EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

12 October 2016

(Compliance check – Nanomaterials – Request for information – Legal certainty)

Case number	A-009-2015
Language of the case	English
Appellant	IQESIL SA, Spain
Representatives	Ruxandra Cana, Eléonore Mullier and Craig Simpson Steptoe & Johnson LLP, Belgium
Contested Decision	CCH-D-0000004724-72-03/F of 17 December 2014 adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 41 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 Sari Haukka (Legally Qualified Member and Rapporteur)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. On 16 March 2015, the Appellant lodged the present appeal against the Contested Decision on a compliance check of the Appellant's registration dossier for silicic acid, aluminum sodium salt (CAS No 1344-00-9, EC No 215-684-8; hereinafter 'the Substance'). The Contested Decision requests the Appellant to submit the following information:

   - Name, molecular and structural formula or other identifier of the Substance (Section 2.1 and 2.2 of Annex VI to the REACH Regulation; all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise);
   - Composition of the Substance (Section 2.3 of Annex VI); and
   - Description of the analytical methods used to determine the identity and composition of the Substance (Section 2.3.7 of Annex VI).

2. The Appellant requests the Board of Appeal to partially annul the Contested Decision, refund the appeal fee and take such other or further measures as justice may require.

Background to the dispute

3. The Appellant is a co-registrant of the Substance. The Substance was registered in February 2010 as a joint registration dossier.

4. On 4 November 2013, the Agency initiated a compliance check of the Appellant's registration dossier for the Substance pursuant to Article 41(1).

5. On 17 December 2013, the Agency sent a draft decision to the Appellant (hereinafter the 'Draft Decision'). The Draft Decision required the Appellant to submit the following information concerning the identity of the Substance:

   '*1. Name, molecular and structural formula or other identifier of the substance (Annex VI, 2.1 and 2.2): Information which is suitable and necessary to allow [the Agency] to establish and verify the name and the identity of the registered substance, […];*

   2. Composition of the substance (Annex VI, 2.3): Information which is suitable and necessary to allow [the Agency] to establish and verify the composition and the identity of the registered substance, […];

   3. The description of the analytical methods (Annex VI section 2.3.7.), […]'.

6. On 21 January 2014, a telephone conference took place between the Agency and several co-registrants of the Substance, including the Appellant, to discuss the Draft Decision.

7. On 31 January 2014, the Appellant submitted comments to the Agency on the Draft Decision. In its comments on the Draft Decision, the Appellant indicated in particular that the Agency's differential treatment of the co-registrants of the Substance constitutes an infringement of the right to good administration and the principle of equal treatment. The Appellant further provided comments on specific parts of the Contested Decision, for example regarding the meaning of the term 'grade' and 'form' and whether the Substance is a 'nano structured substance'.

8. On 12 June 2014, the Agency notified the Draft Decision to the Competent Authorities of the Member States (hereinafter the 'MSCAs') and invited them, pursuant to Article 51(1), to submit proposals for amendment within 30 days.

9. On 17 December 2014, as no proposals for amendment were received from the MSCAs, the Agency adopted the Contested Decision pursuant to Article 51(3).

Procedure before the Board of Appeal

10. On 16 March 2015, the Appellant lodged the present appeal.

11. On 15 April 2015, the Executive Director of the Agency informed the Board of Appeal that he had not used the possibility provided for in Article 93(1) to rectify the Contested Decision.

12. On 1 September 2015, the Agency lodged its Defence requesting the Board of Appeal to dismiss the appeal as unfounded.

13. On 27 November 2015, the Appellant lodged observations on the Agency's Defence.

14. On 5 April 2016, the Agency submitted observations on the Appellant's observations on the Defence, as well as replies to questions posed by the Board of Appeal.

15. On 22 April 2016, the Parties were notified of the Board of Appeal's decision to close the written procedure. On 29 April and 3 May 2016 respectively, the Appellant and the Agency requested a hearing to be held. Both Parties also informed the Board of Appeal that they did not object to the Board of Appeal's proposal to hear Cases A-008-2015, A-009-2015, A-010-2015 and A-011-2015 at the same hearing as they concerned the same substance, raised similar pleas and arguments, and involved the same representatives.

