~~Confidential~~

Helsinki, 19 April 2024

Addressee
Registrant of JS_CSF_222-492-8 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
22 March 2018

Registered substance subject to this decision ("the Substance")
Substance name: cesium formate
EC/List number: 222-492-8

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 ***26 April 2027***.

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

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

1. *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. Only if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. is obtained, *in vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: EU B.17./OECD TG 476 or EU B.67./OECD TG 490).

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

3. Extended one-generation reproductive toxicity study, also requested below (Annex IX, Section 8.7.3.).

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

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

5. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) in rats, oral route, specified as follows:
    - Ten weeks premating exposure duration for the parental (P0) generation;
    - The highest dose level in P0 animals must be determined based on clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals as specified in request 5.3.3., or follow the limit dose concept. The reporting of the study must provide the justification for the setting of the dose levels;
    - Cohort 1A and 1B (Reproductive toxicity); and
    - Cohort 3 (Developmental immunotoxicity).

You must report the study performed according to the above specifications. Any expansion of the study must be scientifically justified.

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 addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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

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 related to the information under Annex VIII of REACH

1. *In vitro* micronucleus study

1 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

2 You have provided:

(i) an *in vitro* cytogenicity study in mammalian cells (1995) with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided study does not meet the specifications of the test guideline(s)

3 To fulfil the information requirement, the study has to be an *in vitro* chromosomal aberration test or an *in vitro* micronucleus test conducted in mammalian cells. The study must comply with the OECD TG 473 or the OECD TG 487, respectively (Article 13(3) of REACH). Therefore, the following specifications must be met:

b) the negative control data is ideally within the 95% control limits of the distribution of the laboratory's historical negative control database;

c) data on the cytotoxicity and the frequency of cells with structural chromosomal aberration(s) for the treated and control cultures is reported.

4 In study (i):

a) the historical control range of the laboratory is not reported;

b) data on the cytotoxicity and the frequency of cells with structural chromosomal aberrations for the treated and control cultures were not reported.

5 The information provided does not cover the specifications required by the OECD TG 473.

6 Therefore, the information requirement is not fulfilled.

7 In your comments to the draft decision, you provide the full study report which is addressing the study deficiencies identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set in the decision.

1.3. Study design

8 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

9 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.

10 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).

2. *In vitro* gene mutation study in mammalian cells

11 An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII, 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 the information requirement

12 Your dossier contains (I) a negative result for *in vitro* gene mutation study in bacteria, and (II) inadequate data for the *in vitro* cytogenicity study in mammalian cells.

13 The *in vitro* cytogenicity study in mammalian cells provided in the dossier is rejected for the reasons provided in request 1.

14 The result of the request 1 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3. is triggered.

15 Consequently, you are required to provide information for this information requirement, if the the *in vitro* micronucleus study provides a negative result.

2.2. Information provided

16 You have provided:

(i) an *in vitro* gene mutation study in mammalian cells (2008) with the Substance.

2.3. Assessment of the information provided

2.3.1. The provided study does not meet the specifications of the test guideline(s)

17 To fulfil the information requirement, a study must comply with the OECD TG 476 or the OECD TG 490 (Guidance on IRs and CSA, Table.7.7-2) (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) at least 4 concentrations are evaluated, in absence and in presence of metabolic activation;

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

18 In study (i):

a) No information on the number of concentrations that were evaluated in absence and in presence of metabolic activation;

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

19 The information provided does not cover the specifications required by the OECD TG 490.

20 Therefore, the information requirement is not fulfilled.

21 In your comments to the draft decision, you provide the full study report which is addressing the study deficiencies identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set in the decision.

2.4. Study design

22 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.

Reasons related to the information under Annex IX of REACH

3. Extended one-generation reproductive toxicity study

23 An extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is an information requirement under Annex IX, Section 8.7.3., if the available repeated dose toxicity studies indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity. Furthermore Column 2 defines the conditions under which the study design needs to be expanded.

3.1. Triggering of the information requirement

24 In your dossier, you provide the following statements to omit study: "The study does not need to be conducted because the substance is known to have reprotoxic effects […]."

