EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

2 March 2017

(Dossier evaluation – Compliance check –
Substance identity – Nanomaterials – Nanoforms)

Case number	A-011-2014
Language of the case	English
Appellants	Huntsman P&A UK Limited, formerly Tioxide Europe Limited, United Kingdom Cinkarna Metalurško-kemična Industrija Celje d.d., Slovenia Cristal Pigment UK Limited, United Kingdom Du Pont Coordination Center, Belgium Evonik Industries AG, Germany Kronos International Inc., Germany Precheza a.s., Czech Republic Sachtleben Chemie GmbH, Germany Tronox Pigments (Holland) B.V., The Netherlands
Representatives	Ruxandra Cana, Indiana de Seze, Anna Gergely and Craig Simpson Steptoe & Johnson LLP
Intervener	The French REACH Competent Authority
Contested Decision	CCH-D-0000004804-72-03/F of 17 June 2014 adopted by the European Chemicals Agency pursuant to Article 41(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; hereinafter the 'REACH Regulation')

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Sari Haukka (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the dispute

1. This appeal is directed against a compliance check decision concerning the substance identity information contained in the registration dossier submitted by Huntsman P&A UK Ltd, formerly Tioxide Europe Limited, (hereinafter the 'first Appellant') for titanium dioxide (CAS No 13463-67-7, EC No 236-675-5; hereinafter the 'Substance').
2. The Appellants request the Board of Appeal to:
   - annul the Contested Decision in so far as it requires the first Appellant to submit information related to phases, nanoforms and surface treatment of nanoforms (as listed in Section II, the '*Information required*', of the Contested Decision, and described in detail in Sections III.A.1.b, III.A.2.a and III.A.2.b, the '*Statement of Reasons*', of the Contested Decision);
   - order the Agency to refund the appeal fee; and
   - take such other or further measures as justice may require.
3. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

Background to the dispute

4. Titanium dioxide is an inorganic substance that exists in many forms differing in crystal phase, particle size and surface treatment. Titanium dioxide can consist of primary particles that are less than 100 nm in size, or of aggregates or agglomerates of such particles, which meet the definition of nanomaterial set out in Commission Recommendation 2011/696/EU on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38).
5. Titanium dioxide is used in a large range of industrial and consumer products including paints, coatings, adhesives, catalyst systems and floor coverings. Titanium dioxide nanoforms, also referred to in the Contested Decision as '*subpigmentary forms*', are used, for example, as an ingredient in sunscreens.
6. The first Appellant registered titanium dioxide as lead registrant for the joint submission on 30 September 2010. The other Appellants registered the Substance as members of the joint submission.
7. On 13 November 2013, the Agency initiated a compliance check limited to the substance identity information contained in the first Appellant's registration dossier.
8. On 3 March 2014, the first Appellant commented on the Draft Decision prepared by the Agency in accordance with Articles 41(3) and 50(1) of the REACH Regulation (all references to Recitals, Articles and Annexes hereinafter regard the REACH Regulation unless stated otherwise).
9. On 8 April 2014, the Agency notified the Draft Decision, as revised in consequence of the first Appellant's comments, to the Competent Authorities of the Member States. As no proposals for amendment were submitted, the Agency adopted the Contested Decision in accordance with Article 51(3) on 17 June 2014.

10. The Contested Decision concerns exclusively the substance identity information contained in the registration dossier. Section II of the Contested Decision requires the first Appellant to submit the following information '*[p]ursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2*':

    - the name or other identifier of the registered substance in accordance with Section 2.1 of Annex VI;
    - the composition of the registered substance in accordance with Section 2.3 of Annex VI; and
    - a description of the analytical methods in accordance with Section 2.3.7 of Annex VI.

11. Section III of the Contested Decision, entitled '*Statement of reasons*', further describes the requested information in the following terms:

    '*[Section III.A.1.b:] Name, molecular and structural formula or other identifiers of the Substance (Annex VI, 2.1 and 2.2) […] Phases covered by the registration*

    […]