16. In view of the Appellant's and the Agency's requests for a hearing to be held, and pursuant to Article 13 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), the Parties were summoned to a hearing which was held on 7 June 2016 together with Cases A-008-2015, A-010-2015 and A-011-2015. At the hearing, the Parties made oral submissions and responded to questions from the Board of Appeal.

Reasons

17. In support of its appeal, the Appellant raises six pleas in law.

18. The Appellant claims first that the Contested Decision violates the principle of legal certainty through the use of undefined and unclear terminology. Second, the Appellant claims that the Agency acted *ultra vires* and in breach of the REACH Regulation in so far as it requests the Appellant to submit information at a level of detail that is not provided for in the REACH Regulation. Third, the Appellant claims that the Contested Decision is not based on factually accurate or reliable information, in particular as the Appellant had provided comments that the information requested in the Contested Decision is not relevant or applicable for the Substance. Fourth, the Appellant claims that the Contested Decision breaches the principle of legitimate expectations. The Appellant claims in particular that its legitimate expectations, created by the Agency's Guidance on the identification of substances in so far as the definition of Substances of Unknown or Variable Composition, Complex Reaction Products or Biological Materials ('UVCB') is concerned, have been frustrated by the requirements in the Contested Decision which go beyond the limits defined by the law and the applicable guidance. Fifth, the Appellant claims that the Contested Decision was adopted in breach of the principle of equal treatment and non-discrimination in so far as it treats the Appellant differently than other co-registrants of the Substance. In particular, the Appellant claims that the Agency only addressed decisions under the compliance check procedure to a limited number of co-registrants of the Substance. Sixth, the Appellant submits that the Contested Decision breaches the principle of proportionality in so far as it requests extensive information to be submitted on the 'grades', 'forms', 'surface treatment' and 'nanoforms' of the Substance. In this respect, the Appellant claims that the Contested Decision places a disproportionate burden on the Appellant by

requesting additional information that is not required by legislation and is not relevant or necessary.

19. In the Notice of Appeal, the Appellant raised arguments regarding the legality of the Agency's practice of not allowing registrants to comment on revisions made to a draft decision following previous comments from those registrants before the draft decision is submitted to the MSCAs. The Appellant clarified at the hearing, however, that this was not intended to be a separate plea. As a result, this will not be considered further by the Board of Appeal.

The Appellant's first plea alleging a violation of the principle of legal certainty

Arguments of the Parties

20. The Appellant argues that the Agency breached the principle of legal certainty in so far as the requests for information in the Contested Decision relate to 'forms', 'grades' and 'nanoforms'. The Appellant argues that the lack of clarity regarding these terms means that the Appellant is not able to determine with certainty its rights and obligations and what steps it must take to comply with the Contested Decision.

21. The Appellant argues that the terms 'grade', 'form' and 'nanoform' are not defined in the REACH Regulation or in the available Agency guidance. Furthermore, the Appellant states that the Contested Decision fails to define or describe the meaning of these terms clearly.

22. The Appellant argues that the Agency's explanations during the present proceedings as to why it employed the terms 'grade' and 'form' in the Contested Decision are not relevant to considering the Appellant's plea of whether the meaning of those terms is clear in the Contested Decision.

23. The Appellant argues that whilst it has its own understanding of which of its materials it considers to be nanomaterials, it has no way of knowing, in the absence of a definition of 'nanoform' in the Contested Decision, what the Agency understands by that term. The Appellant argues that there is no single, accepted meaning of the word 'nano', and that it is not defined consistently in different jurisdictions or even in European legislation.

24. The Agency claims that the plea concerning the breach of the principle of legal certainty must be rejected as unfounded. The Agency argues that, specifically for nanomaterials which are characterised by their size, it is not sufficient to identify a substance based on its composition alone (i.e. a chemical element and its compounds). According to the Agency, the necessary information to characterise nanomaterials is not only the composition but also the form, including the size, of the substance as manufactured or imported. The Agency states that '*it would therefore be misleading for the Contested Decision to refer only to compositions when addressing nanomaterials*'. The Agency claims that in order to avoid such misunderstandings, the Contested Decision refers to 'grades', which reflects considerations of both the composition and the form of the Substance.