25 You acknowledge that the available 28-day and 90-day repeated dose toxicity studies indicate adverse effect "on the male reproductive system (testes, epididymis and sperm number/maturation/motility" as further described below:

- A short-term study conducted with the Substance (2008, report [redacted]) indicates changes in the testis weight as well as atrophy of the testes, dilatation of the seminiferous tubules, reduced spermatozoal content, cellular debris and a reduced secretory content in seminal vehicles observed in males and a reduction of the ovary weight in females at High Dose.
- A sub-chronic study conducted with the analogue substance Cesium Chloride EC 231-600-2 (2016, report [redacted]) indicates severe effects starting at the Mid-dose: tubular degeneration/atrophy in the testes, effects on the the sperm maturation (statistically significant changes in sperm morphology, motility (increase of beat cross frequency only) as well as significant reductions in cauda epididymal sperm numbers.
- A sub-chronic study conducted with the analogue substance Cesium hydroxide monohydrate CAS 35103-79-8 (2012) indicates effects in the testes and the epididymides weight at the Mid-and High doses, with related histopathological findings observed at the High Dose ; decreased intensity of spermatogenesis (9/10), and lack of mature spermatozoa in the seminiferous tubuli of testes (9/10) and in the ductuli of epididymides (9/10). Sperm was also affected at the Mid-and High Doses.
- A screening study conducted with the analogue substance Cesium nitrate EC 232-146-8 (2013) indicates a statistically significant increase at the High Dose of the immotile sperms and sperm cells with abnormal morphology (separated head and tail) (91.5 and 11.2 %, respectively) as compared to the control group (12.6 and 0.1 %, respectively).

26 To summarize, the available repeated dose toxicity studies conducted with the Substance itself and the analogue Substances indicate adverse effects on reproductive organs.

27 Therefore, the information requirement is triggered.

28 In your comment to the draft decision, you agree to perform the requested study.

3.2. Information requirement not fulfilled

29 The information provided, its assessment and the specifications of the study design are addressed under request 5.

Reasons related to the information under Annex X of REACH

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

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

4.1. Information provided

31 You have omitted the study with the following justification: "A study on a second species is not required as the substance did not show any developmental effects in the first tested species".

4.2. Assessment of the information provided

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

32 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex X, Section 8.7., Column 2.

33 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex X, Section 8.7, Column 2.

34 Therefore, you have not demonstrated that this information can be omitted.

35 Therefore, the information requirement is not fulfilled.

36 In your comment to the draft decision, you agree to perform the requested study.

4.3. Study design

37 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species. The study in the first species was carried out by using a rodent species (rat).

38 Therefore, a PNDT study in a second species must be performed in the rabbit as preferred non-rodent species.

39 As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex X, Section 8.7.2., Column 1).

40 Based on the above, the study must be conducted in rabbits with oral administration of the Substance.

5. Extended one-generation reproductive toxicity study

41 An extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is an information requirement under Annex X, Section 8.7.3. Furthermore Column 2 defines the conditions under which the study design needs to be expanded.

5.1. Information provided

42 ECHA understands that you have adapted this following standard information requirement under Annex XI, Section 3.2 (a) (b) substance-tailored exposure-driven testing. To support your adaptation, you have provided the following statement: "The study does not need to be conducted because the substance is known to have reprotoxic effects, there are only industrial uses (no consumer uses) and appropriate risk management measures are in place

to limit exposure". In addition, you state that "A clear NOAEL for the effects was derived, equivalent to 10 mg Cs/kg bw/day […]" and "the substance does not have wide-dispersive use. There are no consumer uses. Any exposure is by industrial, well trained, workers and appropriate risk management measures are in place to limit exposure. Also, industrial activities take place in rigorously contained systems with minimization of release to the environment. In this specific case, the EOGRT study will not contribute significant new information to ensure the safety of cesium and its salts; it is therefore proposed to waive this study requirement."

5.2. Assessment of the information provided

5.2.1. Condition 3.2. (a) (ii) for substance-tailored exposure-driven testing is not fulfilled

43 To be considered adequate, the adaptation has to fulfil the following conditions under Annex XI, Section 3.2(a)(ii):

- a relevant derived no effect level (DNEL) can be determined and,
- that the DNEL is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes.