    - *The Registrant shall describe the substance covered by the joint registration in broad terms in the "description of the substance" field in section 1.1 of the IUCLID dossier (e.g. "The registered substance is titanium dioxide in the following phases (list of phases – anatase, rutile, etc.) in the following forms (list of forms – pigmentary, subpigmentary, etc.) and the sub-pigmentary forms surface treated with (list of surface treatment agents)".*
    - *The Registrant shall also specify in the "description of the substance" field in section 1.1 of the IUCLID dossier if the substance manufactured/imported by him only relates to some of the forms/phases covered by the joint registration […].*
    - *The specific compositions manufactured/imported by the Registrant shall be reported in section 1.2 of the IUCLID dossier. The Registrant shall report each composition in terms of their constituents/impurities and their respective phase (anatase, rutile, etc.) and form (sub-pigmentary, surface treated (e.g. trimethoxyoctylsilane modified, alumina modified, etc.) as obtained from the respective manufacturing process. Sufficient analytical data for each of the compositions reported in section 1.2 shall be included in section 1.4 of the IUCLID dossier.*
    - *A supporting justification demonstrating that the phase specific properties have been addressed and that all test data has adequately taken phase into account so that the dossier addresses the hazard profile of all phases registered and their corresponding risk management measures shall be included as an attachment in Section 1.4 of the IUCLID dossier. The Registrant may in this section also include any other relevant information, including appropriate citations, that will enable the approach taken to be assessed.*

    […]

    [Section III.A.2.a:] Composition of the substance (Annex VI, 2.3) […] Nanoforms

    […]

    - *The Registrant shall describe the substance covered by the joint registration in broad terms in the "description of the substance" field in section 1.1 of the IUCLID dossier (e.g. "The substance jointly registered is titanium dioxide in the following phases (list*

of phases – anatase, rutile, etc.) in the following forms (list of forms – pigmentary, subpigmentary, etc.)").

- *The Registrant shall also specify in the "description of the substance" field in section 1.1 of the IUCLID dossier if the substance manufactured/imported by him only relates to some of the forms/phases covered by the joint registration […].*
- *The specific compositions manufactured/imported by the Registrant shall be reported in section 1.2 of the IUCLID dossier. The Registrant shall report each composition in terms of their constituents/impurities and their respective phase (anatase, rutile, etc.) and form (sub-pigmentary).*
- *Sufficient analytical data for each of the compositions reported in section 1.2 shall be included in section 1.4 of the IUCLID dossier. […]*

[Section III.A.2.b:] Composition of the substance (Annex VI, 2.3) […] Surface treatment of nanoforms

[…]

[W]here the Registrant intends to cover under his registration dossier grades of the substance that fulfil the Recommendation on nanomaterial where the surface chemistry of free primary particles or their aggregates or agglomerates is deliberately modified via surface treatment, he shall identify such grades by submitting the following information:

- *The Registrant shall describe the surface treatments of the nanoforms of the substance covered by the joint registration in broad terms in the "description of the substance" field in section 1.1 of the IUCLID dossier (e.g. "The substance jointly registered is titanium dioxide in the following phases (list of phases – anastase [sic], rutile, etc.) in the following forms (list of forms – pigmentary, subpigmentary, etc.) and the sub-pigmentary forms surface treated with (list of surface treatment agents)").*
- *The Registrant shall also specify in the "description of the substance" field in section 1.1 of the IUCLID dossier if the substance manufactured/imported by him only relates to some of the surface treated nanoforms covered by the joint registration (e.g. "The substance manufactured/imported by the Registrant is titanium dioxide in the following phases (list of phases) in the following forms (list of forms) and the sub-pigmentary forms surface treated with (list of surface treated [sic] agent)).*
- *The Registrant shall report together with each specific compositions [sic] manufactured/imported by him whether it is surface-treated (e.g. trimethoxyoctylsilane modified, alumina modified, etc.). For each of these specific compositions, information on each main constituent (i.e. the specific surface treated grade of [titanium dioxide]) of the respective compositions shall also be included in section 1.2 of the UICLID [sic] dossier in the form of appropriate identifiers, including chemical name, numerical identifiers and other identifiers.*

[-] Sufficient analytical data for each of the compositions reported in section 1.2 shall be included in section 1.4 of the IUCLID dossier. […]'

Procedure before the Board of Appeal

12. The Appellants filed this appeal on 16 September 2014.

13. On 19 December 2014, the Agency filed its Defence.

14. On 11 February 2015, the French REACH Competent Authority (hereinafter the 'Intervener') was granted leave to intervene in this case in support of the Agency. The Intervener did not submit a statement in intervention.

15. On 6 March 2015, the Appellants filed observations on the Defence.

16. On 8 May 2015, the Agency submitted observations on the Appellants' observations on the Defence.

17. Following consultation with the Parties, the appeal proceedings were stayed between 9 June and 1 September 2015 in accordance with Article 25 of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; hereinafter the 'Rules of Procedure').

