EUROPEAN CHEMICALS AGENCY

Helsinki, 08 December 2020

Addressees
Registrants of strontium sulfate ec 231-850-2 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
26/04/2016

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Strontium sulphate
EC number: 231-850-2
CAS number: 7759-02-6

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

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***15 December 2022***.

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

A. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.; test method: OECD TG 443) in rats, oral route, specified as follows:
   - At least two weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting shall aim to induce systemic toxicity at the highest dose level;
   - Cohort 1A (Reproductive toxicity);
   - Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation which shall be followed to weaning;
   - Cohorts 2A and 2B (Developmental neurotoxicity).

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

Reasons for the request(s) are explained in the following Appendix:

- Appendix entitled "Reasons to request information required under Annex IX of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-

1000 tpa;

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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.

Approved[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[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 A: Reasons to request information required under Annex IX of REACH

1. Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.)

The basic test design of an extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is a standard information requirement under Annex IX to REACH, 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.

In your comments to the draft decision, you propose to perform an OECD TG 443 study, if at all, only following the basic design as an Annex X standard information requirement. You disagree on the triggers for performing the test at Annex IX.

You have provided a read-across adaptation using reproductive toxicity study with the analogue substance strontium ranelate (CAS no 5459-90-4; [redacted] 2001). The study was performed according to the ICH Harmonised Tripartite Guideline - Detection of toxicity to reproduction for medical products, Washington June 24, 1993; ICH Harmonized Tripartite Guideline, Addendum: Toxicity to male fertility, July 1996.

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

Adverse effects on reproductive organs or tissues or other concerns in relation with reproductive toxicity are observed in available studies. More specifically, there are indications of one or more modes of action related to endocrine disruption because in the sub-chronic study performed with the analogue substance strontium chloride (EC no 233-971-6), following a protocol similar or equivalent to OECD TG 408 (Kroes et al., 1977), the relative thyroid weights were statistically significant increased in males at 1200 ppm (corresponding approximately to 50 mg/kg bw/day) and 1400 ppm (by 33% ($p>0.01$) and 26% ($p>0.001$), respectively). There were no treatment-related changes in body weights in the study.

In the same study, the relative prostate weights were statistically significant decreased in males at 75 and 1200 ppm (by 28% ($p>0.01$) and 21% ($p>0.05$), respectively), and the relative pituitary weights were statistically significant decreased in females at 75 and 1200 ppm (by 16% ($p>0.05$) and 24% ($p>0.01$), respectively). Although there was no clear dose-response for the decrease in relative prostate and pituitary weights, the findings support triggering of the Extended one-generation reproductive toxicity study at Annex IX.

ECHA considers that the criteria in Column 1, Annex IX, section 8.7.3 are met because existing information shows evidence of deviations in hormonally sensitive organs in both sexes without notable general toxicity (see further ECHA Guidance R.7a, Appendix R.7.6–2 EOGRTS Study Design).

Regarding the mean relative prostate weight, you state in your comments to the draft decision that the statistically significant result was not biologically significant due to lack of dose response and histopathological findings. ECHA agrees that histopathological findings are important and indeed sensitive markers. However, you have provided suggestions but not provided conclusive argument excluding a concern; indication in prostate weight could be considered as supportive information among other changes seen in hormonally sensitive organs.

Regarding the mean relative pituitary weight seen in females, you state in your comments to the draft decision that the statistical significance of mean relative pituitary weights without histopathological observations were related to relatively high control values in the study and not considered biologically significant. However, ECHA considers that data from in-study control animals should be used, and that the absence of appropriate historical control values does not invalidate the study. There is a decreasing trend in organ weights in treated females which may indicate one or more modes of action related to endocrine disruption and therefore supports triggering together with other changes seen in hormonally sensitive organs.

For a response to your comments to the draft decision related to changes in thyroid weights please see further under "Cohorts 2A and 2B" below.

Based on the above ECHA retains the view that an EOGRT study according to OECD TG 443 as specified in this decision is an information requirement for your registration, because Column 1 criteria at Annex IX, section 8.7.3 are met.

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

[1] have adequate and reliable coverage of the key parameters addressed in the corresponding test methods referred to in Article 13(3), in this case an extended one generation reproductive toxicity study (OECD TG 443) which includes the following key parameters:
   a. full histopathology of organs and tissues (P0 and F1)

[2] cover an exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3), in this case (OECD TG 443) which includes, at least exposure of 10 weeks prior to pairing for P0 animals unless the Cohort 1B animals are mated to produce the F2 generation, which is followed to weaning.