44 You have used a reproduction/developmental toxicity screening test to derive the worker long-term systemic DNEL for inhalation effects and worker long-term systemic DNEL for dermal effects.

45 However, a DNEL derived from a used a reproduction/developmental toxicity screening test or repeated dose 90-day toxicity study is not considered appropriate to omit an extended one-generation reproductive toxicity study.

46 Therefore, you have not provided a relevant and appropriate DNEL.

5.2.2. Condition 3(2)(b) for substance-tailored exposure-driven testing is not fulfilled

47 To be considered adequate, the adaptation has to fulfil the following condition under Annex XI, Section 3(2)(b)):

- the registrant must demonstrate and document for all relevant scenarios that strictly controlled conditions, as set out in Article 18(4)(a) to (f), apply throughout the life cycle (see further Guidance on Intermediates and Practical Guide 16).

48 You have stated that the "activities take place in rigorously contained system with minimisation of release to the environment" without any documentation demonstrating strictly controlled conditions.

49 In your exposure assessment, you provide various exposure estimates that are not in accordance with strictly controlled conditions or a rigorously contained system as set out in Article 18(4)(a) to (f). In particular, in exposure scenario 1, contributing scenario 9, you estimate a systemic long-term inhalation exposure of 0.05 mg/m^3 and systemic long-term dermal exposure of 0.034 mg/kg bw/day.

50 Therefore, the use of the Substance under strictly controlled conditions is not demonstrated.

51 Consequently, your adaptations under Annex XI, Section 3.2 (a) (b) must be rejected and the information requirement is not fulfilled.

52 In your comment to the draft decision, you agree to perform the requested study.

5.3. Study design

5.3.1. Species and route selection

53 As the Substance is a liquid, the study must be conducted in rats with oral administration of the Substance (Annex X, Section 8.7.3, Column 1).

5.3.2. Pre-mating exposure duration

54 The length of pre-mating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

55 Ten weeks pre-mating exposure duration is required to obtain results adequate for classification and labelling and/or risk assessment. There is no substance specific information in the dossier supporting shorter premating exposure duration (Guidance on IRs and CSA, Section R.7.6.).

56 Therefore, the requested pre-mating exposure duration is ten weeks.

5.3.3. Dose-level setting

57 The aim of the requested test must be to demonstrate whether the classification criteria of the most severe hazard category for sexual function and fertility (Repr. 1B; H360F) and developmental toxicity (Repr. 1B; H360D) under the CLP Regulation apply for the Substance (OECD TG 443, paragraph 22; OECD GD 151, paragraph 28; introductory part of Annex IX/X to REACH; Annex I, Section 1.0.1. to REACH and Recital 7, Regulation 2015/282), and whether the Substance meets the criteria for a Substance of very high concern regarding endocrine disruption according to Art.57(f) of REACH as well as supporting the identification of appropriate risk management measures in the chemical safety assessment.

58 To investigate the properties of the Substance for these purposes, the highest dose level must be set on the basis of clear evidence of an adverse effect on sexual function and fertility, but no deaths (i.e., no more than 10% mortality; Annex I, Section 3.7.2.4.4. of the CLP Regulation) or severe suffering such as persistent pain and distress (OECD GD 19, paragraph 18) in the P0 animals.

59 In case there are no clear evidence of an adverse effect on sexual function and fertility, the limit dose of at least 1000 mg/kg bw/day or the highest possible dose level not causing severe suffering or deaths in P0 must be used as the highest dose level. A descending sequence of dose levels should be selected to demonstrate any dose-related effect and aiming to establish the lowest dose level as a NOAEL.

60 In summary: unless limited by the physical/chemical nature of the Substance, the highest dose level in P0 animals must be as follows:

(2) in case of clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals, the highest dose level in P0 animals must be determined based on such clear evidence, or

(3) in the absence of such clear evidence, the highest dose level in P0 animals must be set to be the highest possible dose not causing severe suffering or death, or

(4) if there is such clear evidence but the highest dose level set on that basis would cause severe suffering or death, the highest dose level in P0 animals must be set to be the highest possible dose not causing severe suffering or death, or

(5) the highest dose level in P0 animals must follow the limit dose concept.