18. On 29 October 2015, the Appellants filed further observations.

19. On 10 and 25 February 2016 respectively, the Appellants and the Agency responded to questions from the Board of Appeal. On 25 February 2016, the Agency also provided observations on the Appellants' observations of 29 October 2015.

20. On 4 March 2016, the Agency informed the Board of Appeal that it had '*partially rectified*' the Contested Decision and provided a copy of the '*rectified decision*'. By means of this 'rectification' the Agency deleted the first bullet point of Sections III.A.1.b, III.A.2.a and III.A.2.b of the Contested Decision (cited at paragraph 11 above), which required information, as part of the '*Statement of Reasons*', on the crystal phases, nanoforms and surface treatment of nanoforms covered by the joint registration. Other bullet points of those Sections were also modified slightly in order to reflect this change.

21. On 28 April 2016, the Appellants stated that they wished to pursue the appeal on the basis of the Contested Decision prior to its 'rectification'. On the same date, the first Appellant submitted a separate appeal against the '*rectified decision*' which was registered as Case A-004-2016.

22. On 27 May 2016, the Board of Appeal requested the Agency to provide a part of the '*rectified decision*' which the latter had previously failed to submit and asked the Agency to respond to certain questions concerning the 'rectification'. The Agency duly responded on 10 June 2016.

23. On 15 July 2016, the Appellants filed observations on the Agency's response to the questions of the Board of Appeal concerning the 'rectification'. In their observations the Appellants raised two new pleas in law, claiming that the 'rectification' has no legal basis and breaches the principle of legal certainty.

24. On 17 August 2016, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure. On 30 and 31 August 2016 respectively, the Agency and the Appellants requested a hearing to be held. As a result, in accordance with Article 13 of the Rules of Procedure, the Parties were summoned to a

hearing which took place on 3 November 2016. At the hearing, the Parties and the Intervener made oral statements and responded to questions from the Board of Appeal.

Reasons

I. Admissibility

25. This appeal was filed collectively by nine appellants, one of whom is the addressee of the Contested Decision.

26. The Agency argues that the eight Appellants who are not addressees of the Contested Decision are not directly and individually concerned by that Decision as required by Article 92(1).

27. The Board of Appeal finds, in this regard, that all the Appellants are challenging the same Contested Decision by a single appeal. The appeal is clearly admissible in so far as it has been filed by the first Appellant, who is the addressee of the Contested Decision. This is not disputed by the Agency.

28. Where the same appeal is involved, and it is found that the bringing of the appeal by one appellant is admissible, there is no need to consider whether the other appellants are entitled to bring proceedings (see, by analogy, Case T-190/12, *Tomana and Others* v *Council and Commission*, EU:T:2015:222, paragraph 72).

29. There is consequently no need to decide on the admissibility of the appeal with regard to the other Appellants.

II. Substance

30. The Appellants raise eight pleas in law in support of their appeal. The Board of Appeal will examine the third plea first.

The third plea, alleging that the Agency acted outside its competence and breached the REACH Regulation

Arguments of the Parties

31. By their third plea the Appellants claim, in essence, that the Agency acted outside its competence as the requested information on phases, nanoforms and surface treatment of nanoforms is not information required for a registration under Section 2 of Annex VI.

32. The Appellants argue that it is for themselves to define the substance which they intend to register. They add that, '*[l]ogically, if the substance covered by the registration is defined broadly, [registrants have] to consider related potential hazards and risks, which must be identified and adequately controlled*'. According to the Appellants, it then falls to the Agency to perform a compliance check of the relevant registrations in order to determine whether the '*hazard and risk data*' required for a registration have been provided.

33. The Appellants claim that the Agency should not have required from the first Appellant the information requested on substance identity under Section 2 of Annex VI. The Appellants argue that the information contained in the first Appellant's registration

dossier already complies with the requirements of that Section. The current legal text of the REACH Regulation does not provide for a more detailed identification of a registered substance if it happens to be a nanomaterial.

34. The Appellants argue, furthermore, that the legislator is currently considering a revision of the Annexes to the REACH Regulation with the aim of specifying the substance identity information required for the registration of nanomaterials. Until such a revision enters into force the REACH Regulation contains no requirement to provide more specific substance identity information on nanoforms than on other forms of a substance. The Appellants add that the Agency cannot take upon itself the role of a legislator by adding to the legal text as it currently stands.

