~~Confidential~~

Helsinki, 19 April 2024

Addressee
Registrant of FS_Cesiumiodide as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
16 May 2023

Registered substance subject to this decision ("the Substance")
Substance name: caesium iodide
EC/List number: 232-145-2

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 ***27 April 2026***.

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

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

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

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

3. 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 request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

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

Appendix 1: Reasons for the request(s)

Reasons common to several requests

0.1. Read-across adaptation rejected

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

- *In vitro* micronucleus study (Annex VIII, Section 8.4.2.)
- *In vivo* mammalian bone marrow chromosome aberration (Annex VIII, Section 8.4, column 2)
- *In vivo* mammalian erythrocyte micronucleus test (Annex VIII, Section 8.4, column 2)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.).
- Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

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 (eco)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 substances:

- Cesium Nitrate, EC 232-146-8 (source substance 1);
- Cesium Hydroxide monohydrate EC 627-088-9 (source substance 2);
- Cesium Chloride EC 231-600-2 (source substance 3).

7 You provide the following reasoning for the prediction of (eco)toxicological properties: "*Cesium nitrate, cesium hydroxide, cesium chloride, cesium iodide and cesium sulphate are very* **soluble in water. […]** *the cesium salts dissociate completely into the cesium cation and the respective anion once in contact with aqueous solutions. […] Following oral administration, the cesium ion will become systemically available and is readily distributed throughout the body via the blood stream. […] Since the (eco)toxicological properties depend mostly on the cesium cation* **with the exception of cesium iodide** *it was possible to extrapolate information for the addressed endpoints by using a range of read-across substances with differing anion moieties".*

8 ECHA understands that your read-across hypothesis is based on the formation of common (bio)transformation products. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

9 We have assessed the information provided and we identified the following issues:

0.1.1.1. Missing supporting information on the impact of non-common compound

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 As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance and the of the source substance(s) to a common compound(s). In this context, exposure to the Substance and of the source substance(s) may also lead to exposure to other compounds than the common compound of interest. The impact of exposure to these non-common compounds on the prediction of properties of the target needs to be assessed to ensure that a reliable prediction can be made.

12 In your justification, you mention that the Cesium salts toxicokinetic profile is comparable due to their high solubility. Following oral administration, they readily dissociate into the cesium cation and the respective anion and become systemically available. Both the Cesium cation and the respective anion will be absorbed into the blood stream. You claim that the cesium moiety represents the reactive group, mainly triggering the toxicological profiles with regard to systemic toxicity. You conclude that due to structural similarities and dissociation patterns, the potential for cellular uptake and systemic bioavailability for cesium iodide can be regarded as similar to the source substances as they all include the cesium moiety which readily will be freed once in contact with an aqueous solution.

13 However, you acknowledge that the (eco)toxicological properties do not depend only on the cesium cation for the cesium iodide but you do not provide information characterising the exposure to this non-common compound.

14 More specifically, you do not include experimental data or other adequate and reliable information addressing the impact of the exposure to this non-common compound (i.e., iodide) in the documentation of your read-across approach.

15 In the absence of such information, you have not established that a reliable prediction of the property under consideration of the Substance can be derived on the basis of your read-across hypothesis. Therefore, you have not provided sufficient supporting information to scientifically justify for the read-across.

0.1.1.2. Inadequate or unreliable source studies

16 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 study that shall normally be performed for a particular information requirement.

17 Specific reasons why the studies on the source substance(s) do not meet these criteria are explained further below under the applicable information requirement (sections 2 and 6). Therefore, no reliable predictions can be made for these information requirements.

0.1.2. Conclusion

18 Based on the 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. *In vitro* micronucleus study

19 An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

1.1. Information provided

20 In your registration dossier, you have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on experimental data from the following substances:

(i) an *in vitro* cytogenicity study in mammalian cells (1994) with the source substance Caesium hydroxide, EC 244-344-1;

(ii) an *in vitro* cytogenicity study in mammalian cells (1995) with the source substance caesium chloride, EC 231-600-2.

21 ECHA understands from your registration dossier that you also intended to adapt this information requirement by using Annex VIII, Section 8.4., Column 2. To support the adaptation, you have provided the following information:

(iii) an *in vivo* Mammalian Bone Marrow Chromosome Aberration Test (2012) with the source substance Cesium Hydroxide monohydrate, EC 627-088-9;

(iv) an in vivo Mammalian Erythrocyte micronucleus test (2008) with the source substance Cesium chloride, EC 231-600-2.

1.2. Assessment of the information provided

1.2.1. Read-across adaptation rejected (i, ii, iii, iv)

22 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.