61 You have to provide a justification with your study results demonstrating that the dose level selection meets the conditions described above.

62 Numerical results (i.e. incidences and magnitudes) and description of the severity of effects at all dose levels from the dose range-finding study/ies must be reported to facilitate the assessment of the dose level section and interpretation of the results of the main study.

5.3.4. Cohorts 1A and 1B

63 Cohorts 1A and 1B belong to the basic study design and must be included.

5.3.4.1. Histopathological investigations in Cohorts 1A and 1B

64 In addition to histopathological investigations of cohorts 1A, organs and tissues of Cohort 1B animals processed to block stage, including those of identified target organs, must be subjected to histopathological investigations (according to OECD TG 443, paragraph 67 and 72) if:

- the results from Cohort 1A are equivocal,
- the test substance is a suspected reproductive toxicant or
- the test substance is a suspected endocrine toxicant.

5.3.4.2. Splenic lymphocyte subpopulation analysis

65 Splenic lymphocyte subpopulation analysis must be conducted in Cohort 1A (OECD TG 443, paragraph 66; OECD GD 151, Annex Table 1.3).

5.3.4.3. Investigations of sexual maturation

66 To improve the ability to detect rare or low-incidence effects, all F1 animals must be maintained until sexual maturation to ensure that sufficient animals (3/sex/litter/dose) are available for evaluation of balano-preputial separation or vaginal patency (OECD GD 151, paragraph 12 in conjunction with OECD TG 443, paragraph 47). For statistical analyses, data on sexual maturation from all evaluated animals/sex/dose must be combined to maximise the statistical power of the study.

5.3.5. Cohort 3

67 The developmental immunotoxicity Cohort 3 needs to be conducted in case of a particular concern on (developmental) immunotoxicity.

68 Existing information on the Substance itself and substances structurally analogous to the Substance derived from the available studies show evidence of immunotoxicity including changes in haematological parameters and alterations in immune systems organ weight as spleen and thymus:

- In the sub-acute toxicity study with the Substance (2008, report [redacted]): Increased leucocytes counts (especially neutrophil fraction) at High Dose (both sexes) and Mid dose (females) are reported. There was no recovery for high dose males during treatment-free period. Lymphoid hyperplasia in the spleen at High Dose and Mid Dose in one male.
- In the sub-acute toxicity study with an analogue substance Cesium hydroxide monohydrate (CAS 35103-79-8), a significant reduction of the thymus weights relative to brain weight is observed at the Mid- and High Dose (-28 % and -32 % and respectively).
- In the sub-chronic study with an analogue substance Cesium Chloride (EC 222-492-8), an increase of the spleen weight for females at high dose for 13 weeks was reported and following 16 weeks of recovery. An increase of the extramedullary haemopoiesis was observed in males at the High Dose for 13 weeks. A decrease of

the thymus weight was also reported at the high dose and still obsverd following 8 weeks of recovery. Total leucocyte counts were increased in Week 13 for animals at the High dose, associated with increased neutrophil, lymphocyte, eosinophil and monocyte counts in both sexes.

- In the sub-chronic study with an analogue substance Cesium hydroxide monohydrate (CAS 35103-79-8), the mean thymus weight (absolute and relative to brain weight) in the male animals) and the absolute mean thymus weight in the female animals were less than the control in animals administered at the High Dose. It was acccompagnied by involution of severe degree in one female and of mild degree in one male.

69 To summarize, the available repeated dose toxicity studies indicate changes in haematological parameters and alterations in immune system organ weights such as spleen and thymus.

70 Therefore, the Substance itself and analogue substances show dysregulation of the immune system.

71 Because the immune system is under development in the post-natal period, the dysregulation of the immune system could have a more severe impact on developing organisms.

72 For the reasons stated above, the developmental immunotoxicity Cohort 3 must be conducted.

5.3.6. Further expansion of the study design

73 The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, and/or Cohorts 2A and 2B if relevant information becomes available from other studies or during conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Annex X, Section 8.7.3., Column 2. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in Guidance on IRs & CSA, Section R.7.6.

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 7 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

(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 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.

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).