35. The Agency, supported by the Intervener, argues in essence that registrants are required to include in their registration dossier the information necessary to show that manufacturing, placing on the market or using a registered substance does not adversely affect human health or the environment. Without the information requested by the Contested Decision a reliable assessment of the risks posed by the various crystal phases and/or nanoforms of the Substance cannot be performed.

36. According to the Agency and the Intervener, a registration must, in principle, address separately the toxicological and ecotoxicological properties of every crystal phase and/or nanoform covered by a registration dossier. Alternatively, a registrant can establish scientifically that differences in physical properties between different crystal phases and/or nanoforms do not result in different toxicological and ecotoxicological properties. A registrant may for example 'group' certain crystal phases and/or nanoforms according to objective criteria provided that it justifies the approach taken adequately.

37. The Agency, supported by the Intervener, argues that knowledge of the precise crystal phases and/or nanoforms covered by the first Appellant's registration is therefore an implicit '*prerequisite*' for assessing the hazards and risks posed by the Substance, regardless of whether a 'form-by-form' or a 'grouping' approach is adopted. A strictly literal interpretation of Section 2 of Annex VI would defeat the purpose of that provision, leading to the unacceptable consequence that manufacturers and importers of nanoforms of substances would not be required to assess the relevant hazards and risks.

Findings of the Board of Appeal

38. The Board of Appeal observes that the main point of dispute in this case concerns the scope of the obligations imposed upon registrants by Section 2 of Annex VI, which is the legal basis of the Contested Decision, to provide information on substance identity. In this respect, it is sufficient to examine the third plea insofar as it alleges that the Agency does not have the power to request information on crystal phases and/or nanoforms. The Board of Appeal notes that if the request for information on nanoforms is annulled there would be no need to decide on the request for information on the surface treatment of such nanoforms.

39. Before examining the substance of the Appellants' third plea, the Board of Appeal considers it helpful to summarise the information requested by the Contested Decision and to examine the substance identity information requirements applicable to the registration of the Substance by the first Appellant.

(i) The information requested by the Contested Decision

40. The Board of Appeal observes that the drafting of the Contested Decision, in particular those sections cited in paragraph 11 above, is not easy to follow. First, the information requests are set out in detail only in the part of the Contested Decision entitled '*Statement of reasons*'. Second, similar wording is repeated three times, with slight differences, and it is not self-evident whether the slight changes in wording are significant or not. Third, terms such as '*forms*' and '*grades*' are not defined.

41. In essence, insofar as they were not 'rectified', the contested parts of the Contested Decision require the first Appellant to provide substance identify information on:

- the crystal phases of titanium dioxide which the first Appellant manufactures or imports (e.g. rutile and anatase), including a justification showing that crystal phase-specific properties have been addressed and that all test data has adequately taken the crystal phase into account;
- for each crystal phase, the nanoforms of the Substance which the first Appellant manufactures or imports (for the purposes of this appeal, the term 'nanoform' aims at describing nanomaterials that have the same substance identity, are nanomaterials within the meaning of Commission Recommendation 2011/696/EU, and yet may differ among themselves in other characteristics e.g. size, shape, surface chemistry); and
- any nanoforms manufactured or imported by the first Appellant that are surface treated and what the surface treatment agent is.

(ii) Information requirements applicable to the registration of the Substance by the first Appellant

42. According to the first sentence of Article 1(3), the REACH Regulation '*is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment*'.

43. To this end, Article 6 establishes a general obligation for manufacturers or importers of substances to register those substances with the Agency. Title II of the REACH Regulation, in conjunction with the relevant Annexes, sets out the information required for a registration.

44. According to Recital 19, '*the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration should require them to submit a dossier containing all this information to the Agency*.'

45. The registration requirements therefore contribute to the achievement of the main objective of the REACH Regulation, namely to attain a high level of protection of human health and the environment (see Case C-558/07, *S.P.C.M. and Others*, EU:C:2009:430, paragraph 45, and Case T-135/13, *Hitachi Chemical Europe and Others* v *ECHA*, EU:T:2015:253, paragraph 46).

46. It follows from the considerations laid out in paragraphs 42 to 45 above that, in order to ensure that the risks which may arise from the use of a registered substance are properly managed, a registrant must be able to show that those risks are addressed by, inter alia, the appropriate toxicological and ecotoxicological information provided in its registration dossier.

47. The Board of Appeal further observes that substance identity, as defined in particular in Article 3(1) and Section 2 of Annex VI, is an important element of the requirements for substance registration.

48. It is clear from Article 1(3), read in conjunction with Recital 19, that the decision on which substance it is intending to register lies with the manufacturer or importer concerned (see Case A-008-2012, *PPH UTEX*, Decision of the Board of Appeal of 2 April 2014, paragraph 47). It is however of utmost importance that a registrant unambiguously identifies the substance it is intending to register (see Case A-001-2013, *Infineum UK*, Decision of the Board of Appeal of 9 April 2014, paragraph 71).

49. It follows from the reasons set out above that a registrant is at liberty to give a broad definition of the substance which it intends to register, for example by including both the bulk forms and the nanoforms of various crystal phases of the substance in question. If a registrant gives a broad definition of its substance, however, the hazards posed by all possible forms of the substance covered by the substance definition must be addressed by the toxicological and ecotoxicological information provided in the registration dossier.

50. The Board of Appeal further observes that the extent of the burden on a registrant to provide the relevant information depends on its own choices. For example, the registrant may register precisely what it intends to manufacture or import and provide information accordingly. Alternatively, it may define its substance broadly and provide information covering every endpoint for every composition of the substance covered by its broad definition.

51. In the present case, the definition of the Substance given in the first Appellant's registration dossier is very broad. It comprises, inter alia, the bulk form and all nanoforms of various crystal phases of titanium dioxide, including rutile and anatase.

52. It follows that, in order to comply with the REACH Regulation, the first Appellant must provide in its registration dossier toxicological and ecotoxicological information covering, inter alia, both the nanoforms and bulk forms of the rutile and anatase crystal phases of titanium dioxide.

53. In so doing the first Appellant might, for instance, establish categories of crystal phases and nanoforms of the Substance based on objective criteria. The first Appellant would however need to justify whatever approach it takes. One option would be to establish that these categories are likely to have similar properties, and provide the necessary information accordingly. If the Agency were then to find, for example, that different nanoforms of crystal phases of titanium dioxide potentially have different toxicological properties that have not been adequately addressed, it could request further information through the appropriate regulatory procedure under the REACH Regulation.

54. The Board of Appeal will now examine the interpretation of Section 2 of Annex VI in light of the above considerations.

(iii) Interpretation of Section 2 of Annex VI with regard to information on crystal phases and/or nanoforms

55. The compliance check which led to the Contested Decision in this case did not concern the entirety of the first Appellant's registration dossier but was limited to substance identity information. The Contested Decision has its legal basis exclusively in Articles 41 and 10(a)(ii), in conjunction with Section 2 of Annex VI.

56. In order to decide on the third plea, the Board of Appeal must therefore examine whether Section 2 of Annex VI requires registrants to submit the information at issue when registering a substance.

57. Section 2 of Annex VI lists the information which must be provided by a registrant on the identity of a substance. It is worded as follows:

'*For each substance, the information given in this section shall be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.*

2.1. Name or other identifier of each substance

2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)

2.1.2. Other names (usual name, trade name, abbreviation)

2.1.3. EINECS or ELINCs number (if available and appropriate)

2.1.4. CAS name and CAS number (if available)

2.1.5. Other identity code (if available)

2.2. Information related to molecular and structural formula of each substance

2.2.1. Molecular and structural formula (including SMILES notation, if available)

2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)

2.2.3. Molecular weight or molecular weight range

2.3. Composition of each substance

2.3.1. Degree of purity (%)

2.3.2. Nature of impurities, including isomers and by-products

2.3.3. Percentage of (significant) main impurities

2.3.4. Nature and order of magnitude (… ppm… %) of any additives (e.g. stabilising agents or inhibitors)

2.3.5. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)

2.3.6. High-pressure liquid chromatogram, gas chromatogram

2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.'

58. It is common ground between the Parties that Section 2 of Annex VI makes no explicit provision for substance identity information on crystal phases and/or nanoforms.

59. The Agency and the Intervener argue, in essence, that Section 2 of Annex VI should be interpreted as requiring registrants to submit information on the crystal phases and/or nanoforms of substances which they intend to register. The Appellants dispute this interpretation.