23 In your comment to the draft decision, you reiterate that your intention is to address this information requirement by read-across to the data available with other Cesium salts.

24 You further claim that both the anion and cation of the Substance are well investigated.

25 However, you do not provide supporting information addressing the deficiency identified under section 0.1.1.1. In the absence of such information, your comments on the draft decision do not change the assessment's outcome.

26 In addition, ECHA identified endpoint-specific issue addressed below.

1.2.1.1. The provided adaptation (iii, iv) does not meet the criteria of Annex VIII, Section 8.4.2., Column 2

27 Under Annex VIII, Section 8.4.2., Column 2, the study usually does not need to be conducted "if adequate data from an *in vivo* cytogenicity test are available". The Guidance on IRs and CSA, Section R.7.7.6.3 and Table R.7.7–3 clarifies that the *in vivo* somatic cell cytogenicity test must be either a micronucleus test or a chromosomal aberration test, performed according to the OECD TG 474 or 475, respectively.

28 For the data from an *in vivo* somatic cell cytogenicity test to be considered adequate, the *in vivo* study you submitted has to meet the requirements of the OECD TG 474 or 475. Therefore, the following specifications must be met:

a) the proportion of immature erythrocytes among total (immature + mature)

erythrocytes and the mean number of micronucleated immature erythrocytes are reported for each group of animals for study (iv);
b) the mitotic index and the mean number of cells with aberrations per group are reported for each group of animals for study (iii);
c) a clear negative outcome is concluded when the data available shows that bone marrow exposure to the Substance or its metabolites occurred for study (iii);
d) the negative control data is ideally within the 95% control limits of the distribution of the laboratory's historical negative control database for study (iii) ;
e) the positive controls or scoring controls produce statistically significant increase compared with the negative control for study (iv).

29 In your dossier:

a) the proportion of immature erythrocytes among total (immature + mature) erythrocytes and the mean number of micronucleated immature erythrocytes were not reported for each group of animals in study (iv);
b) the mitotic index and the mean number of cells with aberrations per group were not reported for each group of animals in study (iii);
c) you did not demonstrate that bone marrow exposure to the Substance occurred in study (iii);
d) you did not report if the negative control showed a response within the historical control range of the laboratory in study (iii);
e) you did not report if the positive control (or scoring control) produced a statistically significant increase in the induced response when compared with the concurrent negative control in study (iv).

30 The information provided in your dossier does not cover the specifications required by the OECD TG 474/475.

31 In your comments to the draft decision, you indicate that you will provide the missing information under points a), b), d) , and e) above in a future update of your registration dossier. You however claim that this information "*not a mandatory field in IUCLID*" and that "*ECHAs own guideline was not listing these specific details*".

32 ECHA takes note of your intention to provide additional information on the existing study from your dossier. However, this information is not yet available in your dossier, no assessment can currently be made. Furthermore, ECHA emphasizes that OECD TG 474 and OECD TG 475 specify the information that needs to be reported in order to adequately describe the methodology applied and the results obtained in a specific study. These reporting requirements includes points a) to e) as listed above.

33 Regarding the missing information under point c), you mention that "systemic bioavailability of Cs after acute gavage has been shown in the context of the CA in vivo study with Cesium carbonate as well as after repeated dose toxicity study with CsCl" and you will include those both studies.

34 ECHA understand from your comments that you consider that providing information on point c) above is not necessary. However, ECHA emphasizes that the examination of the bone marrow exposure to the tested substance is one the mandatory conditions listed in the paragraph 44 of the OECD TG 475. This condition must be fulfilled to confirm the reliability of the conclusion drawn from such study when negative results are obtained. Therefore, ECHA maintains that this information must be provided.

35 On this basis, your comments on the draft decision do not change the assessment's outcome.

36 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

1.3. Study design

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

1.3.1. Assessment of aneugenicity potential

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

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

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

40 In your comment to the draft decision, you consider that the additional centromere labelling will not provide additional information relevant for hazard or risk assessment. You state that while "*this approach is in general scientifically understandable [when] no information on the mode of action is available,* […] *in the case of Cs, it is known already that the substance is causing CA in vitro (thus act as a clastogene)*".

41 However, as explained in Section 1.2.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. Therefore, your dossier currently does not include a valid justification as to why the properties of the Substance can be predicted from the data available on the selected analogue substances.

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

42 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1. This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Column 2 or a general adaptation rule under Annex XI.

2.1. Information provided

43 You have provided:

(i) a sub-acute toxicity study (2011) with the Substance

44 In addition, you have adapted the information requirement by using Annex VIII, Section 8.6.1 column 2 and you have provided the following information:

(ii) a sub-chronic toxicity study (2012) with the Source substance Cesium Hydroxide monohydrate EC 627-088-9.

