

Helsinki, 12 March 2020

**Addressees**

Registrants of [REDACTED] listed in the last Appendix of this decision

**Date of submission for the jointly submitted dossier subject of this decision**  
20/06/2019

**Registered substance subject to this decision, hereafter 'the Substance'**

Substance name: Diantimony trioxide

EC number: 215-175-0

CAS number: 1309-64-4

**Decision number:** [Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/D)]

**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 **20 December 2021**.

**A. Requirements applicable to all the Registrants subject to Annex X of REACH<sup>1</sup>**

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method OECD TG 414) in a second species (rabbit), oral route with the Substance.

**Conditions to comply with the requested information**

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

The Appendices state the reasons for the requests for information to fulfil the requirements set out in Annex X of REACH.

The test material used to perform the required studies shall be selected and reported in accordance with the specifications prescribed in Appendix Observations and technical guidance.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

## **Appeal**

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: <http://echa.europa.eu/regulations/appeals>.

Approved<sup>1</sup> under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

---

<sup>1</sup> 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 for the requests to comply with Annex X of REACH**

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier at tonnage above 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII-X to the REACH Regulation.

**1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species;**

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

For the first species, you have provided a Pre-natal developmental toxicity (according to OECD TG 414) conducted in rats with the substance.

For the second species, you have adapted this information requirement by using weight-of-evidence according to Annex XI, Section 1.2. and by using read-across approach according to Annex XI, Section 1.5..

In the initial submission, on which the draft decision was based and provided to you for commenting, you did not provide any documentation for your weight-of-evidence and read-across approach.

In your comments and your updated registration you have provided a justification for your weight-of-evidence and read-across approach. You also refer to version 2 of your revised documents entitled "[REDACTED]" included in section 13 of your submission on 20 June 2019 .

In your revised justification for the weight-of-evidence adaptation, the following independent sources of information (lines of evidence) are presented:

With regard to pre-natal developmental toxicity Table 2 of your justification document refers to three PNDT studies:

- i. Results from Pre-natal developmental toxicity study in rats (OECD TG 414) with the Substance (Sb<sup>3+</sup>substance; 215-175-0) by the inhalation route ([REDACTED], 2003).
- ii. Results from Pre-natal developmental toxicity study in rabbits (OECD TG 414) conducted with antimony metal (Sb; EC 231-146-5) via the oral route ([REDACTED] 2017, presumably [REDACTED] (2017).
- iii. Results from Pre-natal developmental toxicity study in rats (OECD TG 414) substance sodium hexahydroxyantimonate (SHHA; EC 251-735-0) (Sb<sup>5+</sup>substance) by the oral route ([REDACTED] 2014).

You provide additional lines of evidence consisting of:

- iv. Information from studies conducted in the rat of Sb<sup>5+</sup> substances administered by subcutaneous ([REDACTED], 2006; Coelho et al, 2014) or intraperitoneal injection ([REDACTED] 1991)
- v. Information on Sb levels in occupationally exposed humans ([REDACTED], 2017)

**A. Assessment of the weight-of-evidence adaptations, in light of the requirements of Annex XI, Section 1.2.**

In the update you have provided the following justification for your weight-of-evidence

ECHA understands that based on the lines of evidence you argue that there is sufficient weight of evidence from studies investigating parameters of developmental toxicity to show that Sb compounds administered via physiological routes of exposure do not produce developmental toxicity independent of maternal exposure. You further argue that higher levels of systemic exposure to antimony compounds achieved through non-physiological route of administration also demonstrate that there are not severe effects on developmental toxicity.

We assessed the new information you provided and identified the following issue(s):

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

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory information requirement. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Relevant information that can be used to support a weight of evidence adaptation for the information requirement of a pre-natal developmental toxicity study in a second species (EU B.31/OECD TG 414) are in particular the following information on a second species: investigations to detect pre-natal developmental toxicity (including growth, survival, external, skeletal and visceral alterations) and maternal toxicity. Sources of information i, iii and iv do not provide relevant information as the studies have been conducted in rat (first species) and not rabbit (second species).

Source ii provides relevant information in a second species. However, it has the deficiency that is affecting its reliability. Specifically, it has been conducted with an analogue substance for which the read across is rejected (see below).

Regarding point v., a weight of evidence adaptation under Annex XI, Section 1.2. establishes whether a substance has a particular dangerous (hazardous) intrinsic property. Indication of low human exposure does not contribute to the assessment of whether a substance has that a particular dangerous (hazardous) property. Therefore, this element cannot be used as part of weight of evidence adaptation according to Annex XI, Section 1.2.

It is not possible to conclude based on any source of information alone or considered together whether your substance has or has not the potential to cause developmental toxicity in a second species.