60. The Board of Appeal observes that, according to settled case-law, in determining the scope of a provision of European Union law, its wording, context and objectives must all be taken into account (see, for example, Case C-453/14, *Knauer*, EU:C:2016:37, paragraph 27).

61. However, there is in principle no need for interpretation of a provision, particularly in the light of its context and purpose, when its scope can be determined with precision on the basis of its wording alone, the clear text being sufficient in itself (see Case T-521/14, *Sweden* v *Commission*, EU:T:2015:976, paragraph 59).

62. In other words, if the wording of a provision of European Union law is clear and precise, its contextual or teleological interpretation cannot call into question the literal meaning of that provision (see, to that effect, Case C-220/03, *ECB* v *Germany*, EU:C:2005:748, paragraph 31; Case C-263/06 *Carboni e derivati*, EU:C:2008:128, paragraph 48 and Case C-48/07, *Les Vergers du Vieux Tauves*, EU:C:2008:758, paragraph 44). This is expressed by the legal maxim *interpretatio cessat in claris*.

63. The Board of Appeal observes that the wording of Section 2 of Annex VI is clear and precise as regards its application to the facts of this case.

64. The Board of Appeal observes that headings 2.1, 2.2 and 2.3 of Section 2 of Annex VI (respectively '*Name or other identifier of each substance*', '*Information related to molecular and structural formula of each substance*' and '*Composition of each substance*') are not information requirements in themselves but headings to describe the subject matter of the points that follow.

65. Points 2.1.1 to 2.1.5, points 2.2.1 to 2.2.3, and points 2.3.1 to 2.3.7 of Annex VI list the substance identity information to be provided by registrants. In particular, points 2.1.1 to 2.1.5 require registrants to submit information such as names in the IUPAC nomenclature, CAS numbers and trade names. Points 2.2.1 to 2.2.3 require information on molecular and structural formulas, on optical activity and typical ratio of (stereo) isomers, and on the molecular weight or weight range of a registered substance. Points 2.3.1 to 2.3.7 require information on impurities, additives, spectral data, chromatograms and analytical methods. All these requirements are worded with such technical precision and clarity that they leave no scope for doubt as to their meaning. None of these points mention the need to provide information on crystal phases and/or nanoforms.

66. Equally, the first paragraph of Section 2 of Annex VI, which provides that '*the information given in this section shall be sufficient to enable each substance to be identified*', does not constitute an information requirement in itself. It simply states that registrants must provide sufficient information for each of the information requirements listed in Section 2.

67. It must be highlighted, moreover, that Section 2 of Annex VI does not contain an openly worded information requirement such as a reference to 'any other information necessary to identify the registered substance'. Nor does it contain expressions such as

'including' or 'for example'. If this were the case, such wording might give scope to contextual and teleological interpretation. But this is not the case.

68. Similarly, if the terms nanoforms and nanomaterials were mentioned elsewhere in the REACH Regulation there could have been a stronger argument to apply a contextual or teleological interpretation. However, these terms are not used in the REACH Regulation so this is also not the case.

69. In light of the above, the Board of Appeal finds that the wording of Section 2 of Annex VI is clear. It follows that Section 2 of Annex VI cannot be interpreted in the light of its purpose and context with regard to the information requests in the Contested Decision. It must be applied in accordance with its wording as enacted by the legislature.

70. The Agency, supported by the Intervener, claims that substance identity information on the crystal phases and/or nanoforms of titanium dioxide is a '*prerequisite*' for hazard and risk assessment. A literal reading of Section 2 of Annex VI would, in the Agency's opinion, defeat the purpose of the provision, making it impossible to assess properly the hazards and risks posed by the Substance.

71. The Board of Appeal has already found, at paragraph 52 above, that the fact that the first Appellant chose to give a broad definition of the Substance for the purposes of registration means that it is required to submit, inter alia, information concerning the toxicological and ecotoxicological properties for the entirety of the Substance covered by this broad definition.

72. The procedures available to the Agency in the REACH Regulation allow for this information, and potentially other information on the Substance, to be considered to ensure that sufficient information is available regarding the hazards and risks posed by the Substance. For example, a compliance check of the toxicological and ecotoxicological information submitted, rather than substance identity information only, will allow the Agency to consider whether all the required information regarding, inter alia, the human health and environmental effects of the Substance have been submitted. Furthermore, a decision taken pursuant to the substance evaluation process could request further information that is needed to clarify a potential concern.

73. The procedures and processes in the REACH Regulation are carefully structured to preserve the rights and define the obligations of the parties involved in light of the objectives of the REACH Regulation and primarily the protection of human health and the environment. It is not for the Agency or the Board of Appeal to interpret the REACH Regulation in such a way as to amend or extend it.

74. In light of the above the Board of Appeal finds that, in the present case, the literal interpretation of Section 2 of Annex VI does not endanger the protection of human health and the environment, which is the main purpose of the REACH Regulation (see paragraph 45 above). The toxicological and ecotoxicological information in the first Appellant's registration dossier must satisfy the registration requirements set out in the REACH Regulation with regard to all the bulk forms and crystal phases and/or nanoforms of titanium dioxide covered by the registration.

75. The Board of Appeal finds that a literal interpretation of the wording of Section 2 of Annex VI does not lead to an unreasonable result. The alleged contradiction in this case between the purpose and the wording of Section 2 of Annex VI does not stem from the

wording of that provision. It derives from the compliance check in the present case being limited to substance identity information only.

76. Finally, the Board of Appeal takes note of the Agency's and the Intervener's position that it would be desirable for registrants to provide more detailed substance identity information on the nanoforms of registered substances.

77. Requiring such substance identity information would place an additional burden on all registrants of substances in the nanoform. Even if it were demonstrated that such information would be useful or even necessary for the evaluation of substances, it is not for the Agency or the Board of Appeal to create new information requirements when the provision in question is clear in its own right.

78. The power to establish information requirements, in this case for the registration of substances, is reserved exclusively to the legislature of the European Union. The Annexes to the REACH Regulation may be amended in accordance with Article 131. If the legislature sees a need for further information on the nanoforms of substances subject to registration then it would need to amend the Annexes to the REACH Regulation accordingly.

(iv) Conclusion

79. For all these reasons, the requests for information on the crystal phases and/or nanoforms of titanium dioxide exceed the Agency's powers under Section 2 of Annex VI. These requests must therefore be annulled.

80. As the requirement to submit information on nanoforms must be annulled there is no need to examine the requirement to submit information on the surface treatment of such nanoforms.

81. The third plea must therefore be upheld, and the remedy sought by the Appellants granted.

82. The Board of Appeal recalls that the Agency *'partially rectified'* elements of the Contested Decision on 4 March 2016 (see paragraph 20 above). The Agency states, in essence, that it recognised that part of the appeal was well-founded and wanted to take action accordingly by 'rectifying' the elements of the decision which, on reflection, it considered to be unlawful. The Appellants contest the legality of the Agency's action.

83. The Board of Appeal finds that there is no need to decide on the Appellants' challenge to the legality of the 'partial rectification'. On the one hand, if the 'partial rectification' was lawful the relevant elements of the Contested Decision would no longer exist and the Appellants would have no interest in challenging their withdrawal. If, on the other hand, the 'partial rectification' was not lawful and the case had to be decided on the basis of the original Contested Decision, the relevant elements of the Contested Decision would in any event have to be annulled for the reasons stated above, since they requested information on the crystal phases, nanoforms and surface treatment of nanoforms covered by the joint submission. It follows that a decision of the Board of Appeal on the legality of the Agency's action would have no effect on the outcome of this case.

84. As the third plea has been upheld and the contested elements of the Contested Decision annulled there is no need to consider the remaining pleas.

Refund of the appeal fee

85. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.4.2008, p. 6), the appeal fee shall be refunded if the appeal is decided in favour of an appellant.

86. As the appeal has been decided in favour of the Appellants, the appeal fee shall be refunded.

Effects of the Contested Decision

87. According to Article 91(2), an appeal before the Board of Appeal shall have suspensive effect. The Board of Appeal considers that when only some elements of a decision have been contested in an appeal the suspensive effect shall, in principle, only apply to those contested elements.

88. In the present case, as all the contested elements of the Contested Decision are either annulled or have been withdrawn by the Agency, there is no need to interpret the deadline set in the Contested Decision in light of the suspensive effect of the appeal.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls Decision CCH-D-0000004804-72-03/F, adopted by the European Chemicals Agency on 17 June 2014, in so far as it requires the first Appellant to submit information related to phases, nanoforms and surface treatment of nanoforms (as listed in Section II of the Contested Decision and described in detail in Sections III.A.1.b, III.A.2.a and III.A.2.b of the Contested Decision); and**
2. **Decides that the appeal fee shall be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal