~~Confidential~~

Helsinki, 19 April 2023

Addressees
Registrants of Titanium Dioxide - JS TDIC as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
11/03/2022

Registered substance subject to this decision ("the Substance")
Substance name: Titanium dioxide
EC number: 236-675-5

Registered form subject to this decision ("the Set of Nanoforms")
Name of set of similar nanoforms: [redacted]

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 requires that you submit the information needed to bring the registration of the "[redacted]" (hereafter, "the Set of Nanoforms") into compliance with the information requirements listed below by the deadline of ***26 February 2024***.

1. **Characterisation of the clearly defined boundaries of the set of nanoforms in accordance with the parameters set out in the points 2.4.2 to 2.4.5 of Annex VI**

2. **Justification demonstrating that a variation within the boundaries of the set of nanoforms does not affect the hazard assessment, exposure assessment and risk assessment of the similar nanoforms in the set**

In principle, each different nanoform covered by a registration must be reported and assessed individually. By derogation, it should be possible to group nanoforms of the substance with similar characterisation parameters in a set of similar nanoforms. Consequently, the incompliance(s) described above can be resolved by implementing one of the following actions:

1) by reporting and assessing each single nanoform covered by the currently reported set. This implies:

   a. the characterisation of each nanoform in accordance with section 2.4.2 to 2.4.5 of Annex VI; and

   b. the submission of information on hazards, exposure and risk specific to each nanoform; and

   c. the reporting of the above information in such a manner that it is clear which hazards, exposure and risk information pertains to each nanoform.

2) by correcting the incompliances of the currently reported set.

3) by grouping the nanoforms covered by the currently reported set in different sets of similar nanoforms. This implies that:

    a. the boundaries of each set are clearly defined in the parameters in the points 2.4.2 to 2.4.5;

    b. justification is provided for each set of nanoforms demonstrating that the hazard, exposure and risk assessment of the nanoforms in the set can be performed jointly.

    c. the reporting of the above information in such a manner that it is clear which hazards, exposure and risk information pertains to each set of nanoforms.

4) by reporting some of the nanoforms covered by the current set as single nanoforms and grouping the other nanoforms covered by that set in one or different sets of nanoforms. Each reporting approach would have to fulfil the conditions set out respectively in option 1) and option 3).

Under Annex VI, a set of similar nanoforms is a group of nanoforms defined by clear boundaries. Based on the information currently in the dossier (Section 2.4.2 to 2.4.5), ECHA cannot determine the actual nanoforms that the Registrants agreed to cover within the set. Only the Registrant of each nanoform in the set knows the characterisation of that nanoform. Therefore, it is each Registrant's exclusive responsibility 1) to ensure that the boundaries of the set of similar nanoforms are clearly defined in accordance with the points 2.4.2 to 2.4.5 of Annex VI and 2) to justify and demonstrate that a variation within the boundaries of the set of nanoforms does not affect the hazard assessment, exposure assessment and risk assessment of the similar nanoforms in the set.

Consequently, if the information eventually submitted by a Registrant does not enable ECHA to verify that the information in the dossier complies with the requirements set out in this decision, the set of nanoforms will not be considered valid. As a result, all the nanoforms that the set was supposed to cover will be considered as not registered. This could result in national enforcement authorities deciding on possible enforcement actions. The reasons of this decision are set out in Appendix A. The procedural history is described in Appendix B.

The scope of this compliance check decision is limited to the standard information requirements of Annex VI applicable to the set of similar nanoforms.

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.

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 to request information on the submitted set of similar nanoforms under Annex VI of the REACH Regulation
Appendix 2: Procedure
Appendix 3: Addressees of this decision and their corresponding information requirements

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

Appendix 1: Reasons for the decision

1. Reasons to request information on the submitted set of similar nanoforms under Annex VI of the REACH Regulation

1.1. Characterisation of the clearly defined boundaries of a set of similar nanoforms in accordance with the parameters set out in the points 2.4.2 to 2.4.5 of Annex VI (introduction to Annex VI)

1 Annex VI of REACH requires that each set of similar nanoforms is identified by clearly defined boundaries in the parameters in the points 2.4.2 to 2.4.5 of the individual nanoforms within the set.