In the provided study (2001, ICH guideline):

- For reproductive organs only weights were recorded and histopathology was only investigated from F0 males for epididymis and testes.
- F0 males were exposed for 28 days prior to pairing until six days after the treated females started littering. Females were exposed from day six of gestation until day twenty of lactation. The exposure in your study is considerably shorter than as required by OECD TG 443.

Regarding the study on strontium ranelate by ICH you argue in your comments to the draft decision that "*Since this study investigated the effects on both male and female fertility as well as embryo-fetal and pre-/postnatal development, it was used to cover the data requirements on developmental toxicity and toxicity to reproduction. For this reason the information on test design and results has been provided in the IUCLID endpoints for Developmental toxicity (Subgroup A and C) and Toxicity to Reproduction (Subgroup B and D). This might have led to the erroneous conclusion from ECHA that female fertility and pre- and postnatal development were not included in the available study.*"

ECHA has taken the complete study design into consideration. Nevertheless, as also concluded by the Expert statement on reproduction toxicity testing of strontium carbonate by [redacted], the provided ICH reproduction toxicity study does not cover the exposure duration of 2 weeks prior to pairing for females as required in the standard information requirement requested for this endpoint. Therefore, this study cannot be considered to provide equivalent information as requested by the OECD TG 443.

In the statement by [redacted] the experts agrees with ECHA that the study according to ICH guideline ([redacted] 2001) does not fulfil the information requirements as in OECD TG 443: *"As exposure of P0 was limited compared to the exposure design of the EOGRTS and the F1 generation was not directly exposed, it is agreed with ECHA that information on reproduction toxicity is not according to current data requirements."* Furthermore, the experts agree with ECHA that the exposure period for females is too short in order to investigate female fertility as according to the OECD TG 443. Therefore, the experts conclude that *"an EOGRTS should be performed starting 10 weeks premating – unless F2 is triggered - and with exposure of the F1 generation, which shall be followed to week 13 (Cohort 1A) and week 14 (Cohort 1B) of age and including full histopathological examination of the required organs and tissues."*

In your comments to the draft decision, you submitted a read-across justification. As the read-across approach under Annex XI, Section 1.5 in the draft decision was rejected based on adequacy and reliability of source studies, only and there is no information in the draft decision on other aspects of the submitted read-across justification, this information is therefore considered not relevant.

Therefore, the provided study, which specifically investigates male fertility, does neither investigate female fertility nor post-natal developmental toxicity until adhulthood.

Therefore, your adaptation is rejected and the information requirement is not fulfilled.

The specifications for the study design

Premating exposure duration and dose-level setting

The length of premating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.
A 2-week premating exposure duration for P0 animals is sufficient for your Substance, because the F1 animals of Cohort 1B are mated to produce the F2 generation and, thus, the premating exposure duration will be 10 weeks for these Cohort 1B animals.

Therefore, the requested premating exposure duration is at least two weeks.

In order to be compliant and not to be rejected due to too low dose levels, the highest dose level shall aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose level selection should be based upon the fertility effects. A descending sequence of dose levels should be selected in order to demonstrate any dose-related effect and to establish NOAELs.

If there is no relevant data to be used for dose level setting, it is recommended that range-finding results are reported with the main study.

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

Cohorts 1A and 1B

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

Extension of Cohort 1B

If the Column 2 conditions of 8.7.3., Annex IX are met, Cohort 1B must be extended.

The extension is inter alia required, if the use of the registered substance is leading to significant exposure of consumers and professionals (column 2, first paragraph, lit. (a) of Section 8.7.3., Annex IX) and

- there are indications of one or more relevant modes of action related to endocrine disruption from available *in vivo* studies or non-animal approaches (column 2, first paragraph, lit. (b), third indent of Section 8.7.3., Annex IX).

The use of the Substance reported in the joint submission leads to significant exposure of consumers and professionals because the Substance is used by professionals in paints and coatings (e.g ERC 8c,f; PROC 2 and 3; 8a,b; 9-11; 13; 24; and 26), and by consumers in paints and coatings (ERC 8c,f).

Furthermore, there are indications of one or more modes of action related to endocrine disruption based on the organ weights of hormonally sensitive organs (thyroid, prostate and pituitary)as described above in the sub-chronic study performed with the analogue substance strontium chloride (EC no 233-971-6), following a protocol similar or equivalent to OECD TG 408 (Kroes et al., 1977).

In your comments to the draft decision, you agree that in the Kroes et al. (1977) study there were some statistically significant deviations of relative organ weights.