25. The Agency argues further that, contrary to the Appellant's assertions, the Contested Decision did define the term 'grade'. More specifically, the Contested Decision explicitly defines this term as '*grades (compositions of specific form e.g. powders, ultra-fine powders, etc.)*'.

26. The Agency states that, during the commenting phase, the Appellant expressed concerns that the term 'grade' would refer to each commercial product of the Substance. The Agency claims that it reassured the Appellant during a telephone conference that the Contested Decision does not require the submission of information on each commercial product manufactured by the Appellant. The Agency argues that the Appellant acknowledged this clarification in its comments on the Draft Decision.

27. The Agency states that since there is no term in the REACH Regulation or in a guidance document that reflects the information requirements relating to nanomaterials, which go beyond the composition, the term 'grade' has been used in the Contested Decision rather than 'composition'.

28. The Agency argues that the term 'form' is used by the Appellant in its own dossier for defining the Substance as a '*non-stoichiometric amorphous form of the precipitated synthetic reaction product of aluminium sulphate and sodium silicate*'. The Agency adds that the Contested Decision defines 'form' in relation to the Substance as covering '*fibers, powders, nanopowders, surface treated forms, etc. as relevant*'. This refers to the morphology characteristics relevant for hazard assessment. The Agency points out that the Contested Decision also clarifies that the term 'form' '*includes more specifically the nanoforms of substances*'.

29. The Agency states that the Contested Decision refers to 'nanoforms' as specified by Commission Recommendation 2011/696/EU on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38). The Agency adds that the term 'nanoform' is commonly used to describe more concisely the '*nanomaterial form of a bulk substance*'. The Agency states that as a result, the term 'nanoform' is implicitly covered by the definition of nanomaterials in Commission Recommendation 2011/696/EU and that it is extensively used by the European regulatory community, including institutions and economic operators, to refer to the nanomaterial forms of a bulk substance.

30. The Agency states that the consortium supporting the joint registration of the Substance refers specifically to the term 'nanoforms' in the Frequently Asked Questions displayed on its website. According to the Agency, the Appellant also did not raise any issues with the term 'nanoform' during the commenting phase of the Draft Decision.

31. Finally, the Agency claims, referring to joined cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00 and T-141/00, (*Artegodan GmbH and Others v Commission*, EU:T:2002:283), that according to the case-law of the Court of Justice of the European Union the protection of human health must take precedence over economic considerations.

Findings of the Board of Appeal

32. The Appellant claims that the Contested Decision breaches the principle of legal certainty as the terms 'forms', 'grades' and 'nanoforms' used therein are not defined in the REACH Regulation, in the Agency's guidance documents or in the Contested Decision. The Appellant submits that, as a result, it is unable to ascertain unequivocally how to comply with the Contested Decision.

33. The principle of legal certainty requires that every act of the administration which produces legal effects should be clear and precise so that the person concerned is able to know without ambiguity what his rights and obligations are and to take steps accordingly (see Case C-279/95 P, *Langnese-Iglo v Commission*, EU:C:1998:447, paragraph 78 and Joined Cases T-427/04 and T-17/05, *French Republic and France Télécom SA v Commission*, EU:T:2009:474, paragraph 300).

34. For the purposes of considering the Appellant's plea, the Board of Appeal will examine whether the terms 'forms', 'grades' and 'nanoforms' employed in the Contested Decision are clear and precise and, if they are not, whether the Appellant was nonetheless able to ascertain what information it must provide to the Agency in order to comply with the Contested Decision.

'Grades' and 'Forms'

35. The Board of Appeal observes that, as confirmed by the Agency during the present proceedings, the terms 'grade' and 'form', within the meaning of the Contested Decision, are not defined in the REACH Regulation or in the Agency's guidance.

36. The Board of Appeal notes that the terms 'grades' and 'forms' are used on numerous occasions in Section III ('Statement of reasons') of the Contested Decision.