2.2. Assessment of the information provided

2.2.1. The provided study (i) does not meet the specifications of the test guidelines

45 To fulfil the information requirement, a study must comply with the OECD TG 407 (Article 13(3) of REACH). Therefore, the following specifications must be met:

b) full histopathology, including incidence and severity, is performed as specified in paragraphs 47-49 of OECD TG 407.

46 In study (i):

a) the following histopathology item was not studied: Thyroid in the control and in the high dose animals, although this is specified in paragraph 43 of OECD TG 407.

47 In your comment to the draft decision, your indicate that "*thyroid with parathyroid histopathology was investigated and only few preparations were not examined due to technical failure*." You also mention that you will provide additional data in an update of your registration dossier.

48 ECHA takes note of your clarification that the thyroid has been investigated in the provided study. However, as you have not provided this information as part of your comments to the draft decision, ECHA cannot assess independently the information on thyroid histopathology. In addition, you refer to technical issues that prevented the examination of this organ in three animals in the control group and four animals in the high dose group, in both sexes. According to the guidance (OECD Test Guideline 407, paragraph 47), "*Full histopathology should be carried out on the preserved organs and tissues of all animals in the control and high dose groups*." Thyroid is a mandatory requirement for the detection of the endocrine disrupters (OECD TG 407, paragraph 43 and Annex 2). ECHA notes that the technical issues encountered in the course of this study have led to a reduced statistical power for the examination of effects on the thyroid and therefore to a reduced sensitivity do detect potential endocrine disrupting properties.

49 Based on this information, study (i) does not cover the specification required by the OECD TG 407.

2.2.2. Your adaptation under Annex VIII, Section 8.6.1., Column 2, Paragraph 1, Indent 1 is rejected (study ii)

50 Under Annex VIII, Section 8.6.1., Column 2, Paragraph 1, Indent 1, the study may be omitted if a reliable sub-chronic (90 days) or chronic toxicity study is available or proposed by the registrant.

51 The study (ii) is described as a sub-chronic (90 days) study conducted on an analogue substance (Cesium Hydroxide monohydrate, EC 627-088-9).

52 However, 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. Therefore, your dossier does not contain reliable information on sub-chronic (90 days) toxicity for the Substance and your adaptation is rejected.

53 Therefore, the information requirement is not fulfilled.

54 In your comments to the draft decision, you state that "*comprehensive data packages for both cation and anion are available and will be used to cover this endpoint*".

55 As this strategy relies on a read-across approach that has not yet been fully described and justified (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.

2.3. Study design

56 Following the criteria provided in Annex VIII, Section 8.6.1., Column 2, and considering the Guidance on IRs and CSA, Section R.7.5.6.3.1., the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance.

57 According to the OECD TG 407, the rat is the preferred species.

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

59 The study design is addressed in request 3.

3. Screening study for reproductive/developmental toxicity

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

3.1. Information provided

61 You have provided the following statement: "*the study does not need to be conducted because a pre-natal developmental toxicity study is available or proposed*".

62 ECHA understands that you have adapted this information requirement by Annex VIII, Section 8.7., Column 2. To support the adaptation, you have provided the following information:

(i) a pre-natal developmental toxicity study in rats (2012) with the source substance Cesium Hydroxide monohydrate CAS 35103-79-8.

3.1.1. Your adaptation under Annex VIII, Section 8.7., Column 2 (study i)

63 Under Annex VIII, Section 8.7., Column 2, the study does not need to be conducted if a pre-natal developmental toxicity study (OECD TG 414) referred to in Annex IX, point 8.7.2 is available.

64 The study (i) is described as a developmental toxicity study conducted on an analogue substance (Cesium Hydroxide monohydrate, CAS 35103-79-8).

65 However, 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. Therefore, your dossier does not contain reliable information on pre-natal developmental toxicity for the Substance and your adaptation is rejected.

66 Therefore, the information requirement is not fulfilled.

67 In your comment to the draft decision, you indicate that you will provide "*a solid read across using data of both the Cesium analogs and the iodine sodium and/or potassium salts instead of conducting the further animal testing*".

68 As this strategy relies on a read-across approach that has not yet been fully described and justified (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.

3.2. Study design

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

The information requirement for the 28-day repeated dose toxicity study is not fulfilled for the reasons explained under request 2.

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

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

Therefore, the study must be conducted in rats 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).
Guidance for monomers and polymers; ECHA (2012).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 07 October 2022.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

ECHA 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.

Appendix 3: Addressee 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]

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 (https://echa.europa.eu/practical-guides).

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

1.2 Test material

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

(1) Selection of the Test material(s)

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

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

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values.

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).