However, you further comment that "*an effect on relative thyroid weight observed in males only is not considered a scientific justified trigger to include an F2 generation or a developmental neurotoxicity cohort in an EOGRTS. In case of an endocrine disruptive effect in P0-animals, this would have consequences for the F1 generation. The addition of an F2 generation is in these cases not of added value.*"

Regarding the mean relative prostate weight and the mean relative pituitary weight noted in the study by Kroes et al. (1977) we refer to the response to your comment under A.1. above. For a response to your comments related to changes in thyroid weights please see further under "Cohorts 2A and 2B" below.

In the available Kroes et al. (1977) study, which is similar to OECD TG 408, the reproductive and endocrine organs have been examined in adult male and non-pregnant adult female animals. ECHA considers that it is important to expose all the developmental stages of the sperm and follicles in order to be able to evaluate any potential adverse effect of thyroid toxicity on fertility.

Furthermore, ECHA disagrees with the assumption that "*In case of an endocrine disruptive effect in P0-animals, this would have consequences for the F1 generation. The addition of an F2 generation is in these cases not of added value.*" In this respect, ECHA emphasises that "*The extension of the Cohort 1B (mating of the Cohort 1B animals to produce the F2 generation) provides information on the fertility of the offspring, (i.e. the F1 generation), which has been exposed already during primordial germ cell and germ line formation, preimplantation, in utero and postnatal periods. The fertility of Cohort 1B animals, if mated, is evaluated after exposure of full spermatogenesis*" (ref to ECHA Guidance, page 475).

Therefore, ECHA concludes that Cohort 1B must be extended to include mating of the animals and production of the F2 generation, because the uses of the Substance are leading to

significant exposure of professionals and consumers and there are indications of modes of action related to endocrine disruption from the available Kroes et al. study.

In your comments to the draft decision, you propose to perform an EOGRTS starting with a 10-week premating period and with exposure of the F1 generation, which shall be followed to week 13 (Cohort 1A) and week 14 (Cohort 1B) of age and including full histopathological examination of the required organs and tissues. According to your proposal, extension to F2 (and DNT Cohort) would not be triggered by the current results.

For your Substance the criteria for inclusion of extension of Cohort 1B are met. This are concern-based criteria including exposure and toxicity, and meeting the criteria means that the concern is high that reproductive toxicity of the offspring may be affected. Regarding 10 weeks premating exposure duration, it would not produce information on reproductive toxicity of the offspring and cannot replace the extension of Cohort 1B. On the other hand, 10 weeks premating exposure duration is not requested for P0 generation because there is no concern for accumulation and 10 weeks premating exposure duration is covered before mating F1 animals.

Based on the above ECHA retains the view that an extension of the Cohort 1B is information requirement for your registration, because the Column 2 criteria of Annex X, section 8.7.3 are met.

Therefore, Cohort 1B must be extended.

The F2 generation shall be followed to weaning allowing assessment of nursing and lactation of the F1 parents and postnatal development of F2 offspring. Investigations for F2 pups must be similar to those requested for F1 pups in OECD TG 443 and described in OECD GD 151[2]. It is recommended to aim to 20 litter per dose group in order to have similar statistical power for investigations than in P0 generation.

Cohorts 2A and 2B

The developmental neurotoxicity Cohorts 2A and 2B need to be conducted in case of a particular concern on (developmental) neurotoxicity.

Existing information on the analogue substance strontium chloride (EC no 233-971-6) derived from a sub-chronic study following a protocol similar or equivalent to OECD TG 408 (Kroes et al., 1977), show evidence of thyroid toxicity in males. Relative thyroid weights were statistically significant increased at 1200 and 1400 ppm (by 33% ($p>0.01$) and 26% ($p>0.001$), respectively). There were no treatment-related changes in body weights in the study. Thyroid toxicity rises a particular concern on developmental neurotoxicity (ECHA Guidance R.7a).

ECHA considers that the criteria to include Cohorts 2A and 2B are met, because existing information shows evidence of deviations in hormonally sensitive organs in both sexes without notable general toxicity (see further ECHA Guidance R.7a, Appendix R.7.6–2 EOGRTS Study Design).

In your comments to the draft decision, you argue that "*Inclusion of a developmental neurotoxicity cohort in the EOGRTS is triggered by effects on thyroid and thyroid hormones*

[2] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2013)10&doclanguage=en

in repeated dose toxicity studies. As in the repeated dose toxicity study increased thyroid weight was restricted to high dose males only, inclusion of a DNT cohort in the EOGRTS is not scientifically justified. Developmental neurotoxicity may be linked to disturbed thyroid hormone regulation in females during pregnancy, but male thyroid effects have no direct link to endocrine disrupting reproductive effects, i.e. effects on neurodevelopment in the offspring."

In relation to historical controls you explain that the applicant has approached the laboratorium that performed the 90-day study for historical control data. However, the laboratorium did not have historical control data for the Wistar rat treated around 1977 anymore. A literature search for historical control data did also not yield relevant information. Therefore, historical control data of the Wistar rat used by [redacted] were collected from the old database Toxdata going back to 2014 and the new database Provantis (2019)." Based on this information you conclude that the reported value of the relative thyroid weight of the control group of 0.0054 is quite low compared to all values of the treated groups (and is just outside the P95 limit of the [redacted] Toxdata historical control data).

You also state that "*...developmental neurotoxicity has been examined in the available reproduction study with strontium ranelate ([redacted] 2001)... No effects on F1 breeders was seen on any of the developmental neurotoxicity parameters determined. Based on these considerations, inclusion of developmental neurotoxicity cohorts is considered not required (no scientific justification).*"

ECHA notes that according to ECHA Guidance R.7a , Appendix R.7.6–2 EOGRTS Study Design, the statistically significant higher mean relative thyroid weights in males are relevant and an acceptable trigger from a repeated dose toxicity study. Furthermore, treated females may not have been unaffected as there was also a trend in increased mean relative thyroid weights also in treated females compared to controls.

You agreed that thyroid hormones are essential for normal brain development (Mughal et al, 2018), but "*only effects on female thyroid during pregnancy can influence developmental neurotoxicity of the pups*". In your comments you refer to the study with strontium ranelate [redacted] 2001) stating that the developmental neurotoxicity studies partly cover the parameters required for OECD TG 443.

ECHA notes however that the [redacted] 2001 study uses a different exposure period for P0 and F1 animals compared to the OECD TG 443 and therefore the results do not fully cover the study design for this endpoint. Furthermore, it is important to acquire information on similar exposure duration to both sexes, and especially, exposure on females during pregnancy.

ECHA acknowledges that the lack of individual data, standard deviations and historical control data is challenging, but the study does provide reliable comparison with a control group, and this is sufficient to trigger the cohort. Further, ECHA notes that the historical control data should always reflect the same strain, same laboratory, and the same study design/duration, collected from fairly recent studies (± 2 years to the study year). For these reasons, the historical control data you have referred to (Toxdata, 2014; Provantis, 2019) does not provide relevant information for the study under consideration.

ECHA concludes that available data indicate that, in the absence of overt general toxicity, the study by Kroes 1977 demonstrate a concern for thyroid toxicity. A concern for reproductive (and developmental) toxicity has therefore been identified and a need for further information

is triggered. Taken together, ECHA maintains its opinion that the mentioned effects are indicative of mode(s) of action related to endocrine disruption.

Therefore, the developmental neurotoxicity Cohorts 2A and 2B need to be conducted.

The study must be performed in rats with oral[3] administration.

Further expansion of the study design

No triggers for the inclusion of Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including Cohort 3 if relevant information becomes available from other studies or during the conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex IX. 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 ECHA Guidance[4].

[3] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[4] ECHA Guidance R.7a, Section R.7.6.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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[5].

B. 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 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[6].

[5] https://echa.europa.eu/practical-guides
[6] https://echa.europa.eu/manuals

Appendix C: 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 5 June 2019.

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

ECHA took into account your comments and did not amend the request(s) or the deadline.

Extension of deadline

In your comments to the draft decision, you point out that registrants of several Joint Submissions have received draft decisions from ECHA with requests for studies on strontium and its salts. To be able to A) comply with Article 25 (1) and develop and justify a read-across approach, B) discuss with the CRO responsible to develop the study, and C) coordinate the activities of registrants of several Joint Submissions, you request an extension of the deadline for this decision from 24 to 30 months. ECHA disagrees with your request because regarding A) It is in your discretion to generate and provide the necessary supporting information in order to justify your read-across adaptation. If you do so, you are responsible for demonstrating the fulfilment of the requirements of Section 1.5 of Annex XI to REACH. If it fails and the resulting data does not support, or even contradict, your read-across hypothesis, you remain responsible for complying with this decision by the set deadline and regarding B) and C) the discussions with a contract organisation and the coordination of activities of registrants of several Joint Submissions are your responsibility. In any case, ECHA considers the deadline of 24 months sufficiently covers these activities in order to fulfil the standard information requirements. Therefore, ECHA did not extend the deadline of the draft decision.

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 D: List of references - ECHA Guidance[7] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[8]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[9]

[7] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[8] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[9] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix E: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.