37. The term 'grade' is used in the information requirement section of the Contested Decision concerning the name, molecular and structural formula or other identifiers of the Substance (Section III.A.1 of the Contested Decision) as follows:

'*The Registrant shall thus consider whether a change of the materials and/or the process parameters yields grades of the same substance or results in different substances. Where the registered substance is manufactured/imported as different grades of the same substance, information on the manufacturing parameters shall be reported separately for each grade. For each grade the respective composition of defined stoichiometric ratio, phase(s) (amorphous, crystalline) and form(s) (fibers, powders, nanopowders, surface treated forms, etc. as relevant) shall also be reported*'.

'…a*morphous silicas are known to have grades (compositions of specific form e.g. powders, ultra-fine powders, etc.) that meet the EU recommendation for nanomaterials […] in terms of primary particle size and/or specific surface area*'.

'*…where the Registrant intends to cover grades that meet the definition in the EU recommendation for nanomaterials in this registration dossier, information on these grades in terms of their manufacturing process, their respective composition, phase(s) and form(s) (including information about particle sizes) will need to be included in section 1 of the dossier*'.

'*Similarly, the Registrant shall note that where it intends to cover chemically surface treated grades of high specific surface area in the dossier, information on these grades in terms of their manufacturing process, their respective composition, phase(s) and form(s) (including information about particle sizes) will also need to be provided. This is particularly relevant as in the description of the manufacturing process included in section 3.1, the Registrant mentions surface treatment;* "*Optionally, the product can be milled, granulated or surface treated after the drying step." The Registrant shall note that chemically surface treated grades of high specific surface area can only be covered by the registration if they have been reported in the dossier. In this respect, the Registrant shall note that the FAQ available on the ECHA website concerning the exemption from registration obligations for chemically surface treated substances […] is not applicable to high surface area particulates, as the question tackled by this FAQ only relates to "macroscopic particles" of low specific surface area*'.

'*Details of the grades (composition(s) of specific stoichiometry its phase and form where relevant) of the UVCB substance shall be included in the Description field in IUCLID Section 1.1, respectively together with the description of the manufacturing process used. The composition of each grade shall be reported separately in section 1.2. and sufficient analytical data for the grade shall be included in section 1.4. If the registrants intends to cover nanoforms with this registration as specified by EU recommendation for nanomaterials […], the respective particle sizes covered by this registration should also be reported in Section 4.5 of IUCLID (i.e. in the form of particle size distribution)*'.

'*[The Agency] highlights that failure to report sufficient information on each grade of a substance in the dossier, including nanoforms, whether surface treated or not, may result in these grades not being covered by this registration.*

In the absence of suitable information, [the Agency] cannot be in a position to determine whether the registration covers any specific nanoforms of the substance.

Only the Registrant of the substance knows the relevant forms under which the substance is manufactured or imported. Only the Registrant is therefore able to determine the particle size distribution of constituent particles and to report sufficient information on the respective grades manufactured. The information should be sufficient to ensure that [the Agency] is in a position to determine the particle size distribution of primary particles of the substance and to allow [the Agency] to identify each grade covered by the registration'.

38. The term 'grade' is also used in the information requirement section of the Contested Decision concerning the composition of the Substance (Section III.A.2 of the Contested Decision) as follows:

'*Where the Registrant covers different grades (compositions of specific stoichiometry, phase and form as relevant) of the same substance in a registration, the Registrant shall report separately the compositional information of each grade. This means that if the substance covered by the registration has two (or more) different grades, then these must be presented separately. Corresponding analytical data to enable the identity and composition of each grade listed in 1.2 to be verified shall be included in Section 1.4. For each grade, the name and other identifiers for each constituent shall specify the phase and form the composition refers to. This information shall be sufficient to enable the specific grades of the substance registered by this legal entity to be verified and shall be consistent with the information included in Section 1.1 on the "name and other identifiers" for the substance. All grades reported are required to refer to the same substance identified in Section 1.1 of the dossier […]*

As noted in reported in Section III.A.1, [the Agency] highlights that failure to report separately the compositional information of each grade of a substance may result in one or more grades not being covered by this registration'.

39. The term 'form' is used in the information requirement section of the Contested Decision concerning the name, molecular and structural formula or other identifiers of the Substance (under Section III.A.1 of the Contested Decision) as follows:

'*[…] For each grade the respective composition of defined stoichiometric ratio, phase(s) (amorphous, crystalline) and form(s) (fibers, powders, nanopowders, surface treated forms, etc. as relevant) shall also be reported*'.