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

#### **B. Assessment of the Grouping of substances and read-across approach, in light of the requirements of Annex XI, Section 1.5.**

ECHA understands that you intend to apply a grouping and read across approach as part of your weight of evidence using a read-across hypothesis which is based on the formation of common (bio)transformation products. ECHA understands that the properties of your

Substance are predicted to be quantitatively equal to those of the source substance.

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 (addressed under 'Scope of the grouping'). 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.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

### **Scope of the grouping**

In the justification document you report that you have grouped antimony and antimony compounds. You have further identified three sub-groups according to valency and other parameters such as in vitro gastric bioaccessibility. For Sub-group Sb<sup>3+</sup> you have used valency of +III and bioaccessibility to define the group which comprises the following substances:

Antimony (EC 231-146-5, CAS 7440-36-0)  
Diantimony trioxide (ATO, EC 215-175-0, CAS 1309-64-4);  
Antimony sulphide (ATS, EC 215-713-4, CAS 1345-04-6);  
Antimony trichloride (ATC, EC 233-047-2, CAS 10025-91-9); and  
2,5,7,10,11,14-hexaoxa-1,6-distibabicyclo[4.4.4]tetradecane (ATEG, EC 249-820-2, CAS 29736-75-2)

You provide the following reasoning for the grouping the substances: the substances show limited release of Sb<sup>3+</sup> ion and have moieties or impurities which do not have a greater systemic toxicity profile than Sb<sup>3+</sup> ion. You consider that the moieties are either essential elements, with none/negligible reproductive toxicity or normal metabolites which are readily metabolized. You exclude substances if there is evidence that the final speciation of released (oxygen)ions is not comparable.

ECHA understands that this is the applicability domain of the Sb<sup>3+</sup> grouping and will assess your predictions on this basis.

#### **A. Predictions for properties**

ECHA understands that you intend to apply a grouping and read across approach as part of your weight of evidence using a read-across hypothesis which is based on the formation of common (bio)transformation products. Namely, that the above grouping are substances which release Sb 3+ ions which may be available for absorption and drive the toxicity profile of the substances. ECHA understands that the properties of your Substance are predicted to be quantitatively equal to those of the source substance. You further consider that the difference in moieties can be omitted for the purposes of read-across.

ECHA notes the following shortcoming(s) with regards to prediction(s) of toxicological properties.

### Missing supporting information

Annex XI, Section 1.5 of the REACH Regulation states that “physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)”. For this purpose “it is important to provide supporting information to strengthen the rationale for the read-across”<sup>2</sup>. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on other category members.

Supporting information may include toxicokinetic information on the formation of the common compound, bridging studies to compare properties of the substance and source substance.

#### *Missing supporting information on the formation of common compound*

As indicated above, your read-across hypothesis is based on the (bio)transformation of the category members to a common compound(s). In this context, information characterising the, rate and extent of the transformation of the category members is necessary to confirm the formation of the proposed common biotransformation product and to assess the impact of the exposure to the parent compounds.

In your justification document, you refer to recent aqueous solubility data and *in vitro* bioelution assays conducted using artificial gastric fluid for your antimony substances (████████, 2019).

The bioaccessibility data show that for Group Sb<sup>3+</sup> it is antimony metal powder which is most soluble and has highest ‘oral’ bioaccessibility.

ECHA notes that it cannot currently be assessed whether the bioaccessibility results can be used as a basis for predicting *in vivo* toxicity by the oral route. Further information would be needed to confirm the relevance of the *in vitro* bioaccessibility results to predicting *in vivo* toxicological properties following the oral route of exposure. Such information to allow comparison between the substances could include information from *in vivo* toxicokinetics and information on the toxicodynamic properties of the substances in your Sb<sup>3+</sup> grouping.

You have not provided any *in vivo* validation of your bioaccessibility based approach; therefore it is impossible to translate bioaccessibility into *in vivo* bioavailability, which is the parameter of interest, for read-across predictions. Furthermore, in your justification document you refer to a draft document (████████, 2017) in which it is reported that as a generalization uptake efficiency is <1%. However, in that document differences in absorption were also reported for some substances in your Sb<sup>3+</sup> group (for example ATO versus ATC). The authors consider that differences in the solubility and the counter ion of the antimony compound(s) impact absorption *in vivo*.

ECHA considers that you have not addressed whether differences in absorption impact your read across hypothesis and that *in vivo* relevance of the bioaccessibility model can not be confirmed.

#### Missing supporting information to compare properties of the substances

As indicated above, your read-across hypothesis is based on the assumption that the

---

<sup>2</sup> Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

ECHA notes that you have provided in your justification document reference to two developmental toxicity studies conducted according to OECD 414 (with GLP) for substances in your Sb<sup>3+</sup> grouping.

In your justification document you refer to a study by [REDACTED] (1987) on ATC. However, these data are not present in your registration and cannot therefore be taken into account.

ECHA considers that [REDACTED] 2003 and [REDACTED] 2017 constitute your source studies for the grouping and read across approach for the Sb<sup>3+</sup> grouping.

In the justification document you refer to the results of an OECD 414 GLP study of the Substance (ATO) in rat by inhalation ([REDACTED], 2003) in which no effects on parameters of development were observed at the highest exposure concentration (6.3 mg/m<sup>3</sup>) while adverse localised effects in the lung (NOAEL, 2.6 mg/m<sup>3</sup>) were observed in parental animals.

In the justification document you refer to a pre-natal developmental toxicity study (OECD 414, GLP) of the analogue substance "antimony powder", in rabbit by oral gavage at doses of 30, 100 and 230/300 mg/kg bw/day, in which adverse effects on parameters of developmental toxicity (reduced foetal weights, retarded ossification) were seen in the presence of maternal toxicity (please also see below section *Information on study design*). In your justification document, you consider that the information on the role of maternal toxicity on the developmental effects is uncertain and you speculate that antimony may influence calcium metabolism and ossification as a possible mode of action for the retardation effect.

ECHA considers that you have provided a pre-natal developmental toxicity study for one substance on one species and another study on another substance in a different species. Furthermore, the studies in different species appear to show different toxicological profiles. Therefore, it is not possible to draw a direct comparison of the toxicological profiles as there may be a species specific effects.

In addition, you do not provide adequate information from studies of comparable design, for example, bridging studies, which allow side-by-side comparison of the developmental toxicity properties of the Substance with other substances in your Sb<sup>3+</sup> grouping.

You therefore have no basis to compare the properties of the Substance with those of the source substances. In the absence of such information, you have not established that the Sb<sup>3+</sup>-category members are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

In addition you have provided source data on other analogue substances which are not part of your Sb<sup>3+</sup> grouping (For studies ii., iv, and v).

Annex XI Section 1.5 requires that whenever a read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summaries of the source studies.

You have not provided documentation as to why this information is relevant for your substance. In the absence of such documentation ECHA cannot verify that the properties of your substance can be predicted from these substances. In addition, you consider them unreliable as they have methodological deficiencies and/or miss key information to interpret the results and/or also conducted via non-physiological routes of exposure which "*...would not be relevant for the purpose of REACH hazard assessment and classification...*". ECHA agrees with your conclusion.

Therefore the requirements of Annex XI, Section 1.5 are not fulfilled with respect to all read-across data provided and your adaptation is rejected.

### C. Your comments on your testing programme

In your comments you refer to testing programme provided also as a matrix. Under this programme you intend to generate information strengthen your read across and weight of evidence approaches. You plan to rank Sb substances as to lowest and greatest oral bioavailability and identify "ideal" substances for further investigation, conduct 2 week oral dose range finder/tolerability studies, conduct oral reproductive/developmental toxicity screening studies (OECD 422) on one or two substances per group and then consider need of any pre-natal developmental toxicity study(ies) (OECD 414).

Concerning the sequential testing ECHA notes that you are planning a series of studies in order to substantiate the read across hypothesis and generate the necessary supporting information and source studies to support your adaptations.

ECHA notes that it is at the discretion of the registrant to undertake additional testing to substantiate your read-across but the outcome of the testing programme may or may not confirm your hypothesis. The timeline in the decision allows for sequential testing of OECD 421/2 and OECD 414 studies.

#### Information on study design

In order to be compliant and enable concluding if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in two species.

The test in the first species was carried out by using a rodent species (rat).

A PNDDT study according to the test method OECD TG 414 shall be performed in rabbit as preferred non-rodent species.

In your comments on the draft decision you suggest to use the mouse as the second species due to concerns related to the rabbit species.

You have provided the following justification for changing the preferred second speciesL "*rabbits will typically not eat powdered diet, so only re-pelleting the diet or gavage would be possible*". You further refer to the "*confounding factor of gastric irritation with death and abortions at the high dose*" observed in the [REDACTED] (2017) study. Finally, you refer to a ECHA poster dated September 2018 "*accepting that rabbits seem to be particularly sensitive to gastric irritation*" [...].

We have assessed the information provided in your comments on the draft decision and identified the following issues:



The guideline considers rabbit as the preferred non-rodent species. If another species is used it must be justified. Such justification has to provide substance specific reasons why using the other species is necessary.

You explain that *"Rabbits will typically not eat powdered diet, so only re-pelleting the diet or gavage would be possible. Our enquiries indicate that re-pelleted diet can only be provided by a single CRO (██████████), only in ██████████ Experience also indicates that even where the diet is pelleted, rabbits may still refuse to eat, confounding the effects of the test material on study outcome."*

ECHA agrees with you that rabbits do not eat powdered diet and pelleting is necessary for a dietary study on rabbits. ECHA notes that you were able to identify at least one test laboratory which is able to re-pellet diet and you might further consider other facilities offering pelleting services to produce pellets for a dietary study. With respect to your claim that rabbits might even reject eating pellets, ECHA notes that pelleted diet is standard rabbit diet; the observation that rabbits refuse to eat pellets results usually from other factors such as stress, but not from pellet-shaped diet.

You further explain that *"Gavage administration, however, typically yields a spike concentration curve toxicokinetics profile (compared to the flatter, more even, area under the curve for dietary), which is not an ideal model for human exposure, and can be further complicated by the rabbit's semi-ruminant digestion, reliant on coprophagy, which may also alter the toxicokinetic profile."*

ECHA notes that your claim of spiking is speculative because you have not shown that the registered substance has such toxicokinetic profile after gavage dosing. Furthermore, you have not provided any evidence showing that coprophagy indeed results in altered toxicokinetics. In this respect, ECHA emphasises that in hazard assessment, the intrinsic properties of the Substance need to be elucidated. Spiking after gavage dosing is such intrinsic property which is of interest for hazard assessment and such information can be used to improve human risk assessment.

ECHA furthermore notes that the ██████████ (2017) study in rabbits "██████████ (2017)" you refer to in your comments is not provided in the dossier. However, ECHA understands that you may intend to refer to the ██████████ (2017) study in rabbits "██████████ (2017)" (oral, gavage), available in the registration dossier. Due to this inconsistency ECHA is unable to respond to your comment or make a judgement on the study results you refer to. Nevertheless and for the sake of clarity, ECHA would like to note that for the ██████████ study (2017) in rabbits using an analogue substance and for which the read-across approach is rejected the high dose was causing excessive toxicity (i.e. mortality, BW reduction, changes in GI tract etc). However, the low and mid dose did not show similar changes and are dose levels which can be used for hazard assessment. ECHA observes that it cannot be confirmed that the registered substance would exert similar excessive toxicity at the highest dose level which was observed in ██████████ 2017 for the read-across substance. Even if the registered substance would show similar toxicity, adjusting dose levels seems possible to investigate pre-natal developmental toxicity. However, your assumption that *"rabbits may not be the optimal second species for Sb oral studies, and it is proposed that mice may provide a better model"* is remains speculative in absence of supporting evidence.

Finally, regarding your claim that *"rabbits seem to be particularly sensitive to gastric irritation"* it is discussed in the poster that the available information is currently too limited to derive conclusions on the influence of GI toxicity on developmental toxicity and that a

dose-range-finding study investigating such effects should be conducted, to conclude on the suitability of the rabbit as test species.

Based on the deficiencies described above taken together, it cannot be confirmed that the rabbit is an inadequate animal species for testing the Substance. Therefore, use of another rodent species such as mouse instead of the default non-rodent species rabbit is not justified.

ECHA considers that both re-pelleting the diet and administration via gavage are possible routes of administration in rabbits.

Hence, as your comments were not supported by adequate evidence and documentation the study shall be performed with oral<sup>3</sup> (gavage or dietary) administration of the Substance in rabbits.

**Appendix B: Procedural history**

The compliance check was initiated on 22 January 2019.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

Among the comments you provided, some comments were of generic nature, i.e. "*Parallel Compliance Check and Substance Evaluation processes*" and "*commitment to minimization of (vertebrate) animals testing*". These comments did not refer to the requests in the decision or to their justifications, but to other general considerations. Accordingly, ECHA explained in a separate communication how they were taken into account.

You were notified in the draft decision that ECHA does not take into account any dossier updates after the draft decision was sent on 18 April 2019. You updated your registration on 20 June 2019. Given the exceptional circumstances, ECHA has taken into account the above dossier update when processing this decision and assessed the revised justification documents and the additional study records. ECHA did not amend the request(s).

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 C: Observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.
2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

### 4. Test material

#### Selection of the test material(s)

The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

While selecting the test material you must take into account the impact of each constituent/impurity is known to have or could have 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.

#### Technical reporting of the test material

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values and other parameters relevant for the property to be tested, in this case crystal structure/phase and particle size distribution. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPOD dossiers" on the ECHA website (<https://echa.europa.eu/manuals>).

### 5. List of references for the Guidance documents<sup>4</sup> referred to in this decision

#### 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 in this decision.

#### 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.

---

<sup>4</sup> <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

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.

## **6. Test guidelines, GLP requirements and reporting**

According to Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

According to Article 13(4) of REACH ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

According to 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: 'How to report robust study summaries'<sup>5</sup>.

---

<sup>5</sup> <https://echa.europa.eu/practical-guides>

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

<b>Registrant Name</b>	<b>Registration number</b>	<b>(Highest) Data requirements to be fulfilled</b>
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]