformations), measurement of anogenital distance in all live rodent foetuses.

62 The study (i) is described as according to OECD TG 414. However, the following specifications are not according to the requirements of OECD TG 414:

a) an exposure duration from day 6 to day 15 post coitum, with termination at day 21;

b) no data on examinations of dams: incidence and severity. In particular, you claim that severe clinical signs of reaction to treatment were observed at the top dose, without specifying the nature of these effects. This conflicts with your statement that no detailed clinical observations were made;

c) no data on examinations of foetuses: incidence and severity. In particular, the following investigations are missing: number of live foetuses and anogenital distance.

63 Based on the above, the study does not provide an adequate and reliable coverage of the key parameter(s) addressed by the OECD TG 414 and this study is not an adequate basis for your read-across predictions.

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

65 In your comments to the draft decision, you state: "*We agree that there is insufficient information to support the use of the study performed on the read-across substance to fill this endpoint*," and you agree to perform the requested study. You specify that you intend to conduct a study according to OECD TG 422.

4.3. Specification of the study design

66 When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided. Such an approach offers the possibility to avoid carrying out a 28-day study according to OECD TG 407, because the OECD TG 422 can at the same time fulfil the information requirement of REACH Annex VIII, 8.6.1 and that of REACH Annex VIII, 8.7.1. (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

67 A study according to the test method EU B.64/OECD TG 422 must be performed in rats.

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

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 2 June 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.

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.

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.

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;

Registrant Name	Registration number	Highest REACH Annex applicable to you
[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