'*[…] amorphous silicas are known to have grades (compositions of specific form e.g. powders, ultra-fine powders, etc.)*'.

'*To ensure a high level of protection of human health and the environment, the REACH Regulation imposes the determination of hazards and risk irrespective of the form of the substances concerned […]*'.

'*Furthermore, it is self evident that in order to determine the hazardous properties and the appropriate risk management measures for substances in different forms, it is necessary to characterise the substance in terms of its physical form, in particular regarding nanoforms, before determining the corresponding hazards and assessing the exposure of humans and the environment and the associated risk management measures […]*'.

'*[…] Consequently, where the Registrant intends to cover grades that meet the definition in the EU recommendation for nanomaterials in this registration dossier, information on these grades in terms of their manufacturing process, their respective composition, phase(s) and form(s) (including information about particle sizes) will need to be included in section 1 of the dossier'*.

'Similarly, the Registrant shall note that where it intends to cover chemically surface treated grades of high specific surface area in the dossier, information on these grades in terms of their manufacturing process, their respective composition, phase(s) and form(s) (including information about particle sizes) will also need to be provided…'.

'Details of the grades (composition(s) of specific stoichiometry its phase and form where relevant) of the UVCB substance shall be included in the Description field in IUCLID Section 1.1, respectively together with the description of the manufacturing process used […]'.

'In the absence of suitable information, [the Agency] cannot be in a position to determine whether the registration covers any specific nanoforms of the substance. Only the Registrant of the substance knows the relevant forms under which the substance is manufactured or imported. Only the Registrant is therefore able to determine the particle size distribution of constituent particles and to report sufficient information on the respective grades manufactured. The information should be sufficient to ensure that [the Agency] is in a position to determine the particle size distribution of primary particles of the substance and to allow [the Agency] to identify each grade covered by the registration'.

40. The term 'form' is also used in the information requirement section concerning the composition of the Substance (Section III.A.2 of the Contested Decision) as follows:

'*[…] From this limited information, due to the inconsistencies in the identifiers of the reference substance, as reported in Section III.A.1, the compositions of the specific stoichiometric ratio(s) and its corresponding phase(s) and form(s) where relevant cannot be verified*'.

Where the Registrant covers different grades (compositions of specific stoichiometry, phase and form as relevant) of the same substance in a registration, the Registrant shall report separately the compositional information of each grade. This means that if the substance covered by the registration has two (or more) different grades, then these must be presented separately. Corresponding analytical data to enable the identity and composition of each grade listed in 1.2 to be verified shall be included in Section 1.4. For each grade, the name and other identifiers for each constituent shall specify the phase and form the composition refers to […]'.

41. The term 'form' is further used in the information requirement section of the Contested Decision concerning the description of the analytical methods (under Section III.A.3 of the Contested Decision) as follows:

'*Specifically the Registrant has included […] SiNMR spectra, IR spectra and XRD patterns for one grade of the substance registered. This information is sufficient to determine that the substance includes silica functional groups (NMR and IR spectra) and that the phase of the test sample is amorphous (XRD pattern). It is not however sufficient for the determination of the chemical composition of any of the specific stoichiometric ratios registered by this legal entity, their respective phase(s) and form(s) as relevant*.'

'*In line with Annex VI, 2.3.7., the Registrant shall include information on the methods used to quantify all substance constituents in terms of their stoichiometries, phase and form where relevant*.'

42. The Board of Appeal also observes that, as noted in the minutes of the telephone conference which took place between the Agency and several co-registrants of the Substance on 21 January 2014 to discuss the Draft Decision, the Appellant had already raised concerns as to the meaning of the terminology used in the Contested Decision prior to its adoption. For example, the minutes record:

'*The registrant indicated that [the Agency] should clarify/define the meaning of grade and form. He further asked whether we mean product grade.*

[The Agency] explained that grade and form are specified in section III 2. Paragraph 6 of the [Draft Decision]. Grade does not mean the commercial product grade. Furthermore, [the Agency] clarified that indeed the decision does not mean commercial

product grade, and that the word phase refers to crystalline vs. amorphous phase of the substance.'