1.1.1. Information provided

2 The lead registrant of the joint submission has reported the Set of Nanoforms in the form of a boundary composition and identified the boundaries of the Set of Nanoforms in Section 1.2 of their registration dossier and in a document entitled "[redacted]".

1.1.2. Assessment of the information provided

3 We have assessed the information provided and we have identified the following issues on the basis of which we consider that the Set of Nanoforms does not fulfil the requirement for clearly defined boundaries in the parameters in section 2.4.2 of Annex VI:

1.1.2.1. Unclear reporting of boundaries of the surface treatment/functionalisation

4 The Annex VI, Section 2.4.3. of the REACH Regulation requires reporting of "description of surface functionalisation or treatment and identification of each agent including IUPAC name and CAS or EC number".

5 Further, Section 4.3 of 'Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification' outlines that the reporting of the surface-treatment in a boundary composition must include:

1) A list of all the agents used for surface treatment of all the nanoforms covered under a set (i.e., list of IUPAC names, CAS and EC numbers) or in case of confidentiality concerns a description of the chemical nature of the surface-treating agents as specifically as possible as described in Step 36 of ECHA manual 'How to prepare registration dossiers covering nanoforms'.

2) A description of the common type of reaction/treatment applied (e.g., hydrolysis, oxygen treatment, acid washing) with relevant ranges of process parameters such as reaction conditions (e.g., pH, temperature) and any purification step applied

3) A description of the functionalities introduced by the treatment(s) (e.g., carboxyl, amino, hydroxyl groups)

6 You have reported the surface treatment agent as "[redacted]" and stated in 'Description' field that "[t]*he chemical identity of the*

surface treatment agent is Confidential Business Information, thus cannot be reported in the boundary composition of the (set of) nanoform but in the respective legal entity composition. List of typical surface treating agents have been identified to establish TiO2 substance identification and sameness. The list of typical surface treatment agent are as follows:

7 [redacted] In the 'Remarks' field you further state that "[t]*he description of the surface treatment substances and the functionalisation process is highy variable and will be provided in the respective legal entity composition*". You report the range of [redacted] to be [redacted] and the percentage of coverage of particle surface [redacted].

8 However, the information you have provided does not fulfill the requirements specified in 'Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification'.

1) Concerning the first requirement on the reporting of all the agents used for surface treatment:

   Firstly, the reference substance "[redacted]" does neither specify the IUPAC name, CAS or EC number nor describe the chemical nature of the surface-treating agents.

   Secondly, the list of typical surface treatment agents provided in 'Description' field does neither specify the IUPAC name, CAS or EC number nor describe the chemical nature of the surface-treating agents to the extend that the validity of the justification can be assessed.

   Thirdly, the provided list only relates to typical surface-treating agents. It is not an exhaustive list of surface-treating agents specific to the Set of Nanoforms and it does not specify each surface-treating agent setting the boundaries for the Set of Nanoforms.

2) Concerning the second requirement on the description of the common type of reaction/treatment applied:

   You have not provided a description of the common type of reactions/treatments applied in the surface-treating process of the nanoforms in the Set.

3) Concerning the third requirement on the description of the functionalities introduced by the treatment(s):

   You have not at all described functionalities introduced by the treatment(s).

9 Furthermore, the REACH Regulation requires that the Set of Nanoforms is defined by clearly defined boundaries. ECHA notes that the registrants relying on the Set of Nanoforms provide information in their respective dossier on the surface treating agent(s) relevant for their specific nanoforms. The obligation of each registrant to characterise the nanoforms they specifically manufacture or import in their respective registration dossier does not affect the requirement to identify the clearly defined boundaries of the Set of Nanoforms. Without clear boundaries of the Set of Nanoforms, the validity of the justification cannot be assessed.

10 Therefore, the description of the surface-treatment and the identification of each surface-treatment agent that you have reported do not establish clear boundaries for the Set of Nanoforms.

11 You must report the information on description of surface functionalisation or treatment in such manner that the boundaries of the Set of Nanoforms are clear. This can be achieved by correcting the incompliances outlined in the points 1 to 3 above. In particular, you must identify each surface treating agent by its IUPAC name and CAS or EC number or by describing the chemical nature of the surface treating agents in such details that boundaries of the Set of Nanoforms are clear and the validity of the justification for joint hazard, exposure, and risk assessment of the nanoforms can be assessed. You must also provide description of the common type of reactions/treatments applied in the surface-treating process and the details on functionalities introduced by the treatment. The information must be included in Section 1.2 of the IUCLID dossier reporting the Set of Nanoforms.

1.1.2.2. Unclear boundaries of the shape and morphology - Shape

12 The REACH Annex VI section 2.4.4. requires reporting of "shape, aspect ratio and other morphological characterisation: crystallinity, information on assembly structure including e.g., shell like structures or hollow structures, if appropriate".

13 Further, Section 4.2 of 'Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification' outlines the principles for reporting of shape, aspect ratio and other morphological characterisation for a set of similar nanoforms. It stipulates that nanoforms consisting of particles falling under different shape categories must in principle not be part of a same set of similar nanoforms.

14 The 'Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification' also stipulates that the following information must be reported for each set of nanoforms:

- The shape category of the set (e.g., spheroidal);
- A list of the specific shapes covered under a certain set (e.g., spherical, cubic, pyramidal).

15 For a set containing nanoforms with only elongated particles:

- The range of the aspect ratios of the different nanoforms covered under the set;
- The maximum and minimum length of the nanoforms that are part of the set.

16 You have reported that the Set of Nanoforms contains [redacted]. You have reported the [redacted] and the aspect ratio to be [redacted]. Furthermore, you report [redacted] values of the particle size [redacted], respectively.

17 However, the information provided is vitiated by the following deficiencies:

1. Section 3.1.2.1.3 of 'Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification' specifies that for [redacted] the aspect ratio [redacted]. Thus, the minimum

aspect ratio [redacted] cannot be [redacted] as reported for the Set of Nanoforms.

2. You report the [redacted] but at the same time you report the maximum [redacted]. The reported maximum [redacted] implies that there is a nanoform [redacted]. These values are inconsistent as [redacted].

18 Therefore, the boundaries of the Set of Nanoforms are not clear.

19 Therefore, [redacted] are not consistent with each other and are not compatible with the reporting requirements applicable to [redacted].

20 You must report the information on shape of the particles in such manner that the boundaries of the Set of Nanoforms are clear. This can be achieved by correcting the incompliances outlined in the points 1 and 2 above. In particular, you must provide consistent information on d-values describing the particle size distribution of the nanoforms containing [redacted] and the corresponding values of [redacted]. The information must be included in Section 1.2 of the IUCLID dossier reporting the Set of Nanoforms.

1.2. Justification demonstrating that a variation within the boundaries of the set of similar nanoforms does not affect the hazard assessment, exposure assessment and the risk assessment of the similar nanoforms in the set (introduction to Annex VI)

21 Annex VI of the REACH regulation requires that a "justification shall be provided to demonstrate that a variation within these boundaries does not affect the hazard assessment, exposure assessment and risk assessment of the similar nanoforms in the set".

1.2.1. Information provided

22 The lead registrant's dossier includes a justification document for the Set of Nanoforms entitled "[redacted]" under IUCLID section 1.2.

1.2.2. Assessment of the information provided

23 We have assessed the information provided and we have identified the following issues on the basis of which we consider that the Set of Nanoforms does not fulfil the requirement for a justification demonstrating that a variation within these boundaries does not affect the hazard assessment, exposure assessment and risk assessment of the similar nanoforms in the set:

1.2.2.1. Lack of scientific evidence on which this justification is based

24 Section 4 of Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification (Version 2.0 – January, pages 22-30)[2] states that the 'registrant must also submit the adequate and reliable scientific evidence on which this justification is based'.

25 In your justification to demonstrate that the hazard assessment of the nanoforms covered by the Set can be performed jointly, you state that, regarding environmental fate and ecotoxicity, "*mobility, bioavailability and toxicity can be expected to be low for all TiO2 nanoforms*" and conclude lack of environmental hazard.

[2] Section 4.1 (Page 22) and 4.2.2.1 (page 23) of the Appendix for Nanoforms applicable to the Guidance on Registration and the Guidance on Substance Identification, ECHA (2022)

26 In relation to human health, to support the lack of repeated dose toxicity, you state that "*There is currently no animal data available on the repeated dose toxicity via oral route for nano forms of titanium dioxide. However, based on the fact that (a* [redacted] *did not show any adverse effects in two chronic oral feeding studies and several other repeated dose toxicity studies via gavage (b)* [redacted] *and therefore need to be considered as* [redacted]" and "*it appears unlikely that nano forms of titanium dioxide show a significantly different toxicological profile to* [redacted]".

27 You have neither provided detailed information on bioaccumulation, adsorption and (eco)toxicology on nanoforms relevant to the Set in your justification nor have you linked your statements to specific studies in order to substantiate your justification.

28 In addition, you claim that "*commercial surface treatments are all without intrinsic toxicity*". However, you do not support this claim with data nor do you specify the coating agent(s) used. Therefore, the information provided in the justification document does not allow an independent assessment of the validity of your claim.

29 Similarly, you claim that the "*studies in the REACH dossier have been thoroughly reviewed and there is no evidence in any of the studies for any endpoints for any differences in hazard due to crystal phase*". However, you do not specifiy to which studies, in (or outside) the dossier, you are referring to.

30 Therefore, in the absence of scientific evidence substantiating the justification, you have not demonstrated that the hazard assessment of the nanoforms can be performed jointly.

1.2.2.2. Missing (robust) study summaries

31 In the justification document, you refer to several studies, namely:

- "[redacted]", with regards to the impact *aspect ratios on hazards.*
- You also refer to several publications in support of your arguments (e.g. [redacted] 2005 and references therein; [redacted] 2018a-c, 2019a-c; [redacted] 2014 a,b and [redacted] 1998 and references therein), with regards to stability and mobility of TiO2 nanoforms. Specifically, in support of nanoforms stability, you provide tabulated data on "[redacted]", referring to [redacted] 2018a-c, 2019a-c. However, limited details on test conditions (e.g. pH and separation method) and no comprehensive information of the test materials is reported.
- [redacted]2014, in support of the dustiness data provided.

32 However, you have not provided a robust study summary or study summaries for any of these studies.

33 In the absence of robust study summaries or study summaries, ECHA cannot assess the reliability of your justification. Furthermore, in the absence of comprehensive information on the test materials, ECHA cannot assess the relevance of the provided data to the Set of Nanoforms.

34 Therefore, you have not demonstrated that the hazard assessment of the nanoforms can be performed jointly.

1.2.2.3. Hazard/fate data provided on nanoforms outside the Set of Nanoforms

35 In accordance with Annex VI of REACH, the parameters in the points 2.4.2 to 2.4.5 of the individual nanoforms are used to define the boundaries of a 'set of similar nanoforms' which "allow to conclude that the hazard assessment, exposure assessment and risk assessment of these nanoforms can be performed jointly." This implies that the justification can be based only on hazard information resulting from nanoforms with characterisation parameter values within the boundaries of this set.

36 You have defined the boundaries of the Set of Nanoforms as follows:

37 [redacted] You have provided data on solubility and dustiness in the justification document.

38 The provided solubility tests ([redacted] 2018a-c, 2019a-c) were performed at pH 6 and 8 on [redacted] nanoforms [redacted] The information provided clearly indicates that all nanoforms were [redacted]. As a result, they are necessarily outside the boundary of the Set of Nanoforms.

39 The provided dustiness tests ([redacted] 2014) were performed on [redacted] nanoforms: [redacted] None of the nanoforms tested for dustiness can pertain to this Set of Nanoforms due to [redacted]. That is, only the tested nanomaterial [redacted] listed above could be relevant for this Set based on the reported crystal phases (i.e. [redacted]). However, as the tested nanomaterial [redacted] is claimed to be [redacted] it falls outside this ([redacted]) Set of Nanoforms. As a result, they are necessarily outside the boundary of the Set of Nanoforms.

40 On this basis, the provided information on dissolution and dustiness is not relevant for the Set of Nanoforms.

41 Therefore, in the absence of hazard information relating to the nanoforms covered by the Set, you have not justified that the hazard assessment of the nanoforms in this Set can be performed jointly.

1.2.2.4. Missing justification for joint exposure assessment of the Set of Nanoforms

42 Annex VI of REACH regulation requires a justification to demonstrate that a variation within the boundaries of the Set of Nanoforms does not affect joint performance of the hazard assessment, exposure assessment and risk assessment of the nanoforms.

43 Section 4 of the 'Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification' (Version 2.0 – January 2022, page 22-23) states that a justification must be provided as to "why the exposure (…) can also be performed jointly for the set of nanoforms". It specifically requires that "a common conclusion on exposure assessment can be reached for the set". This is demonstrated when the potential release is similar for all the nanoforms with regards to all their respective exposure routes. For example, for airborne exposure, this is demonstrated by similar value of dustiness (or by using a dustiness value that is conservative); for aquatic exposure, it is demonstrated as a minimum by similar dispersion stability, dissolution behaviour and surface functionalisation of all nanoforms within the set.

44 While you provide information on dissolution ([redacted] 2018a-c, 2019a-c) and dustiness ([redacted] 2014) which are relevant properties for the assessment of the exposure, this information is not relevant to the Set of Nanoforms as explained in sections 1.2.1.3 and 1.2.1.4 above. As a consequence, you have not demonstrated that the potential release of the nanoforms is similar and that the exposure assessment of all the nanoform in the Set can be performed jointly.

45 Therefore, it is not demonstrated that a common conclusion on exposure assessment can be reached for the Set. Hence, the risk assessment of the Set of Nanoforms cannot be performed jointly.

References

The following documents may have been cited in the decision.

Guidance on registration of nanoforms
Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification' (version 2.0, January 2022)
How to prepare registration dossiers covering nanoforms (version 1.2, October 2021)

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Appendix 2: Procedure

The Substance is listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2018.

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

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

The compliance check was initiated on 07 July 2021.

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

In the comments on the draft decision, the Lead Registrant of the Joint Submission, on behalf of all co-registrants, requested an extension of the deadline to provide information, from 3 months initially indicated in the draft decision to 10 months from the date of adoption of the decision. Following ECHA's request for clarifications substantiating this extension on 05 September 2022, the Lead Registrant provided a detailed work plan to address the incompliances set out in the draft decision. Based on these clarifications, ECHA consider that actions described to address the incompliances identified in the decision justify reasonnably the request for deadline extension. Therefore, ECHA has extended the deadline to 10 months.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s) and referred the modified draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee unanimously agreed on the draft decision during its MSC-81 meeting. ECHA adopted the decision under Article 51(6) of REACH.

Appendix 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

Registrant Name	Registration number
[redacted]	[redacted]
[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.