43. The Board of Appeal finds however that the abovementioned citations from the Contested Decision, and the clarifications that the Agency provided to the Appellant during the decision-making process, are insufficient to clarify the meaning of the terms 'forms' and 'grades' for the purposes of allowing the Appellant to understand what information is required by the Contested Decision.

44. As the Appellant has demonstrated during the present proceedings, the Agency inconsistently defines the meaning of 'grade' in the Contested Decision. For example, the Contested Decision states at one point '*grades (composition(s) of specific stoichiometry its phase and form where relevant)*' and at another point that grades are defined as '*compositions of specific form e.g. powders, ultra-fine powders, etc.*'.

45. Furthermore, the Contested Decision states that '*…amorphous silicas are known to have grades (compositions of specific form e.g. powders, ultra-fine powders, etc.) that meet the EU recommendation for nanomaterials in terms of primary particle size and/or specific surface area*'. As observed by the Appellant, from this wording it is unclear whether the examples in the list are 'grades' or 'forms'. Similarly, is it unclear from this whether 'powder' is a 'grade' or 'form', or whether each different type of powder is a 'grade' or 'form'.

46. The Board of Appeal also considers that the lack of certainty regarding the meaning of the terminology used in the Contested Decision is highlighted by the fact that the Agency was unable to provide sufficient clarity to the meaning of those terms during the present proceedings. This is demonstrated by the fact that the explanations of the terms given by the Agency during these appeal proceedings differ from those set out in the Contested Decision. For example, in the Agency's written replies to the Board of Appeal's questions the Agency stated that 'grade' refers to '*composition/form/phase*' and 'form' refers to '*size/shape/structure (surface chemistry)*'. This is clearly different to the explanations of the terms given in the Contested Decision as set out, for example, in paragraphs 44 and 45 above.

47. Furthermore, the explanations of the terms 'grade' and 'form' given in the Contested Decision leave it unclear, for example, whether the Agency means that separate, or range, information should be provided whenever one of the 'variables' mentioned in the previous paragraph changes or exactly what information is needed for each variable. More importantly, it is not clear from the Contested Decision when one grade is considered to be distinct from another grade for the purposes of establishing the Substance's identity, especially bearing in mind the many 'variables' involved. This lack of clarity makes it impossible for the Appellant to know with any certainty what information it has to provide to comply with the Contested Decision.

48. In view of the above, the Board of Appeal finds that the terms 'forms' and 'grades' are not clearly defined in the Contested Decision. On the contrary, the Contested Decision does not allow a diligent registrant to be sure with any degree of certainty what information it is required to provide to ensure compliance with the Contested Decision.

Nanoforms

49. The Contested Decision makes the following references to 'nanoforms':

'*[The Agency] notes that amorphous silicas are known to have grades (compositions of specific form e.g. powders, ultra-fine powders, etc.) that meet [Commission Recommendation 2011/696/EU] in terms of primary particle size and/or specific surface area*.

To ensure a high level of protection of human health and the environment, the REACH Regulation imposes the determination of hazards and risk irrespective of the form of the substances concerned. This includes more specifically nanoforms of substances, which may trigger specific hazardous properties and risks, as already highlighted by various institutions, including the European Parliament […].

In fact, the current scientific knowledge establishes that the risks of nanoforms of substances would require separate assessment. Indeed, the specific risks of nanoforms are not founded on mere hypotheses that have not been scientifically confirmed. These risks have actually been fully demonstrated by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) […]. The fact that there is still some degree of scientific uncertainty as to the existence or extent of such risks does not, by itself, discharge registrants from characterising nanoforms in order to carry out their duties under the REACH Regulation. Based on the above, the Registrant is compelled to scientifically assess the potentially adverse effects of nanoforms.

Furthermore, it is self evident that in order to determine the hazardous properties and the appropriate risk management measures for substances in different forms, it is necessary to characterise the substance in terms of its physical form, in particular regarding nanoforms, before determining the corresponding hazards and assessing the exposure of humans and the environment and the associated risk management measures. The characterisation of nanoforms of the substance is a pre-requisite to the determination of all the hazardous properties and appropriate risk management measures concerning the registered substance. Therefore, it is essential that suitable information on nanoforms is submitted, especially in order to identify precisely whether the registered substance includes nanoform.'

'*In his comments to the draft decision, the Registrant notes that "[the Substance] represents a nano structured substance. This means external particle size (aggregate and agglomerate) exceeds 100 nm, while size of theoretical primary particle is below 100 nm. [The Substance] does not contain free primary particles." [The Agency] notes that the EU Recommendation explicitly includes aggregates and agglomerates within the scope of 'nanomaterial' when the smallest constituent particle is less than 100 nm and/or the volume specific surface area is >60 m^2/cm^3. Where the registered grades meet these criteria, they are nanomaterials according to the EU recommendation. Consequently, where the Registrant intends to cover grades that meet the definition in the EU recommendation for nanomaterials in this registration dossier, information on these grades in terms of their manufacturing process, their respective composition, phase(s) and form(s) (including information about particle sizes) will need to be included in section 1 of the dossier*'.

'*[The Agency] highlights that failure to report sufficient information on each grade of a substance in the dossier, including nanoforms, whether surface treated or not, may result in these grades not being covered by this registration.*

In the absence of suitable information, [the Agency] cannot be in a position to determine whether the registration covers any specific nanoforms of the substance. Only the Registrant of the substance knows the relevant forms under which the substance is manufactured or imported. Only the Registrant is therefore able to determine the particle size distribution of constituent particles and to report sufficient information on the respective grades manufactured […]'.

50. The Board of Appeal observes, as confirmed by the Agency during the present proceedings, that the term 'nanoforms' is not defined, or used, in the REACH Regulation or in Commission Recommendation 2011/696/EU.

51. During the present proceedings, the Agency clarified that the terms 'nanoform' and 'nanomaterial', which are used interchangeably in the Contested Decision, both refer to a substance that meets the criteria for 'nanomaterial' set out in Commission Recommendation 2011/696/EU.

52. Given the Agency's use of the term 'nanoform', the Board of Appeal considers that the wording of the Contested Decision implies that the Agency started from a presumption that the Appellant intended to register the Substance both in 'bulk form' and as a nanomaterial within the meaning of Commission Recommendation 2011/696/EU. For example, as cited in paragraph 49 above, the Contested Decision states that '*…it is essential that suitable information on nanoforms is submitted, especially in order to identify precisely whether the registered substance includes nanoform'.* Similarly, the Contested Decision states that *'…where the Registrant intends to cover grades that meet the definition in the EU recommendation for nanomaterials in this registration dossier…' and '… failure to report sufficient information on each grade of a substance in the dossier, including nanoforms, whether surface treated or not, may result in these grades not being covered by this registration'.*

53. However, the Board of Appeal considers that it should have been clear to the Agency from Section 1.1 of the Chemical Safety Report ('CSR') that the Appellant only intended to register the Substance as a nanomaterial within the meaning of Commission Recommendation 2011/696/EU. In other words, the Appellant did not intend to register the Substance in a 'bulk form'.

54. This intention was reiterated in the Appellant's comments of 31 January 2014 on the Draft Decision in which the Appellant stated: *'[the Substance] represents a nano structured substance. This means external particle size (aggregate and agglomerate) exceeds 100nm, while size of theoretical primary particle is below 100nm. [The Substance] does not contain free primary particles. This information was provided in the CSR of the submitted dossier. There was no tick-box for nano at the time the dossier was prepared and no update has been done since. When updating the dossier with the analytical data, we will select the tick-box for a nanomaterial…*'.

55. The Appellant also made a similar statement to the Agency during the telephone conference which took place between the Agency and several co-registrants of the Substance on 21 January 2014, according to the minutes of that meeting.

56. The Board of Appeal therefore considers that it should have been clear to the Agency that, as explicitly confirmed by the Appellant during the oral hearing, the Appellant only intended to register the Substance as a nanomaterial. In consequence, requiring further information on 'nanoforms', while the Appellant has already provided information on the substance it intends to register and which, according to the Appellant, is a nanomaterial within the meaning of Commission Recommendation 2011/696/EU, creates uncertainty as to what additional information the Appellant is to provide. At the oral hearing, the Agency was unable to clarify for example whether the requests for information in the Contested Decision are to be understood as meaning that the Appellant must provide details of the size of the Substance beyond that required to show that it is indeed a nanomaterial within the meaning of Commission Recommendation 2011/696/EU. The Board of Appeal considers that this adds to the uncertainty created by the use of the terms 'grades' and 'forms' as set out in paragraph 48 above.

57. The Board of Appeal also observes that Section 3.2.1 of the Agency's guidance document on '*IUCLID 5 Guidance and Support – Nanomaterials in IUCLID*' (February 2013; hereinafter the 'Guidance on IUCLID 5') (case 1: the nanomaterial is a distinct substance and only one composition is included) instructs registrants to '*follow the instructions for completing the IUCLID dossier as for any other substance*'. Whilst the Board of Appeal notes that this guidance was not available at the time the registration was submitted, and that this point is not decisive in arriving at a decision in the current

appeal, the Guidance on IUCLID 5 does not indicate in any way that the information on a nanomaterial should be reported differently to a substance which is only manufactured or imported as 'bulk' material.

58. In view of the above, the Board of Appeal finds that the Contested Decision does not allow the Appellant to clearly ascertain how to ensure compliance with the requests set out therein.

59. The findings of the Board of Appeal are also not affected by the Agency's arguments that the protection of human health overrides the protection of economic interests when considering the principle of legal certainty. According to the case-law cited by the Agency (see paragraph 31 above) the conditions for the withdrawal of a marketing authorisation for a medicinal product must be interpreted in accordance with the general principle, identified in the case-law, that protection of public health must unquestionably take precedence over economic considerations. The Board of Appeal observes that by the present plea the Appellant is not raising arguments related to the economic impact resulting from an obligation imposed on it, or on a right withdrawn from it, but is rather arguing that it is unable to know how to comply with the Contested Decision due to the uncertainty surrounding the terminology used therein. The Board of Appeal has decided above that the Contested Decision is unclear regarding certain of the terminology used therein. Furthermore, the Board of Appeal observes that a clear and well-defined decision requesting information on the identity and properties of a substance can actually help to achieve the objective of protecting human health as it will help to ensure that the information provided is as complete and accurate as possible. The argument of the Agency in this regard must therefore be rejected.

60. The Board of Appeal therefore finds that the Contested Decision breaches the principle of legal certainty and the Appellant's first plea should therefore be accepted.

Consequences of the Board of Appeal's Decision

61. The Board of Appeal observes that at the oral hearing the Appellant stated that, as it was unable to clearly identify sections of the Contested Decision which it wants to be annulled, it requests the Board of Appeal to annul the Contested Decision in so far as it refers to the terms 'grades', 'forms' and 'nanoforms'. The Board of Appeal also notes that in the Notice of Appeal the Appellant states that it does not challenge the Contested Decision in its entirety.

62. However, the Board of Appeal considers that the terms 'grades', 'forms' and 'nanoforms' are an integral part of the reasoning for all three information requirements set out in the Contested Decision. The Board of Appeal considers that those terms are inseparable from the content of the Contested Decision. The Board of Appeal is therefore unable to simply remove those terms from the Contested Decision and order the Appellant to comply with the remainder of the Contested Decision. The Board of Appeal therefore annuls the Contested Decision in its entirety and remits the case to the Agency for further action.

63. Notwithstanding the fact that the appeal has been upheld in so far as the Appellant requests the Board of Appeal to annul the Contested Decision with regard to the terms 'grades', 'forms' and 'nanoforms', the Appellant is encouraged to upgrade its registration dossier to clarify the 'nano structured substance' it is registering to the extent possible.

64. As the appeal has been decided in favour of the Appellant, the Board of Appeal will not consider the Appellant's additional pleas set out in paragraph 18 above. In particular, since it is not clear from the Contested Decision exactly what information the Appellant is required to provide, the Board of Appeal is unable to decide on the legality of those requests.

Refund of the appeal fee

65. 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.

66. As the appeal has been decided in favour of the Appellant the appeal fee shall be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls Decision CCH-D-0000004724-72-03/F of 17 December 2014.**

2. **Remits the case to the competent body of the Agency for re-evaluation.**

3. **Orders the refund of the appeal fee.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal