EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

30 June 2017

(Substance evaluation – Nanomaterials – Potential risk – 'Forms' of a nanomaterial – Proportionality – Error of assessment – Article 25 – Legal certainty)

Case number	A-015-2015
Language of the case	English
Appellants	Evonik Degussa GmbH and Others (see Annex for full list of Appellants)
Representatives	Ruxandra Cana, Indiana de Seze and Eléonore Mullier Steptoe & Johnson LLP, Belgium
Interveners	(I) PETA International Science Consortium Ltd (PISC), United Kingdom (II) ClientEarth, United Kingdom, and Center for International Environmental Law (CIEL), United States of America (III) Solvay Advanced Silicas Poland SP ZOO, Poland
Contested Decision	Decision of 11 March 2015 on the substance evaluation of silicon dioxide adopted by the European Chemicals Agency pursuant to Article 46(1) 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

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Background to the dispute

1. On the basis of an opinion of the Member State Committee (hereinafter the 'MSC') of the European Chemicals Agency (hereinafter the 'Agency'), and due to initial grounds for concern relating to '*the substance characterisation, nanoparticles and toxicity of different forms of the substance*', silicon dioxide (CAS No 7631-86-9, EC No 231-545-4) was included in the Community rolling action plan (hereinafter the 'CoRAP') for substance evaluation in 2012 pursuant to Article 44(2) of the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise). The CoRAP was published on the Agency's website on 29 February 2012. The Competent Authority of the Netherlands was appointed to carry out the evaluation (hereinafter the 'eMSCA').

2. The Agency stated during the proceedings that the European Inventory of Existing Commercial Chemical Substances ('EINECS') entry used as the basis for the registration was for silicon dioxide whilst the relevant registrations are made for synthetic amorphous silica (hereinafter 'SAS').

3. According to the Contested Decision, '*the [eMSCA] has conducted a targeted evaluation that does not include a full evaluation of all elements of the registration dossiers. The evaluation is targeted to the characterisation of the substance, human health hazard assessment in relation to the inhalation route and exposure assessment of [SAS]*'.

4. According to the Appellants, '*SAS is a substance used, amongst other uses, as a reinforcing agent, as a thickening agent, as an absorbing agent in technical applications, and approved in consumer products including cosmetics, pharmaceuticals, food contact, food and feed, amongst others, as a free flowing agent in powdery products and as a clarification agent*'.

5. As stated in the Contested Decision, and confirmed during the present proceedings, SAS comprises the following four types: pyrogenic SAS, precipitated SAS, silica gel and colloidal SAS. Annex I to the Contested Decision defines '*SAS types*' as '*pyrogenic silica, precipitated silica, silica gel and colloidal silica*'. The Contested Decision also makes a number of references to '*SAS forms*' which are defined in Annex I to the Contested Decision as '*…all individual size grades and trade names that can be identified separately per SAS type, based on differences in characteristics*'.

6. Pursuant to Article 46(1), the eMSCA prepared a draft decision and, on 27 February 2013, submitted it to the Agency.

7. On 4 April 2013, the Agency sent the draft decision to the Appellants and invited them to provide comments within 30 days pursuant to Article 50(1).

8. By 6 May 2013, the Appellants provided comments to the Agency on the draft decision. The draft decision was modified by the eMSCA following the comments of the Appellants.

9. On 29 August 2013, a meeting was held between the eMSCA and, amongst others, a number of the Appellants at which the draft decision and the comments submitted by one of the Appellants were discussed.

10. On 17 December 2013, the Appellants provided additional information to the eMSCA including a study on exposure of workers to SAS.

11. On 12 May 2014, a further meeting was held between the eMSCA and, amongst others, a number of the Appellants at which the draft decision was discussed.

12. On 4 September 2014, in accordance with Article 52(1), the eMSCA notified the Competent Authorities of the other Member States (hereinafter the 'MSCAs') and the Agency of the modified draft decision and invited them, pursuant to Articles 52(2) and 51(2), to submit proposals for amendment within 30 days.

13. Proposals for amendment were subsequently received from four MSCAs and the Agency.

14. On 10 October 2014, the Agency notified the Appellants of the proposals for amendment and invited them, pursuant to Articles 52(2) and 51(5), to provide comments within 30 days.

15. The eMSCA reviewed the proposals for amendment and further amended the draft decision accordingly (hereinafter the 'amended draft decision').

16. On 20 October 2014, the Agency referred the amended draft decision to the MSC.

17. On 10 November 2014, the Appellants provided comments on the proposals for amendment.

18. The amended draft decision was discussed at the MSC meeting of 8 to 11 December 2014 at which representatives of some of the Appellants were present. On 9 December 2014, the Appellants presented their views on the proposals for amendment and on the comments of the eMSCA and the Agency. The MSC reached a unanimous agreement on the amended draft decision, as modified at the meeting, on 11 December 2014.

19. The Contested Decision was adopted by the Agency on 11 March 2015. It requires the Appellants to submit the information set out in paragraphs 20 to 24 below by 20 March 2017.

20. With regards to '*[SAS] (excluding surface-treated forms)'* the Appellants were requested to provide the following information (hereinafter the 'first request'):

    '*1. Information on the following physicochemical properties of each individual SAS form […] that is manufactured, imported and/or placed on the market, using the indicated test method(s) under standardised conditions that are fully described:*

    a. *The granulometry, which shall include primary particle size, aggregate/ agglomerate size, and particle size distribution (number-based). […];*
    b. *The specific surface area (by volume). […];*
    c. *The hydroxylation state. […];*
    d. *The water solubility. […];*
    e. *The density. […];*
    f. *The dustiness. […];*
    g. *The point of zero charge. […].*

    The information on the physicochemical properties shall be provided for each individual SAS form covered by the registration of silicon dioxide and shall be provided for the substance forms as produced, processed and placed on the market. Only the Registrant(s) of the substance know the details of each of its forms necessary for their characterisation. Based on this knowledge, they may consider that a test method requested by [the Agency] is not suitable in order to characterise each form of [SAS]. Nevertheless, it is the Registrant(s)' exclusive responsibility 1) to ensure that [the Agency] is in a position to characterise precisely each form of [SAS] and 2) to justify the reasons for the use of another test method instead of a method explicitly required in the present decision.

As an alternative, grouping may be used to provide information on physicochemical properties of SAS forms. In such case the Registrant(s) shall provide a clear justification and documentation as further specified in section III [of the Contested Decision].'

21. With regards to *'[SAS] (excluding surface-treated forms)'* the Appellants were further requested to provide the following information (hereinafter the 'second request'):

'2. Sub-chronic toxicity study (90-day; OECD 413), in rats via the inhalation route with the following four pyrogenic SAS forms as manufactured that represent:

i. the lowest specific surface area with the lowest number of hydroxyl groups,

ii. the lowest specific surface area with the highest number of hydroxyl groups,

iii. the highest specific surface area with the lowest number of hydroxyl groups,

iv. the highest specific surface area with the highest number of hydroxyl groups,

[…]

As an alternative, in case for one of the identified forms a sub-chronic toxicity study (90-day, via inhalation) is available (taking into account the modifications to OECD 413 indicated above), and the tested form […] is fully characterised according to request 1 of this Decision, this information may be provided to cover the information request for this one form.'

22. With regards to *'[SAS] (excluding surface-treated forms)'* the Appellants were also requested to provide the following information (hereinafter the 'third request'):

'3. Information on the uses of each individual form of SAS […] that is manufactured, imported and/or placed on the market.'

23. With regards to '*surface-treated SAS*' the Appellants were requested to provide the following information (hereinafter the 'fourth request'):

'4. Information on the following physicochemical properties of each individual surface-treated SAS form […] that is manufactured, imported and/or placed on the market, using the indicated test method(s) under standardised conditions that are fully described:

a. The granulometry, which shall include primary particle size, aggregate/agglomerate size and particle size distribution (number-based) […];

b. The specific surface area (by volume). […];

c. The hydroxylation state. […];

d. The surface treating agent(s), including chemical identity (IUPAC name and numerical identifiers (CAS and EC)) and type of reaction with the SAS surface;

e. The water solubility. […];

f. The density. […];

g. The dustiness. […];

h. The point of zero charge. […].

The information on the physicochemical properties shall be provided for each individual surface treated SAS form of silicon dioxide and shall be provided for the substance forms as produced, processed and placed on the market. Only the Registrant(s) of the substance know the details of each of its forms necessary for their characterisation. Based on this knowledge, they may consider that a test method requested by [the Agency] is not suitable in order to characterise each form of the substance.

Nevertheless, it is the Registrant(s)' exclusive responsibility 1) to ensure that [the Agency] is in a position to characterise precisely each surface treated form of the substance and 2) to justify the reasons for the use of another test method instead of a method explicitly required in the present decision.

As an alternative, grouping may be used to provide information on physicochemical properties of SAS forms. In such case the Registrant(s) shall provide a clear justification and documentation as further specified in section III [of the Contested Decision].'

24. With regards to '*surface-treated SAS*' the Appellants were further requested to provide the following information (hereinafter the 'fifth request'):

'5. All toxicological information on surface-treated SAS as manufactured, imported and/or placed on the market as available to the Registrant(s). This includes all exposure routes, all toxicological endpoints and all forms of surface-treated SAS. Further, a scientific justification shall be provided that substantiates if and why the toxicological information on untreated SAS can be used for safety assessment of surface-treated SAS.'

Procedure before the Board of Appeal

25. On 10 June 2015, the Appellants lodged the present appeal at the Registry of the Board of Appeal.

26. On 2 September 2015, applications to intervene were received from PISC and Solvay Advanced Silicas Poland SP ZOO in support of the Appellants. On the same day, an application to intervene was submitted jointly by ClientEarth and CIEL in support of the Agency.

27. On 21 September 2015, the Agency submitted its Defence requesting the Board of Appeal '*to dismiss the appeal as inadmissible in part or as unfounded*'.

28. By decisions of 2 and 4 December 2015 respectively, the Board of Appeal, having heard the Parties, granted the applications to intervene submitted by Solvay Advanced Silicas Poland SP ZOO and PISC. On 10 February 2016, having heard the Parties, the Board of Appeal granted the application to intervene submitted by ClientEarth/CIEL.

29. On 15 January 2016, the Appellants submitted their observations on the Defence.

30. On 31 March 2016, the Agency submitted its observations on the Appellants' observations on the Defence.

31. On 29 April 2016 and 2 May 2016 respectively, PISC and ClientEarth/CIEL submitted their statements in intervention. Solvay Advanced Silicas Poland SP ZOO did not provide a statement in intervention.

32. On 31 May 2016, the Appellants and the Agency submitted their observations on the statements in intervention.

33. On 5 August 2016, the Parties and the Interveners were notified of the Board of Appeal's decision to close the written procedure.

34. On 10 August 2016, the Appellants submitted additional evidence in support of their appeal entitled '*Results of a PWG review of the Reuzel et al. study (1987)*' (hereinafter the 'PWG review') dated 16 June 2016.

35. On 12 and 17 August 2016 respectively, the Appellants and the Agency requested that a hearing be held. In view of the Appellants' and the Agency's requests, 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; as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.5.2016, p. 4; hereinafter the 'Rules of Procedure'), the Parties were summoned to a hearing which was held on 7 November 2016. At the hearing, the Parties, PISC and ClientEarth/CIEL made oral presentations and responded to questions from the Board of Appeal. The Agency was also granted additional time to provide oral observations on the PWG review. Solvay Advanced Silicas Poland SP ZOO did not attend the hearing.

36. During the hearing the Chairman stated that the Board of Appeal would decide on the admissibility of the PWG review in its final decision. Moreover, the Board of Appeal granted the Agency one month from the date of the hearing to provide written observations on that document.

37. On 7 December 2016, the Agency provided observations, including those of the eMSCA, on the PWG review, including arguments that this evidence is inadmissible.

38. On 7 December 2016, the Parties and the Interveners were informed that the proceedings before the Board of Appeal were closed. At the same time, the Appellants were informed that the Board of Appeal had rejected their request of 16 November 2016 to provide further observations on the Agency's observations on the PWG review.

Form of order sought

39. The Appellants, supported by Solvay Advanced Silicas Poland SP ZOO and PISC, request the Board of Appeal to:

- set aside the decision to include silicon dioxide on the CoRAP,
- annul the Contested Decision in its entirety,
- order the Agency to refund the appeal fee, and
- take such other measures as justice may require.

40. PISC requests further that, if the Contested Decision is upheld, the Appellants should be ordered to follow a step-wise approach whereby the physicochemical data is submitted and reviewed before any decision is taken on further animal testing.

41. The Agency, supported by ClientEarth/CIEL, requests the Board of Appeal '*to dismiss the appeal as inadmissible in part or as unfounded*'.

Reasons

42. Before examining the Appellants' substantive pleas the Board of Appeal will examine the Agency's arguments related to the admissibility of the PWG review which was submitted to the Board of Appeal on 10 August 2016.

43. As a preliminary observation the Board of Appeal notes that during the substance evaluation and the present appeal proceedings there was considerable discussion of a publication from 1991 (Reuzel P., Bruijntjes J., Feron V., Woutersen R., '*Subchronic inhalation toxicity of amorphous silicas and quartz dust in rats*', Food and Chemical Toxicology, (1991) 29(5):341-354; hereinafter the '1991 Reuzel *et al.* publication'). This publication sets out the findings of a study conducted and reported in 1987 by Reuzel and others (hereinafter the '1987 Reuzel *et al.* study' or 'full 1987 study report'). Where the present decision focuses on the findings of this study, rather than on the study as reported, in either 1987 or 1991, it will refer to the 'Reuzel *et al.* study'.

I. Admissibility of evidence (the PWG review) submitted on 10 August 2016

Arguments of the Parties

44. The Agency claims that, pursuant to Article 12(1) of the Rules of Procedure, the PWG review submitted by the Appellants on 10 August 2016 is inadmissible. The Agency suggests that, in line with the principles applied by the Court of Justice of the European Union, the legality of a measure should be assessed on the basis of the elements of fact and of law existing at the time the measure was adopted. Information which did not exist at the time of the adoption of the Contested Decision should therefore be dismissed. In particular, the Agency considers that the evidence was submitted after the closure of the written part of the proceedings and without a valid justification as to why this evidence was submitted at such a late stage of the proceedings. The Agency also argues that the new evidence is limited to demonstrating a different scientific view on existing data and does not add anything new to the proceedings.

45. The Appellants claim that the PWG review substantiates facts and arguments raised and relied upon by the Appellants during the proceedings leading to the adoption of the Contested Decision, most notably the fact that the 1991 Reuzel *et al.* publication does not demonstrate fibrosis because any effects observed are reversible and are in any case due to lung or particle overload.

46. The Appellants argue that the delay in submitting the PWG review has been explained. The Appellants claim that on 9 December 2014 they made a presentation to the MSC in which they announced, amongst other things, that a review of the 1987 Reuzel *et al.* study had been initiated. The Appellants claim that the time it took to eventually submit the PWG review was not unreasonable. The Appellants state that the PWG review was completed in June 2016 and submitted in August 2016 once contractual arrangements for its submission had been agreed between the Appellants.

Findings of the Board of Appeal

47. In accordance with Article 12(1) of the Rules of Procedure, no further evidence may be introduced after the first exchange of written pleadings unless the Board of Appeal decides that the delay in offering the evidence is duly justified.

48. The Board of Appeal observes that the PWG review was not available to the eMSCA or the Agency during the substance evaluation process. It was finalised on 16 June 2016 and submitted to the Board of Appeal on 10 August 2016, which is after the closure of the written procedure on 5 August 2016. The PWG review was submitted by the Appellants to support their contention that the Reuzel *et al.* study does not indicate a concern related to fibrosis that requires further investigation. In particular, the Appellants use it to support their arguments that the effects observed in the Reuzel *et al.* study were reversible and due to particle overload.

49. As the evidence was submitted after the first exchange of written pleadings, the Board of Appeal will consider whether the delay in offering the PWG review as evidence was justified in the present case.

50. The Agency has not disputed that a review of the 1987 Reuzel *et al.* study was announced by the Appellants in a presentation to the MSC (see paragraph 46 above). In this respect, the Appellants attached to the Notice of Appeal a presentation they made to the MSC in which they announced that '*…a pathological reanalysis of organ sections originating from the Reuzel study will be conducted*'. The Appellants also referred in their Notice of Appeal to the on-going review of the Reuzel *et al.* study. The Board of Appeal also observes that it was not until the Appellants received the draft decision on 4 April 2013 that they became aware that the eMSCA interpreted the results

of the Reuzel *et al.* study as indicating a potential inhalation toxicity concern. It is therefore understandable that they had not initiated a review of the 1987 Reuzel *et al.* study before that time.

51. The Board of Appeal finds that the time it took to submit the PWG review was not unreasonable bearing in mind, for example, the time needed to obtain the slides used in the 1987 Reuzel *et al.* study, refresh, prepare and read those slides, re-evaluate the tissues and prepare the report. The Board of Appeal considers that the Appellants have also demonstrated that the delay between announcing the intention to perform the review of the 1987 Reuzel *et al.* study and finally producing it in the present proceedings was justified.

52. In view of the above, the Board of Appeal finds that the delay in submitting the PWG review as part of these appeal proceedings is duly justified and it should therefore be accepted as admissible evidence in the present proceedings. The Agency's claim of inadmissibility must therefore be dismissed as unfounded.

II. Admissibility of the Appellants' claim concerning the illegality of the decision to include silicon dioxide in the CoRAP

Arguments of the Parties

53. The Appellants submit that the Agency's decision of 29 February 2012 to include silicon dioxide on the CoRAP is illegal. As a result, the Contested Decision is based on an unlawful decision and must be annulled.

54. The Appellants argue that the Agency's decision to include silicon dioxide on the CoRAP must be considered as having been adopted for the purposes of Articles 51 and 52 as it is a *sine qua non* condition for the substance evaluation to proceed. As such, the Board of Appeal is competent to set it aside by virtue of the powers granted to it under Article 91.

55. The Appellants also claim that the Board of Appeal is competent to decide on the legality of the decision to include silicon dioxide on the CoRAP by analogy to Article 277 of the Treaty on the Functioning of the European Union (hereinafter the 'TFEU').

56. The Appellants argue that '*if the underlying act is invalid, this affects the legality of the Contested Decision which was adopted on the basis of that underlying act. However, an appellant may have had no standing to challenge the underlying act directly. The purpose of the plea of illegality is therefore to have the underlying act set aside for the purpose of the proceedings directed against the Contested Decision, and to have the Contested Decision annulled accordingly […]. The Appellants do not seek the annulment of the CoRAP listing directly before the Board of Appeal*'.

57. The Appellants argue that the justification provided in the CoRAP and the background documents thereto shows that the inclusion of silicon dioxide on the CoRAP does not meet the criteria established by Article 44 nor the '*Selection Criteria to prioritise substances for Substance Evaluation*' (ED/32/2011 of 26 May 2011; hereinafter the 'Selection Criteria') developed by the Agency. The Appellants claim that the initial grounds of concern for silicon dioxide, specifically '*substance characterization/ nanoparticles, toxicity of different forms of the substance*' are not '*grounds of concern*' justifying inclusion of a substance on the CoRAP.

58. The Appellants claim that Article 45(5) is only a mechanism which allows Member States to suggest the inclusion of additional substances on the CoRAP on the basis that these substances are '*a priority for evaluation*.' The Appellants also state that Article 45(5) does not include criteria for selection. According to the Appellants, the word '*priority*' in Article 45(5) refers to the criteria for prioritisation listed under Article 44. In other words,

applying the Article 45(5) procedure does not exempt the Agency from applying the Article 44 criteria.

59. The Agency, supported by ClientEarth/CIEL, states that it '*has doubts regarding the admissibility of the Appellants' request to set aside [the Agency's] decision to include silicon dioxide on the [CoRAP]*'. The Agency states that Article 11(1)(c) of the Rules of Procedure provides that an appeal is inadmissible if the appeal is not brought against a decision referred to in Article 91(1) of the REACH Regulation. The Agency argues that, since the legal basis for the adoption of the CoRAP by the Agency is Article 44 in conjunction with Article 45(5), the decision to include silicon dioxide on the CoRAP may not be challenged before the Board of Appeal and the Appellants' request is therefore inadmissible.

60. The Agency argues that even if the adoption of the CoRAP is an act challengeable before the Board of Appeal, the three-month time-limit for filing the appeal pursuant to Article 92(2) would have expired since the relevant CoRAP was adopted on 29 February 2012.

61. The Agency argues further that the Appellants are not addressees of the CoRAP and are not directly and individually concerned by that act as required by Article 92(1).

62. The Agency, supported by ClientEarth/CIEL, claims further that, if the Board of Appeal decides that the Appellants' claim is admissible, the arguments presented by the Appellants are nonetheless unfounded. In particular, the Agency argues that substances may be added to CoRAP by way of either Article 44 or Article 45(5). In this respect, the Agency states that silicon dioxide was added to the list as a '*national priority*' of the eMSCA. In addition, the Agency argues that, in any case, Article 44 grants the Agency the competence to develop selection criteria which should be considered but are not limited to the elements listed in points (a) to (c) of that Article.

Findings of the Board of Appeal

63. Article 94(1) provides that '*an action may be brought before the [General Court] or the Court of Justice, in accordance with Article [263 TFEU], contesting a decision taken by the Board of Appeal or, in cases where no right of appeal lies before the Board, by the [Agency]*'.

64. According to Article 91(1) '*[a]n appeal may be brought* [before the Board of Appeal] *against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3) and Article 51*'.

65. The CoRAP is adopted by the Agency and published on its website pursuant to Article 44(2). The Contested Decision was therefore not taken under one of the provisions referred to in Article 91(1).

66. According to Article 91(1) the Board of Appeal is not competent to decide on appeals against an Agency decision to include a substance on the CoRAP.

67. Pursuant to Article 11(1)(c) of the Rules of Procedure an appeal is inadmissible if it is not brought against a decision referred to in Article 91(1).

68. The Appellants argue that the Board of Appeal is nonetheless competent to rule on its plea of illegality by analogy with the powers granted to the Court of Justice of the European Union under Article 277 of the TFEU which provides:

'*Notwithstanding the expiry of the period laid down in Article 263, sixth paragraph, [of the TFEU] any party may, in proceedings in which an act of general application adopted by an institution, body, office or agency of the Union is at issue, plead the grounds specified in Article 263, second paragraph, in order to invoke before the Court of Justice of the European Union the inapplicability of that act.*'

69. The Board of Appeal observes, however, that Article 277 of the TFEU applies to actions before the Court of Justice of the European Union and that there is no similar provision applicable to proceedings before the Board of Appeal.

70. Furthermore, when adopting the REACH Regulation, the legislature - the Council and the European Parliament - did not grant the Board of Appeal the competence to decide on appeals against all Agency decisions. As a result, the Board of Appeal considers that applying Article 277 of the TFEU by analogy to proceedings before the Board of Appeal would extend the list of Agency decisions set out in Article 91(1) which can be appealed before the Board of Appeal. As mentioned in paragraph 66 above, this would be contrary to Article 91(1) which sets out the decisions that may be appealed to the Board of Appeal.

71. The Appellants' claim must therefore be dismissed as inadmissible. As a result, it is not necessary to examine the Appellants' claims that the Contested Decision should be annulled on the grounds that it lacked legal basis on the grounds that silicon dioxide was not legitimately included on the CoRAP.

III. Pleas related to the legality of the requests for information in the Contested Decision

72. The Appellants raise a number of pleas in law contesting the legality of the information requirements set out in the Contested Decision. The Board of Appeal will address these pleas as follows.

73. In Section A, the Board of Appeal will examine the Appellants' arguments related to the alleged lack of concern justifying the requests for further information. These arguments apply to all the information requests set out in the Contested Decision (see paragraphs 20 to 24 above).

74. The Board of Appeal will then examine the Appellants' other pleas and arguments with regards to each of the relevant information requests.

75. In Section B, the Board of Appeal will examine the Appellants' pleas regarding the legality of the first request, concerning data on physicochemical properties of non-surface treated SAS.

76. In Section C, the Board of Appeal will examine the Appellants' pleas regarding the legality of the second request, concerning sub-chronic inhalation toxicity testing on pyrogenic SAS.

77. In Section D, the Board of Appeal will examine the Appellants' pleas related to the third request, concerning information on the uses of non-surface treated SAS.

A - Appellants' pleas in law related to the alleged lack of a concern justifying all the information requirements in the Contested Decision

78. The Board of Appeal highlights that, under substance evaluation, in order to establish the necessity of a request for additional information the Agency must *inter alia* be able to indicate the grounds for considering that a substance constitutes a potential risk to human health or the environment. The Agency must also be able to demonstrate that the potential risk needs to be clarified, and that the requested measure has a realistic possibility of leading to improved risk management measures (Case A-006-2014, *International Flavors & Fragrances*, Decision of the Board of Appeal of 27 October 2015, paragraph 76).

79. The Board of Appeal observes further that the identification of a potential risk is based on a combination of hazard and exposure information (for example, Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others*, Decision of the Board of Appeal of 23 September 2015, paragraph 61).

80. With regards to exposure to SAS, the Board of Appeal observes that exposure to nanomaterials may be higher than that to substances of a larger molecular size due to their potentially larger surface area, with implications for the reactivity of the substance, and potentially higher dispersion in the environment and in humans.

81. Furthermore, it has not been disputed in the present proceedings that SAS is produced in high volumes. The Contested Decision itself is addressed to over one hundred registrants. At the hearing, the Agency stated that SAS is produced in volumes of over one million tonnes annually. Furthermore, SAS has a wide variety of uses (see paragraph 4 above) leading to considerable human exposure to SAS, both as individuals and as populations. The Board of Appeal notes that, as stated in the 1991 Reuzel *et al.* publication, there is also widespread occupational exposure to SAS in a number of industrial settings and through a wide variety of industrial applications.

82. Having established that there is potentially considerable exposure to SAS the Board of Appeal will examine the Appellants' pleas alleging that the Agency has failed to demonstrate a potential hazard. In this respect the Board of Appeal notes that, in assessing whether there is a potential risk, where there is high potential exposure to a substance the evidence of a potential hazard may be correspondingly less. This approach is consistent with the European Union Courts' interpretation of the precautionary principle, according to which a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time the measure was taken (judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 144; see also *International Flavors & Fragrances*, cited in paragraph 78 above, paragraph 77).

83. In light of the above, the Board of Appeal will examine the Appellants' arguments that the Agency has not justified the requests for information to clarify a concern.

1. Appellants' allegation that the Agency unlawfully requested information on the grounds that information is '*missing*' from their registration dossiers

Arguments of the Parties

84. The Appellants argue that the Agency cannot justify requests for information on '*forms*' of a substance on the ground that this information is '*missing*' from the registration dossier because no such information has to be provided under the REACH Regulation.

85. The Agency argues that, rather than a lack of information, the Contested Decision is justified mainly by the fact that the findings of an inhalation study – the Reuzel *et al.* study - resulted in a conclusion that at least one of the type of SAS is '*suspected of posing a risk*'.

Findings of the Board of Appeal

86. The Board of Appeal notes that the Contested Decision is, at least in part, based on the fact that certain information was not available in the Appellants' registration dossiers. In this respect the Contested Decision states that:

'*The information included by the Registrant(s) of the substance SAS in their respective dossiers is not sufficient to identify and characterise the individual forms of the substance manufactured, imported or placed on the market by their respective legal entities. Consequently, the scope of the registered substance cannot be verified and therefore safe use of the substance is not demonstrable based on the information provided. Therefore, physicochemical characteristics for the individual forms of SAS are required to draw appropriate conclusions on possible similarities or expected equalities in characteristics, behaviour and potential interactions with their environment*'.

87. The Board of Appeal has previously held that, further information that is needed to clarify a potential concern can be requested pursuant to substance evaluation (Case A-011-2014, *Huntsman P&A UK*, Decision of the Board of Appeal of 2 March 2017, paragraph 72). This is regardless of whether the specific information requested is included in the annexes to the REACH Regulation. Any request for information must also comply with other legal requirements such as proportionality and legal certainty.

88. Consequently, the Agency must demonstrate that there are grounds for considering that a substance constitutes a risk to human health or the environment and that the information requested will contribute to the clarification of that risk.

89. In light of the above, the Board of Appeal will next examine whether the Agency has demonstrated grounds for concern through the fact that SAS is a nanomaterial and the results of the Reuzel *et al.* study.

2. Appellants' allegation that the Contested Decision is unlawfully based on a concern related to the fact that SAS is a nanomaterial

Arguments of the Parties

90. The Appellants, supported by PISC, claim that it is clear from the Contested Decision and discussions during the decision-making procedure that they are requested to generate and submit information on the grounds that SAS meets the definition of '*nanomaterials*' set out in Commission Recommendation 2011/696/EU on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38). The Appellants argue that this is not a lawful basis for requests for information under substance evaluation. The Appellants argue that the Agency therefore failed to identify a valid concern that needs to be addressed.

91. The Appellants claim in particular that there is no universally accepted or legally binding definition for '*nanomaterials*' and that the REACH Regulation does not treat substances which would meet a definition of '*nanomaterials*' differently from other substances which do not meet this definition.

92. The Appellants also argue that a number of issues related to the definition of nanomaterial in Commission Recommendation 2011/696/EU were stressed in the review of that definition by the Joint Research Centre (Scientific and Policy Report, *Towards a review of the EC Recommendation for a definition of the term 'nanomaterial'*, *Part 2: Assessment of collected information concerning the experience with the definition*, August 2014).

93. The Appellants argue further that, according to the Scientific Committee on Emerging and Newly Identified Health Risks ('*Opinion on the scientific basis for the definition of the term "nanomaterial"',* European Commission, 2010; hereinafter the 'SCENIHR Opinion'), there is no scientific evidence that there is a clear size threshold or turning point for changes in physicochemical properties, except for some semi-conductor metals and metal oxides. The Appellants claim that it can be concluded from this that the 100

nm cut-off for defining the size of nanomaterials under Commission Recommendation 2011/696/EU is arbitrary and a political choice rather than a science-based decision.

94. The Appellants claim that it has been acknowledged by the European Commission and in Commission Recommendation 2011/696/EU that '*there is no consistent causal link between nano-size alone and hazard*'.

95. The Agency states that '*although the scientific uncertainty surrounding the potential risks posed by the nanomaterial forms of the substance triggered the substance evaluation of SAS this uncertainty alone is not used to justify the requests for information in the Contested Decision*'. In other words, it is not because SAS is registered in nanomaterial '*forms*' that the Contested Decision has been adopted. According to the Agency, the available data establishes that SAS can be '*suspected to pose a risk*' of toxicity by inhalation.

96. The Agency states further in the Defence that the institutions and bodies of the European Union '*unanimously acknowledge that the probability that the minute size of nanoforms of a substance is likely to result in hazardous properties and risks which are specific to these forms, is not hypothetical*'. The Agency argues that the institutions and bodies of the European Union also recognize that the knowledge of these '*forms*' is lacking. According to the Agency, '*current scientific knowledge establishes that the risks of nanoforms of substances would require separate assessment*. *Indeed, the specific hazard potential of nanoforms has been demonstrated by [the SCENIHR Opinion]*'.

97. The Agency argues that it is a general principle of the REACH Regulation that manufacturers, importers and downstream users must ensure that they manufacture, place on the market or use substances in such a way that they do not adversely affect human health or the environment. This applies to substances in whatever size or '*form*' and for all their identified uses. Consequently, the registration of a nanomaterial '*form*' of a substance has to include all relevant information on that '*form*' as manufactured or imported, covering its identity, the properties, uses, effects and exposure related information as well as the relevant classification and labelling, safety assessment and any relevant exposure scenarios. According to the Agency, where this cannot be verified during the detailed assessment by a competent authority of a Member State during substance evaluation, further information may be requested in order to address the shortcomings identified.

Findings of the Board of Appeal

98. The Parties agreed, most notably at the hearing, that all '*forms*' of SAS covered by the Appellants' registrations are '*nanomaterials*' within the meaning of Commission Recommendation 2011/696/EU. References to nanomaterials in the present decision are therefore references to nanomaterials within the meaning of Commission Recommendation 2011/696/EU.

99. The Agency acknowledged in the Defence that *'[u]nderstanding the specific properties and any potential risk that may result from the nanomaterial forms of SAS was the triggering interest behind the Substance Evaluation of that substance. It is the explicit reason for which the Dutch authorities suggested SAS for inclusion in the CoRAP list*'.

100. The Agency also explained in the Defence (see paragraph 95 above) that the fact that SAS is a nanomaterial is not used to justify the requests for information in the Contested Decision. The Agency stated that *'the Contested Decision is justified mainly by the fact that the findings of an inhalation study resulted in considering that at least one type of SAS is "suspected of posing a risk"'*.

101. The Board of Appeal observes however that the Agency's submissions, and the Contested Decision, are not entirely consistent in this regard and in part suggest that the fact that SAS is a nanomaterial may be sufficient to demonstrate a potential hazard. For example, the Agency stated during the present proceedings that *'[g]iven the scientific uncertainties on the causal links between the minute sizes of nanomaterials and the toxicity of the substance concerned, as well as the indication of divergence of the physicochemical properties reflected in the dossier of SAS, there is a real information need to ensure the safe use of the substance in all of its forms'*. The Agency also stated that *'[t]he scientific uncertainty surrounding nanomaterial forms of substances, in general, raises concerns that merits further regulatory attention*'.

102. At the hearing, however, the Agency stated that it does not use the fact that a substance is a nanomaterial on its own to establish a concern. In other words the Agency does not ask for information on nanomaterials exclusively on the grounds that they are nanomaterials. The Agency added at the hearing that the fact that a substance has the characteristics of a nanomaterial may, however, accentuate the grounds for concern identified elsewhere.

103. The Agency's position in the present case is therefore that there were specific grounds for concern beyond SAS being a nanomaterial. This is implicitly acknowledged by the Appellants in the Notice of Appeal in stating that *'[a]ll information requests in the Contested Decision are based on the interpretation by [the Agency] of one publication only – the Reuzel et al. publication (1991)*'.

104. In light of the above, the Board of Appeal finds that the fact that SAS is a nanomaterial was clearly a major factor in adding silicon dioxide to CoRAP but is not the sole reason SAS was considered, pursuant to substance evaluation, to pose a potential risk for human health or the environment.

105. The Board of Appeal further finds that being a nanomaterial is insufficient on its own to justify a potential concern. The Board of Appeal notes that some nanomaterials are hazardous whilst others are not. Nanomaterial is a categorisation of a substance by its size. However, the fact that a substance is a nanomaterial neither implies a specific risk nor does it necessarily mean that the substance has different hazard properties compared to its non-nano '*form*'. Furthermore, no consistent causal link has yet been established between size and hazardous properties. The Board of Appeal further notes that the definition of nanomaterials establishes a size threshold for substances to be nanomaterials. The definition does not however mean that substances below the threshold are *per se* more hazardous than those above this threshold.

106. In light of the above, the Appellants' claim that the Agency failed to identify a valid concern as it requested information based solely on the grounds that SAS is a nanomaterial alone is dismissed as unfounded.

107. The Board of Appeal will next examine the Appellants' pleas regarding the Agency's reliance on the 1991 Reuzel *et al.* publication to demonstrate a potential concern.

3. Appellants' allegations related to the Agency's reliance on the 1991 Reuzel *et al.* publication as a grounds for concern

108. In contesting the Agency's reliance on the 1991 Reuzel *et al.* publication as grounds for considering that SAS constitutes a potential risk to human health the Appellants claim that the Agency:

(a) breached its duty of good administration by relying on a 1991 publication reporting the findings of the 1987 Reuzel *et al.* study rather than the full study report itself;

(b) breached the duty of good administration by failing to apply a weight-of-evidence approach by not considering all the relevant information available to it; and

(c) committed an error of assessment in interpreting the results of the 1991 Reuz*el et al.* publication as justifying the requests for further data.

109. The Board of Appeal will examine these pleas in turn.

(a) Alleged infringement of the duty of good administration by relying on the 1991 Reuzel *et al.* publication instead of the full 1987 Reuzel *et al.* study report

Arguments of Parties

110. The Appellants argue that the Agency infringed its duty of good administration by relying on the 1991 Reuzel *et al.* publication rather than the full 1987 study report which was available to the Agency. According to the Appellants, the 1991 Reuzel *et al.* publication contained inaccuracies and mistakes that might have created confusion in interpreting the study results. The Appellants add that they raised these inaccuracies during the decision-making procedure. In their registration dossier, the Appellants attributed a Klimisch reliability score of 1 to the full 1987 study report and not to the 1991 Reuzel *et al.* publication.

111. The Appellants claim that while the observed effects are described in the full 1987 study report as '*very slight*', '*slight*' and '*moderate*', in the 1991 Reuzel *et al.* publication '*…the term* 'severe*' is used in varying degrees*'. According to the Appellants, as the Agency has apparently only reviewed the 1991 Reuzel *et al.* publication, the Contested Decision is based on a misinterpretation of the inhalation data and overestimation of the hazard compared to what would have been concluded from reviewing the 1987 Reuzel *et al.* study.

112. The Agency argues that, as far as the findings of the study are concerned, there is no difference between the 1991 Reuzel *et al.* publication and the full 1987 study report and that the former is an accurate reflection of the latter. The Agency adds the '*…full study report was only provided to the [eMSCA] together with the comments of the Appellants on the draft decision. All the information submitted by the Appellants at that stage, including the full study report, has been taken into account by the evaluating Member State. However, for the reasons explained below, the evaluating Member State considered that this information, and especially the full study report, did not change the findings already conveyed in the Reuzel publication*'.

113. The Agency states that the Appellants themselves did not make any distinction between the 1991 Reuzel *et al.* publication and the full 1987 study report in their registration dossiers and that until the draft decision was notified to the Appellants, the full 1987 study report was not made available in their registration dossiers. The Agency claims that in their registration dossiers the Appellants considered the 1991 Reuzel *et al.* publication to be a key study with a Klimisch reliability score of 1.

114. The Agency argues that both the full 1987 study report and the 1991 Reuzel *et al.* publication use the term '*severe*' not to describe the nature of the effects observed but as a comparative adjective applied to the different types of SAS studied. The Agency argues that the Contested Decision employs the term '*severe*' in the same way.

Findings of the Board of Appeal

115. The full 1987 study report was only made available to the eMSCA at the time the Appellants provided comments on the draft decision. The Board of Appeal observes that, irrespective of the stage at which the full 1987 study report was introduced into the

decision-making procedure, and irrespective of the question of whether the eMSCA and the Agency are obliged in all cases to take into account a full study report rather than a publication reporting the findings of that study, the Agency has stated that the full 1987 study report was taken into account by the eMSCA and the Agency.

116. In any event, the Board of Appeal considers that the conclusions reported in the 1991 Reuzel *et al.* publication are consistent with those presented in the full 1987 study report. For example, the conclusion to the 1987 full study report states that:

'*The results of the present study led to the following conclusions:*

- *of the amorphous silica dust examined [the example of pyrogenic SAS tested] at a level of 30 mg/m^3 induced the most severe changes, which only partly recovered during the one year observation period',*
- *the "no adverse effect level of [the example of pyrogenic SAS tested] is lower than 1 mg/ m^3 when exposed to rats for 3 months;*
- *[the example of surface-treated pyrogenic SAS tested] at a level of 30 mg/m^3 induced approximately similar but generally less severe changes than did [the example of the pyrogenic SAS tested] at a level of 30 mg; these changes disappeared almost completely during the non-exposure period;*
- *[the example of precipitated SAS tested] at a level of 30 mg/m^3 generally induced mild changes, which quickly recovered.*
- *[…]*'.

117. The Board of Appeal observes that this is consistent with the 1991 Reuzel *et al.* publication which states, *inter alia*, that:

'*Of the amorphous silicas examined [the example of pyrogenic SAS tested] induced the most severe changes in the lungs, which only partly recovered, whereas [the example of precipitated SAS tested] induced the least severe, completely reversible lung changes*'.

118. In short, both documents state that the pyrogenic SAS tested '*induced the most severe changes*'. Likewise, precipitated SAS induced '*mild changes*' (1987 Reuzel *et al.* study) and '*the least severe […] changes*' in the comparative analysis of the three types tested (1991 Reuzel *et al.* publication). These conclusions are consistent.

119. The findings in the Contested Decision are also consistent with both the full 1987 study report and the 1991 Reuzel *et al.* publication. For example, the Contested Decision reflects the view that the results were more severe in the pyrogenic SAS tested than in the other types of SAS tested. In this respect, the Contested Decision states that '*the study revealed that 30 mg/m^3 [the example of pyrogenic SAS tested] induced more severe changes in the lungs as compared to 30 mg/m^3 [the example of precipitated SAS tested]*'.

120. The Board of Appeal finds therefore that the Appellants have not demonstrated that the 1991 Reuzel *et al.* publication contained inaccuracies that induced the Agency to make incorrect conclusions about the findings of the full 1987 study report and as a result exaggerate the severity of the adverse effects observed in the 1987 Reuzel *et al.* study.

121. In view of the above, the Appellants claim that the Agency infringed the duty of good administration by relying on the 1991 Reuzel *et al.* publication instead of the full 1987 study report must be dismissed as unfounded.

(b) Alleged failure to apply a weight-of-evidence approach, and (c) alleged error of assessment in interpreting the results of the 1991 Reuzel *et al.* publication

122. The Appellants claim that the Contested Decision should be annulled on the ground that the Agency committed an error of assessment in interpreting the results of the 1991 Reuzel *et al.* publication as justifying the requests for further data under substance evaluation. The Appellants also argue that the Agency breached its duty of good administration by failing to apply a weight-of-evidence approach as the information they presented to the eMSCA and the Agency, taken as a whole, does not demonstrate that there is a concern.

123. When examining whether the Agency has made an error of assessment, the Board of Appeal must examine whether the Agency has examined, carefully and impartially, all the relevant facts of the individual case which support the conclusions reached (Case A-017-2014, *BASF*, Decision of 7 October 2016, paragraph 74 and the case-law cited therein). Similarly, in examining the Appellants' plea that the Agency failed to apply a weight-of-evidence approach the Board of Appeal must also consider whether the Agency took into account all the available evidence before deciding, based on that evidence as a whole, that there was a concern which required further investigation.

124. The Board of Appeal will examine both pleas together.

Arguments of the Parties

125. In the Notice of Appeal the Appellants claim that '*[a]ll information requests in the Contested Decision are based on the interpretation by [the Agency] of one publication only – the Reuzel et al. publication (1991)*'.

126. The Appellants state that, throughout the decision-making procedure, they submitted information demonstrating that the Reuzel *et al.* study does not raise a concern that needs to be addressed through new data.

127. The Appellants claim that the Contested Decision relies on the 1991 Reuzel *et al* publication which contained inaccuracies and mistakes that led the Agency to base its conclusions on a misinterpretation of the inhalation data and an overestimation of the hazard compared to what would have been concluded from reviewing the 1987 Reuzel *et al.* study.

128. The Appellants argue that the effects reported in the Reuzel *et al.* study are not necessarily adverse and result from particle overload. The Appellants also presented evidence that the pulmonary effects following exposures to SAS were reversible after exposure. The Appellants argue further that, according to available data, '*there is no evidence for a fibrogenic effect of SAS in human lung*'. In particular, the Appellants state that on 17 December 2013 they submitted to the eMSCA an article entitled '*Cross-sectional study on respiratory morbidity in workers after exposure to synthetic amorphous silica at five German production plants*' (Morfeld (2013); hereinafter the 'Morfeld study'). The Appellants state that according to that study there are '*no adverse effects of cumulative exposure on respiratory disease*', '*no risk for contracting pneumoconiosis*' and '*negligible health effects due to exposure*'. The Appellants claim that the Agency failed to take this information into account and that this study addresses the exposure concern, without the Appellants having to generate or submit additional information. The Appellants claim further that the Morfeld study indicates that appropriate risk management measures have been implemented by the Appellants and that the information requested does not have a realistic possibility of leading to improved risk management measures.

129. During the present appeal proceedings the Appellants also referred to the occupational exposure limit ('OEL') for SAS set by the Federal Institute for Occupational Safety and Health (BAuA) in Germany and adopted in certain other countries. According to the Appellants, the OEL for SAS is based on a scientific evaluation made by the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (hereinafter 'MAK-Commission') of the Deutsche *Forschungsgemeinschaft* (German Research Foundation), which considered amongst other evidence the Reuzel *et al.* study.

130. The Appellants also argue that the Agency has not put forward any basis to conclude that the non-pyrogenic types of SAS might pose a potential risk to human health or the environment. Therefore, the Contested Decision is unlawful insofar as it requires the Appellants to provide information on precipitated, colloidal and gel SAS.

131. The Appellants also argue that the Agency failed to identify a concern with regards to surface-treated SAS. The Appellants state that surface-treated SAS does not present significant differences in toxicological profile compared to non-surface-treated SAS.

132. According to the Appellants, the Agency also breached the principle of proportionality by requesting information which is not necessary as there was no concern to clarify. The Appellants claim that by not considering all the available information the Agency failed to apply a proper weight-of-evidence approach.

133. The Agency claims that '*there is only one relevant key study with respect to the toxic properties of pyrogenic silica'*, namely the 1987 Reuzel *et al.* study. The Agency claims that the other studies presented by the Appellants refer to other types of SAS and that these therefore cannot change the findings of the 1987 Reuzel *et al.* study.

134. The Agency states that the Contested Decision is justified mainly by the fact that the findings of the Reuzel *et al.* study indicate that at least one type of SAS is suspected of posing a risk for inhalation toxicity. The Agency states that this finding is based on an evaluation of all the available data.

135. The Agency claims that the differences in toxicity between the types of SAS identified in the Reuzel *et al.* study result from differences in physicochemical properties between the types of SAS and the '*forms*' of each SAS type.

136. The Agency states in the Defence that, '*based on current evidence there is no reason to believe that there was impaired clearance and particle retention that would have led to lung overload. Instead, it is highly unlikely that the fibrosis observed in the Reuzel study is due to particle overload*'.

137. The Agency states that, although the severity of fibrosis decreased during the recovery period, fibrosis was still evident 52 weeks after the end of exposure and was therefore not fully reversible. The Agency argues further in the Defence that even a reversible effect may be relevant and that '*…reversibility may not be applicable for persons that are continuously exposed to SAS such as workers who may be exposed on a weekly basis during many years*'.

138. The Agency claims that it and the eMSCA took the Morfeld study into account in reaching its conclusions. The eMSCA and the Agency considered however that this study did not disprove the findings of the Reuzel *et al.* study. The Agency argues for example that *'former workers that are retired or have quitted their job (e.g., due to health problems) are not included in the study group. This may have introduced an unknown bias in the study populations and may have introduced the so-called "healthy-worker effect"*'. In addition, the Agency raises doubts regarding the use of cumulative exposure levels as the study does not take into account the intensity of exposure, which may be of greater importance than the duration. The Agency also highlights that the Morfeld study, in

which nearly half of the examined workers were exposed to precipitated SAS and the others to pyrogenic SAS, does not clearly distinguish between exposures to each.

139. The Agency considers that the Morfeld study did not investigate the effects on lungs or other organs of the workers following exposure to SAS and, as a result, in toxicological terms, no dose/response has been described. The Agency adds that '*the conclusions that (all forms of) SAS [have] no or only a minor effect on lung function, can therefore not be endorsed*'. The Agency also argues that '*as most critical effects make it plausible that during longer exposure there may be effects on the lungs which should be further investigated […]. The Morfeld survey is not suitable to change this conclusion as these specific effects were not covered by the survey*'.

140. The Agency states that the MAK-Commission conclusions were introduced for the first time during the present appeal proceedings and that they were not discussed during the substance evaluation process. The Agency argues however that the MAK-Commission conclusions do not disprove the findings in the Contested Decision. The Agency also argues that the information from the MAK-Commission is outdated, dating back to 1991, and in any case may simply demonstrate a difference of scientific opinion.

141. At the oral hearing, the Agency presented a preliminary analysis of the PWG review in which it came to the preliminary conclusion that this evidence would not have altered its decision to request additional information on SAS. In particular, the Agency stated at the hearing that the original slides re-examined in the PWG review were around 30 years old and that the original tissues may have been damaged during re-examination. The Agency added that not all slides were re-examined. Furthermore, according to the Agency, the PWG review gives another opinion of the results of the 1987 Reuzel *et al.* study.

142. The Agency claims that the concern which justifies the request for information on surface-treated SAS can be found in the Reuzel *et al.* study and the conclusions of the SCENIHR Opinion. In particular, the Agency argues that the differences in toxicity observed in the Reuzel *et al.* study for different types of SAS show that surface-treatment can considerably alter the toxicity of a SAS type or form. The Agency also states that '*the potential risk that surface-treated forms of SAS have different toxic effects, is not limited to inhalation toxicity, but may occur for any type of toxicity. This risk exists potentially for all toxicity endpoints which do not contain studies concerning at least one surface treated form of SAS and other surface-treated forms or non-treated forms. It is only in case where the testing material differs in terms of surface treatment that a difference may occur. In any other case, the potential risk of difference of effect cannot be observed'*.

143. The Agency also states that, according to the SCHENIR Opinion, each combination of a nanomaterial and a coating has to be considered as an individual case. The Agency argues that this finding is echoed in the Reuzel *et al.* study which shows differences in effects between surface-treated '*forms*' and non-surface-treated '*forms*' of SAS.

Findings of the Board of Appeal

144. The Reuzel *et al.* study consisted of a 13-week inhalation study followed by post-exposure observation of up to one year. It investigated the inhalation toxicity of three commercial products which are examples of pyrogenic SAS, surface-treated pyrogenic SAS and precipitated SAS. Samples of silica gel, colloidal SAS and other surface-treated types of SAS were not tested.

145. Based primarily on the findings of the Reuzel *et al.* study, the Agency concluded that, at least, pyrogenic SAS posed a potential inhalation toxicity concern that required

further examination. The Agency also contends that the unexplained differences in toxicity between different types of SAS is in itself a potential concern that needs to be clarified.

146. The Board of Appeal, having established an exposure concern (see paragraph 80 to 82 above), will examine the arguments related to the potential hazard of (i) non-surface treated precipitated SAS, silica gel and colloidal SAS; (ii) non-surface treated pyrogenic SAS; and (iii) surface-treated SAS.

147. The Contested Decision requests information on the four types of SAS, namely pyrogenic SAS, precipitated SAS, silica gel and colloidal SAS. The Contested Decision also requests information on '*each individual surface-treated SAS form'.*

(i) Potential concern of non-surface treated precipitated SAS, silica gel and colloidal SAS

148. The Contested Decision seems to acknowledge that there is a concern for inhalation toxicity with regards to pyrogenic SAS only:

'*This is in line with the findings in various other repeated dose inhalation studies available in the registration dossiers that indicate that fibrosis is only associated with exposure to pyrogenic SAS […]*'.

149. The Board of Appeal also observes that whilst the Contested Decision seeks to demonstrate, in particular through the Reuzel *et al.* study, that pyrogenic SAS presents a potential hazard for inhalation toxicity, there is little evidence in the Contested Decision to demonstrate that the other three types of SAS, namely precipitated silica, silica gel and colloidal silica, present a potential hazard that needs to be clarified.

150. This observation is supported for two of the types - precipitated SAS and silica gel - in the Contested Decision itself which states that:

'[n]o fibrosis was observed in any of the available inhalation studies with precipitated SAS or silica gel, apart from the single finding by Reuzel et al. (1991) for [*the example of precipitated SAS* tested]*.'*

151. In its Defence, the Agency states that:

'*[t]he "suspected risk" addressed in the Contested Decision is related to pyrogenic SAS, which is according to the current understanding of [the Agency] the most toxic/potent SAS type. The available information shows that the other three types of SAS - precipitated SAS, silica gel and surface treated SAS - have different or less toxicity properties than pyrogenic SAS and therefore cannot be compared. There is only one relevant key study with respect to the toxic properties of pyrogenic silica (i.e. Reuzel study). The references of the Appellants to other studies and/or publications are therefore not able to change this finding.*'

152. The Agency confirmed in its Defence that:

'[the] request for toxicological information is limited to the SAS type, which according to the findings of the Reuzel study is "suspected of posing a risk". Accordingly, the Contested Decision is restricted to the pyrogenic type of SAS, which needs to be further investigated in order to clarify the existence of an actual concern'.

153. The Board of Appeal observes that there is no examination in the Contested Decision as to whether colloidal SAS presents a potential concern.

154. The Board of Appeal finds that the Agency has not presented any studies to show that precipitated SAS, silica gel and colloidal SAS present a hazard concern that would justify the requests for information set out in the Contested Decision.

155. The Agency has however argued that the information requested in the Contested Decision is also justified by the fact that the Reuzel *et al.* study and the information available in the Appellants' registration dossiers does not explain the difference in toxicity between the four different types of SAS. In this regard, the Contested Decision states that:

'*The available inhalation studies indicate differences in toxicity and potency between different types of SAS, with pyrogenic SAS showing a higher toxic potential than precipitated SAS and silica gel. These differences in potency between SAS types are inextricably bound up with differences in physicochemical characteristics. Physicochemical properties vary significantly between SAS types, but also between different SAS forms within one SAS type […]. Considering this dependency of toxicity on physicochemical characteristics, identification of the individual forms of SAS for their physicochemical characteristics is required*.

[…]

The need for individual characterisation of all registered forms is further emphasised by the fact that both the mammalian and environmental toxicology of SAS are significantly influenced by their physicochemical properties […]. Differences in toxicity between forms of SAS have been demonstrated by Reuzel et al. (1991)'.

156. The Board of Appeal finds, however, that the Agency has not substantiated its argument that '*differences in potency between SAS types are inextricably bound up with differences in physicochemical characteristics*' and that the potential concern established in the Reuzel *et al.* study for pyrogenic SAS therefore extends to other types of SAS.

157. The Agency has explained in the Contested Decision that it would like to examine how the physicochemical properties of '*forms*' and types of SAS affect their toxicity. In principle, the Board of Appeal observes that this could be a legitimate objective of a substance evaluation decision. However, the decision in question would have to clearly establish how the physicochemical data requested would be used, in conjunction with any available data and new hazard testing, to clarify the identified potential concern. For example, a testing programme might be established to identify the physicochemical characteristics that are the drivers of toxicity for a particular substance. In this particular case, however, there is no clear indication as to how the extensive data requested on the physicochemical parameters of all '*forms*' of SAS would be used, in conjunction with available data and/or the inhalation toxicity testing requested on pyrogenic SAS, to identify the drivers of toxicity or show how the different physicochemical properties of types or '*forms*' of SAS affect their toxicity. In short, a considerable amount of data is requested but it has not been explained how these data will be used to meet the objectives pursued.

158. In view of the above, the Board of Appeal considers that the Agency has not demonstrated a potential concern with regards to precipitated SAS, silica gel and colloidal SAS that would justify the requests for information set out in the Contested Decision. The Appellants' arguments that the Agency committed an error of assessment in interpreting the results of the Reuzel *et al.* publication as justifying the requests for further data on precipitated SAS, silica gel and colloidal SAS must therefore be accepted.

159. The Board of Appeal recalls that the requests for information on precipitated SAS, silica gel and colloidal SAS concern the first and third requests as the second request concerns pyrogenic SAS only and the fourth and fifth requests concern surface-treated SAS. As a

result, the first request and the third request must be annulled in so far as they concern precipitated SAS, silica gel and colloidal SAS.

160. The Board of Appeal will next examine the Appellants' arguments in support of their contention that the Contested Decision, in particular through its reliance on the Reuzel *et al.* study, does not demonstrate that pyrogenic SAS presents a potential risk of inhalation toxicity.

(ii) Potential concern of non-surface treated pyrogenic SAS

161. The Board of Appeal observes that in Section III of the Contested Decision, in relation to the first request, under the heading '*Justification why new information is needed*', the Agency cites a study by Johnston *et al.*, '*Pulmonary chemokine and mutagenic responses in rats after sub-chronic inhalation of amorphous and crystalline silica'*, Toxicological Sciences 56 (2000) 405-413 (hereinafter the 'Johnston *et al.* study). The Contested Decision states with regards to that study that:

'*rats were exposed to [the example of pyrogenic SAS tested] for 13 weeks at a concentration of 50 mg/m^3. Histopathology data revealed fibrosis in the alveolar septae, which subsided during a recovery period (≥ 3 months)*'.

162. According to the Appellants, the Johnston *et al.* study was included in their registration dossier with a Klimisch score of 2.

163. The Board of Appeal finds that, whilst relevant to the consideration of the inhalation toxicity of pyrogenic SAS, the Johnston *et al.* study was performed at high doses and, on its own, constitutes weak evidence of a potential inhalation toxicity concern for pyrogenic SAS.

164. The same section of the Contested Decision also refers to other studies:

'*Further, signs of (collagenic) fibrosis were observed by Groth et al. (1981), Klosterkötter (1969) and Schepers et al. (1957a, 1957b), although the reliability of some of the results was questioned and doses were relatively high*'.

165. The Board of Appeal also concludes that, whilst relevant to the consideration of the inhalation toxicity of pyrogenic SAS, as these studies have questions over their reliability and were also performed at relatively high doses they, on their own, also constitute weak evidence of a potential concern.

166. Nonetheless, although the results of the studies mentioned in paragraphs 161 and 164, on their own, constitute weak evidence of a potential inhalation toxicity concern with regards to pyrogenic SAS, they do not demonstrate the absence of a concern. It is therefore clear that the findings of the Reuzel *et al.* study are crucial in determining whether there is a potential concern with regards to the inhalation toxicity of pyrogenic SAS that needs to be clarified. The Agency itself states in the Defence that:

'*There is only one relevant key study with respect to the toxic properties of pyrogenic silica (i.e. Reuzel study). The references of the Appellants to other studies and/or publications are therefore not able to change this finding'.*

167. The Board of Appeal notes that the 1991 Reuzel *et al.* publication states, *inter alia*, that '*[o]f the amorphous silicas examined [the example of pyrogenic SAS tested] induced the most severe changes in the lungs, which only partly recovered, whereas [the example of precipitated SAS tested] induced the least severe, completely reversible lung changes*'. The Board of Appeal finds that the Reuzel *et al.* publication therefore indicates adverse effects with regard to the inhalation toxicity of pyrogenic SAS.

168. The Board of Appeal will next examine the Appellants' arguments that, first, the 1991 Reuzel *et al.* publication inaccurately represents the findings of the 1987 Reuzel *et al.* study which lead the Agency to reach incorrect conclusions; second, the claim that any possible results indicating fibrosis were caused by particle overload; third, the claim that any adverse effects were reversible after a period of recovery; and fourth, the claim that the studies made available to the Agency show that there is no evidence of fibrosis in the human lung after exposure to SAS. By all of these arguments the Appellants claim, in essence, that the Agency failed to take into account all the information available to it.

Alleged inaccuracies in the 1991 Reuzel et al. publication

169. The Board of Appeal has already found, at paragraph 120 above, that the Appellants have not demonstrated that the 1991 Reuzel *et al.* publication contained inaccuracies that induced the Agency to make incorrect conclusions about the findings of the 1987 Reuzel *et al.* study and as a result exaggerate the severity of the adverse effects observed. In particular, the Board of Appeal observes that the findings presented in the 1991 Reuzel *et al.* publication and those in the 1987 full study report are largely consistent and any differences in the presentation of the findings could not be expected to lead to a different or incorrect conclusion. This argument must therefore be rejected as unfounded.

The Appellants' claim that the effects observed in the Reuzel et al. study are caused by particle overload

170. The Appellants claim that any adverse effects, including fibrosis, reported in the Reuzel *et al.* study are due to particle, or lung, overload, in other words that the effects observed resulted from chronic exposure to high concentrations of particles rather than to SAS. The Board of Appeal observes that the Appellants raised this issue during the decision-making procedure, most notably by way of an expert opinion provided to the Agency and that the Appellants' views were addressed in the Contested Decision in several places. For example, the Contested Decision states that:

'*Considering the much higher incidence of fibrosis following exposure to [the example of pyrogenic SAS tested] as compared to [the example of precipitated SAS tested] and [the example of surface-treated pyrogenic SAS tested], and the fact that fibrosis occurs already at low exposure concentrations of [the example of pyrogenic SAS tested], the fibrosis cannot be attributed to just a particle (over)load of the lungs. This is further substantiated by the fact that Reuzel et al. (1991) reported lower silicon content in the lung of rats exposed to [the example of pyrogenic SAS tested] than in the lung of rats exposed to the other SAS forms; the silicon clearance from the lung appeared to be faster in [the example of pyrogenic SAS tested] exposed rats*'.

171. The Contested Decision also states that:

'*The observed fibrosis cannot just be attributed to the number of SAS particles for the following reasons:*

1. Fibrosis is already observed at 1 mg/m^3 pyrogenic SAS (the lowest concentration tested), but not at exposure to 30 mg/m^3 of precipitated SAS or surface-treated pyrogenic SAS, although the number of particles will have been considerably higher in the latter two exposures.

2. Lung silicon content is lowest for pyrogenic SAS as compared to the other two SAS types tested. All three types had similar exposure concentrations of approximately 30 mg/m^3.

Reuzel et al. (1991) measured the total amount of Si in the lungs. The results showed that silicon levels were lowest for [the example of pyrogenic SAS test], in comparison to [the example of precipitated SAS tested] and [the example of surface-treated pyrogenic SAS tested] […]. Further, [the example of pyrogenic SAS tested] was quickly cleared from the lungs; no or only minimal levels were detected at 13 weeks post exposure and longer. Si levels in rats treated with [the example of precipitated SAS tested] and [the example of surface-treated pyrogenic SAS tested] were still detected at 39 weeks post exposure.

If the fibrosis would have been solely caused by a high particle load, pulmonary fibrosis would also have been expected in rats exposed to [the example of precipitated SAS tested], for which significantly higher Si levels in the lung were observed than for [the example of pyrogenic SAS tested]. The lung silicon contents for [the example of pyrogenic SAS tested] and [the example of precipitated SAS tested], as observed in the Reuzel et al. (1991) study, therefore support the conclusion that the fibrosis is not caused by particle overload but is specific for [the example of pyrogenic SAS tested]. Further, fibrosis was already observed at low levels of 1 mg/m^3 and 6 mg/m^3 [the example of pyrogenic SAS tested]. These data altogether suggest that it is highly unlikely that pulmonary fibrosis in rats exposed to [the example of pyrogenic SAS tested] is the result of particle overload.'

172. The Board of Appeal has considered the arguments made by both Parties and, in light of the considerations quoted above, comes to the conclusion that the Agency has taken into account the Appellants' claims that the results observed in the Reuzel *et al.* study are due to particle overload and are therefore not indicative of toxicity. The Board of Appeal finds that the Appellants have not shown that the Agency has committed any error in its assessment or failed to take into account all available information in reaching its conclusion.

173. With regards to the PWG review, the Board of Appeal highlights that it is not a new experimental study, but rather the opinion of experts formed on the basis of a re-evaluation of an existing experimental study. The Board of Appeal finds that whilst the PWG review provides further valuable insight into the results of the 1987 Reuzel *et al.* study it is not capable of answering the potential concern identified with regards to pyrogenic SAS in the Contested Decision. The issues raised in the PWG review regarding fibrosis, reversibility and particle overload have already been examined in the Contested Decision and during the substance evaluation process. As a result, the conclusions of the PWG review do not affect the Board of Appeal's findings above.

174. The Board of Appeal notes that the data available for substance evaluations is in some cases inconsistent or indeed contradictory and in others leaves questions open. It is therefore not surprising that there is often a difference of opinion between experts when assessing the available data. The Board of Appeal notes that one of the main purposes of substance evaluation is to clarify potential concerns and thereby help resolve the differences of opinions between experts and to clarify a concern over which there is a consensus. The testing or information required pursuant to a substance evaluation should be specifically designed to clarify potential concerns taking into account all available information. In this particular case, whilst the Appellants have clearly shown why they disagree with the conclusion reached by the Agency with regards to the potential inhalation toxicity concern, in light of the evidence regarding particle overload, the Board of Appeal finds that the Appellants have not shown that the Agency's conclusion that there is a potential concern is incorrect.

The Appellants' claim that any adverse effects observed in the Reuzel et al. study were reversible

175. The Board of Appeal observes that, as stated in the Contested Decision, in the 1987 Reuzel *et al.* study '*only a part of the effects induced by 30 mg/m^3 [the example of pyrogenic SAS tested] reversed during the post-exposure period, while effects induced by [the example of precipitated SAS tested] were all reversible*'. This is reflected in the 1991 Reuzel *et al.* publication which states that:

'*Although [the example of pyrogenic SAS tested] was very quickly cleared from the lungs and regional lymph nodes, the changes in these organs were only partly reversed during the post-exposure period in rats exposed to 30 mg/m^3. [The example of surface-treated pyrogenic SAS tested] and the lower levels of [the example of pyrogenic SAS tested] resulted in less severe, and mostly reversible, changes*.

[…]

Of the amorphous silicas examined [the example of pyrogenic SAS tested] induced the most severe changes in the lungs, which only partly recovered, whereas [the example of precipitated SAS tested] induced the least severe, completely reversible lung changes'.

176. The Board of Appeal observes that the Arts *et al* study (2007) (Arts JH, Muijser H, Duistermaat E, Junker K, Kuper CF, *Five-day inhalation study of three types of synthetic amorphous silias in Wistar rats and post-exposure evaluations for up to 3 months*, Food and chemical toxicology, 2007 October 31; 45(10):1856-67) was submitted by the Appellants to support their contention that the effects are reversible are five-day studies conducted on rats using different concentrations of precipitated SAS, silica gel and pyrogenic SAS. The Board of Appeal finds that these short-term studies cannot reliably answer the potential inhalation toxicity concern, and the possible reversibility of effects, following long-term exposure.

177. The Board of Appeal observes that, with regards to pyrogenic SAS, the Reuzel *et al.* study did not demonstrate that the adverse effects observed, i.e. fibrosis, were in all cases fully reversible. The Appellants have argued that '*pulmonary effects following exposures to SAS were usually fully reversible after exposure*'. This is not sufficient however to allay the concerns that the effects may not be fully reversible. The inhalation toxicity study requested in the Contested Decision should help to clarify this issue with regards to pyrogenic SAS. The Board of Appeal observes that requesting further information to clarify the potential inhalation toxicity concern, including the reversibility of effects, is consistent with the aims of substance evaluation.

178. For the reasons stated in paragraph 173 above, the conclusions of the PWG review do not affect the Board of Appeal's findings in this regard.

179. The Appellants' arguments on the reversibility of effects must therefore be dismissed.

The Appellants' claim that the studies made available to the Agency show that there is no evidence of fibrosis in the human lung after exposure to SAS

180. The Morfeld study was submitted by the Appellants on 17 December 2013 which is after the draft decision was notified to the Appellants. The Agency argues that it nevertheless did take the study into account in the Contested Decision and has explained, in these proceedings, why it considers that this study does not clarify the concern with regards to inhalation toxicity for pyrogenic SAS.

181. Whilst the Appellants have indicated why they find the evidence in the Morfeld study to be persuasive, the Board of Appeal does not accept that the Morfeld study sufficiently

addresses and clarifies the potential inhalation toxicity concern regarding pyrogenic SAS. The Board of Appeal, having considered the Morfeld study, finds that in light of the lack of a dose/response assessment, and the lack of clarity as to exactly what the workers were exposed to and for how long, the Morfeld study does not clarify the identified concern, namely inhalation toxicity, with regards to pyrogenic SAS and cannot therefore refute the conclusions reached in the Contested Decision.

182. In relation to the OEL established by the BAuA, the Board of Appeal observes that it is not for the Agency to reconsider the assessment that went into establishing the OEL in question. The Agency must consider all the information available to it and reach its conclusions accordingly. Furthermore, the fact that an OEL was established for SAS does not clarify whether there is actually an inhalation toxicity concern or not.

183. For the reasons stated in paragraph 173 above, the conclusions of the PWG review do not affect the Board of Appeal's findings in this regard.

184. In light of paragraphs 161 to 183 above, the Board of Appeal finds that the Agency has established a potential concern with regards to inhalation toxicity for pyrogenic SAS. This, taken in conjunction with the widespread exposure potential (see paragraphs 80 to 82 above), means that the Agency did not make an error of assessment in concluding that there is a potential risk for inhalation toxicity with regards to pyrogenic SAS which requires clarification pursuant to substance evaluation.

185. The Appellants' arguments that, with regards to pyrogenic SAS, the Agency failed to apply a weight-of-evidence approach and committed an error of assessment in interpreting the results of the 1991 Reuzel *et al.* publication must be dismissed as unfounded.

186. The Board of Appeal will next examine whether the Agency has demonstrated a potential concern for surface-treated SAS that needs to be clarified pursuant to substance evaluation.

(iii) Potential concern of surface-treated SAS

187. According to the Contested Decision '*[a]s surface treatment may affect the characteristics of the registered substance, an underestimation of the hazards cannot be excluded based on the available data*'. The Contested Decision states further that the grounds for concern can also be found in a '*generic concern raised in the SCENIHR Opinion*'. According to the SCENIHR Opinion:

'*Purposely applied and environmentally acquired coatings can have a major impact on nanomaterial interaction with biological systems. The coating and core together control the properties of a given nanomaterial and it is not useful to look at either the properties of the core or the coating in isolation as they may not be representative of how the nanomaterial will behave in a given environment. Thus, each combination of a nanomaterial and a coating has to be considered as an individual case when safety evaluation of a specific nanomaterial is considered*'.

188. The Board of Appeal has found that the Reuzel *et al.* study demonstrates a potential concern with regards to pyrogenic SAS only (see paragraphs 78 to 185 above). As stated above, according to the conclusions of the Reuzel *et al.* study the surface-treated '*form*' of pyrogenic SAS tested '*at a level of 30 mg/m^3 induced approximately similar but generally less severe changes than did [pyrogenic SAS] at a level of 30 mg; these changes disappeared almost completely during the non-exposure period'.* In the absence of any other specific evidence related to surface-treated SAS the Board of Appeal finds that this evidence is insufficient to justify further testing to clarify a potential hazard. The Agency's argument that the requests for information on surface-

treated SAS are justified by the Reuzel *et al.* study must therefore be dismissed. The Board of Appeal notes however that the results of any inhalation toxicity testing on pyrogenic SAS may give rise to, or contribute to the evidence of, a potential concern for surface-treated pyrogenic SAS.

189. With regards to the Agency's reliance on the SCENIHR Opinion, the Board of Appeal observes that those conclusions are not specific to SAS but to surface-treated nanomaterials in general. The SCENIHR Opinion also states that not all nanomaterials pose a risk to human health and the environment. Furthermore, the SCENIHR Opinion states that coatings '*can'* have an impact on nanomaterials and that the properties of the coating '*may not be representative*'. The Board of Appeal finds therefore that, as with the alleged general concerns related to nanomaterials (see paragraph 105 above), the Agency cannot rely on a general concern regarding surface-treated substances that are also nanomaterials. The Agency must be able to demonstrate a specific concern in relation to the substance at issue.

190. In addition, in justifying the grounds for concern, the Agency stated that 'the *Appellants have provided no information enabling the identification or the nature of surface-treatment, no information explaining the Reuzel findings in that respect, and no experimental data demonstrating the absence of difference in toxicity between surface-treated and non-surface-treated form of SAS*'. This, however, indicates an absence of information only. The Agency must be able to demonstrate a specific concern that needs to be clarified and how the information and/or testing required will help to clarify that concern (see paragraph 78).

191. The Board of Appeal finds therefore that the Agency has failed to identify a potential concern with regards to surface-treated SAS. The fourth and fifth requests, which specifically concern surface-treated SAS, are therefore annulled in their entirety.

192. The Board of Appeal is therefore not required to examine the Appellants' other pleas related to the legality of the request for additional information on surface-treated SAS, in particular related to legal certainty, the principle of good administration and the principle of legitimate expectations.

(iv) Conclusion on the existence of a concern

193. In paragraphs 148 to 159 above the Board of Appeal has found that the Agency failed to establish a potential concern in relation to precipitated SAS, silica gel and colloidal SAS. The Contested Decision has therefore been annulled in so far as it requests additional information on these types of SAS. For the same reason the Contested Decision has been annulled in so far as it requests information on surface-treated SAS (see paragraphs 187 to 192 above). The Board of Appeal has, however, found that the Agency has demonstrated a potential inhalation toxicity concern with regards to pyrogenic SAS (see paragraphs 161 to 185 above).

194. The Board of Appeal will therefore examine below, in Sections B, C and D, whether the Appellants have identified any other legal flaws that require the first, second and third requests to be annulled in so far as they request additional information on pyrogenic SAS.

B - Appellants' pleas related to the request for information on physicochemical properties (first request) for pyrogenic SAS only

195. Under the first request the Appellants are required to submit information on seven '*physicochemical properties of each individual SAS form […] that is manufactured, imported and/or placed on the market*'.

196. In this section, the Board of Appeal will examine the Appellants' pleas regarding the legality of the first request in so far as it related to pyrogenic SAS only. In particular, the Board of Appeal will examine (1) the allegation that the Agency exceeded its competence by requesting information on '*forms*' of SAS, and (2) the alleged breach of the principle of proportionality.

1. Allegation that the Agency exceeded its competence by requesting information on '*forms*'

Arguments of the Parties

197. The Appellants argue that the term '*form*' does not appear in the REACH Regulation which rather requests information on '*substances*'. The Appellants claim that the requirement to submit information on the physicochemical properties of '*forms*' of SAS, rather than the '*substance*', is unlawful because such a request cannot be made under the REACH Regulation. The Appellants claim that in this respect the Agency exceeded its competence.

198. The Appellants claim that the European Commission's Second Regulatory Review on Nanomaterials (European Commission, '*Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Second Regulatory Review of Nanomaterials'*, COM(2012) 572 final, 3 October 2012) '*expressly confirms that the REACH Regulation does not prescribe the submission of "form"-specific information*'. The Appellants also consider that the Guidance for identification and naming of substances under REACH and CLP (February 2014) confirms that different '*forms*' or grades of a substance do not affect substance identity within the meaning of the REACH Regulation.

199. The Agency argues that the REACH Regulation requires the determination of hazards and risks of a substance irrespective of its '*forms*'. According to the Agency, the hazardous properties of a substance may not only depend on its composition, but also possibly on its '*form*' (including a nanomaterial '*form*'). Accordingly, given the characteristics of a substance, registrants and authorities may need to refer to its '*form*' which is an essential element of its identification.

Findings of the Board of Appeal

200. Under substance evaluation, the Agency can request information on '*forms*' of a substance as long as it can, inter alia, demonstrate that this information will assist in the clarification of the potential concern identified (see, to this effect, *Huntsman P&A UK*, cited in paragraph 87 above, paragraph 72).

201. The Appellants' claim that the Agency exceeded its competence by requesting information on '*forms*' of SAS must therefore be dismissed as unfounded.

202. However, whilst requesting information on '*forms*' under substance evaluation is not unlawful per se, the Board of Appeal notes that any request for additional information, including on '*forms*' with regards to pyrogenic SAS, must assist in the clarification of the potential concern and, in addition, satisfy other legal requirements. The Board of Appeal will therefore next examine the Appellants claim that the first request breaches the principle of proportionality with regards to pyrogenic SAS only.

2. Alleged breach of the principle of proportionality

Arguments of the Parties

203. The Appellants claim that during the decision-making procedure they summarised the information available in the SAS registration dossier. This shows that SAS, as registered,

has a similar toxicological and epidemiological profile across all of its '*forms*', and is not classified as '*hazardous*' under the Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1). The Appellants also claim that they provided the Agency with '*expert evidence that the results of the available inhalation toxicity studies with […] SAS indicate that […] read-across both within the [types] of SAS and also across SAS [types] can be applied*'.

204. The Appellants claim that the information available to the Agency was sufficient to demonstrate the safe use of SAS, as registered (including its '*forms*' and types as defined by the Contested Decision), without the need for the generation and/or submission of data addressing '*forms*' in the meaning of the Contested Decision. According to the Appellants, the Agency therefore not only erred in its assessment but also infringed the principle of proportionality by requesting information which is not necessary.

205. The Appellants argue further that, even if the Board of Appeal decides that the information is necessary, the Agency could have adopted a less onerous measure by accepting the information based on '*grouping*' as proposed by the Appellants. The Appellants argue further that '*the Contested Decision does not allow any reasonable prospect of a less onerous alternative by grouping*'.

206. The Agency claims that '*based on the correlation of findings from the [Scientific Committee on Consumer Safety], […] the Contested Decision rightfully assesses the need […] for information on physicochemical properties of nanomaterial forms of SAS*'. The Agency states that, in any case, the Appellants' dossiers do not contain physicochemical information relating specifically to the nanomaterial '*forms*' of SAS supposedly covered by the registration despite the Appellants acknowledging that the REACH Regulation applies to nanomaterial '*forms*' of substances. The Agency contends that such information is necessary for the assessment of the hazards and risks posed by SAS. The Contested Decision explains that the interaction of nanomaterials with their environment depends significantly on their physicochemical properties.

207. The Agency argues that the relevant authorities cannot assess whether the hazard information and risk assessment are sufficient to address the '*forms*' of a substance if information on physicochemical properties of '*forms*' is not reported in the registration dossier. The specification of '*forms*' in the registration dossier and the characterisation of critical physicochemical properties is therefore an essential prerequisite to determine the safe use of SAS, including in its nanomaterial '*forms*'.

208. The Agency states that the composition of a substance alone does not allow a proper identification of the nanomaterial '*forms*' of a substance. The Agency states that the REACH Regulation requires the determination of hazards and risks for the entirety of the registered substance, that is including relevant types and '*forms*'. Indeed, the hazardous properties of a substance may not only depend on its composition, but also on its '*form*' (including a nanomaterial '*form*').

209. The Agency argues that the Contested Decision explicitly states that '*grouping*' may be used to provide information on physicochemical properties of SAS '*forms*'. The Agency adds that it is the responsibility of the Appellants to propose and scientifically justify a '*grouping*' approach. The Agency argues that its rejection of a '*grouping*' approach proposed by the Appellants does not preclude them from refining and improving this '*grouping*' approach.

Findings of the Board of Appeal

210. The Board of Appeal notes that the principle of proportionality requires that European Union measures do not exceed the limits of what is appropriate and necessary in order to achieve the objectives legitimately pursued by the measure in question. When there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 124 and the case-law cited; see also Case A-005-2011, *Honeywell Belgium*, Decision of the Board of Appeal of 29 April 2013, paragraphs 115 to 117, and *International Flavors & Fragrances*, cited in paragraph 78 above , paragraph 72).

211. The Appellants claim that there is potentially a large number of '*forms*' of SAS, depending on how the term '*forms*' is interpreted, ranging in number from 101 to 101,000. The Agency has not disputed this. The Board of Appeal acknowledges that these figures apply to '*forms*' of all four types of SAS and not to pyrogenic SAS only. The Board of Appeal also observes that the Contested Decision allows for the possibility of '*grouping*' which may reduce the amount of data to be provided by the Appellants. Nonetheless, due to the potential high number of '*forms*' of SAS, even if a '*grouping*' approach was acceptable to the Agency, the Appellants would still be required to generate a large amount of data on numerous '*forms*' of SAS.

212. In the present case, the Board of Appeal has found (see paragraphs 161 to 185 above) that the Agency has demonstrated a potential concern with regards to the inhalation toxicity of pyrogenic SAS only. One of the objectives pursued by the Agency through the Contested Decision is the clarification of the potential concern for the inhalation toxicity of pyrogenic SAS.

213. Through the first request the Agency also seeks to collect information on the physicochemical properties of '*forms*' of SAS to help clarify why there are differences in toxicity between the different types and '*forms*'. This objective is clearly set out in the Contested Decision which states that:

> '*The available inhalation studies indicate differences in toxicity and potency between different types of SAS, with pyrogenic SAS showing a higher toxic potential than precipitated SAS and silica gel. These differences in potency between SAS types are inextricably bound up with differences in physicochemical characteristics. Physicochemical properties vary significantly between SAS types, but also between different SAS forms within one SAS type […]. Considering this dependency of toxicity on physicochemical characteristics, identification of the individual forms of SAS for their physicochemical characteristics is required*'.

214. The Board of Appeal finds however that the Agency has not explained in the Contested Decision, or during the present proceedings, how the requested information on the physicochemical properties of '*forms*' of SAS would allow the Agency to identify the reasons behind the different toxicity between the different '*forms*' and types of SAS. Likewise, the Board of Appeal finds that the Agency has not demonstrated how all the information on the physicochemical '*forms*' of pyrogenic SAS will be used to clarify the concern for inhalation toxicity of pyrogenic SAS which, as the Board of Appeal has already found, is the only potential concern demonstrated in the Contested Decision. As a result, the Agency has not demonstrated how the requested information is appropriate to clarify these concerns.

215. The Board of Appeal also considers that the request for a potentially large amount of physicochemical data on all '*forms*' of SAS, in order to investigate the difference in toxicity between different '*forms*' and types of SAS, is premature. Furthermore, if inhalation toxicity tests on pyrogenic SAS show no concern for inhalation toxicity, or

indeed any other toxicity, then all the information submitted on '*forms'* could have been in vain. In this respect, once the drivers for toxicity are identified, if they exist at all, then it may be necessary to identify certain physicochemical properties of certain '*forms*' and/or types of SAS related to these drivers.

216. The Board of Appeal finds that the cost of generating a potentially large amount of data with no certainty as to how it would be used to clarify the concern, if one is eventually confirmed for pyrogenic SAS, is therefore disproportionate.

217. The Board of Appeal observes that information on physicochemical properties can be relevant to the clarification of the hazards and risks posed by '*forms*' and types of SAS. However, such requests for information must be clearly justified by explaining how information on physicochemical and hazardous properties will be used to clarify potential hazards and risks. In this particular case it is not clear whether SAS in any of its types and '*forms*' poses a hazard. And if any or all of the '*forms*' or types of SAS do pose a hazard, it is not clear what the drivers of that toxicity are. The Board of Appeal accepts that the primary objective of substance evaluation is to clarify such concerns when these concerns are justified but it must be clearly explained how the information requests will do so in a scientifically rigorous as well as, inter alia, proportionate way.

218. In view of the above, the Board of Appeal finds that the Appellants' claim that the first request is disproportionate must be upheld. The first request is therefore annulled without it being necessary for the Board of Appeal to examine the Appellants' remaining pleas related to the first request.

C - Appellants' pleas in law related to the request for information on sub-chronic toxicity studies for pyrogenic SAS only (second request)

219. By the second request the Appellants are required to provide the following information:

'2. Sub-chronic toxicity study (90-day; OECD 413), in rats via the inhalation route with the following four pyrogenic SAS forms as manufactured that represent:

i. the lowest specific surface area with the lowest number of hydroxyl groups,

ii. the lowest specific surface area with the highest number of hydroxyl groups,

iii. the highest specific surface area with the lowest number of hydroxyl groups,

iv. the highest specific surface area with the highest number of hydroxyl groups […]'.

220. The Board of Appeal notes that the second request is limited to the pyrogenic type of SAS with a request for testing on four '*forms*' of pyrogenic SAS.

221. In Section C below, the Board of Appeal will examine the Appellants' remaining pleas regarding the legality of the second request. In particular, the Board of Appeal will examine:

1. The allegation that the Agency exceeded its competence by requesting information on '*forms*' of SAS;

2. The Appellants' plea alleging an error of assessment;

3. The alleged breach of the principle of proportionality;

4. The alleged breach of Article 25;

5. The alleged breach of the duty to state reasons; and

6. The alleged breach of the principle of legal certainty.

1. Allegation that the Agency exceeded its competence by requesting information on '*forms*' for pyrogenic SAS

Arguments of the Parties

222. The arguments of the Parties regarding this plea are set out in paragraphs 197 to 199 above.

Findings of the Board of Appeal

223. In the present case the Board of Appeal has found (see paragraphs 161 to 185 above) that the Agency has demonstrated a potential concern with regards to the inhalation toxicity of pyrogenic SAS.

224. The Board of Appeal has already found (paragraph 200 to 202) that under substance evaluation the Agency, subject to certain general requirements such as proportionality and legal certainty, may request information on '*forms*' of pyrogenic SAS.

225. The Appellants' claim that the Agency exceeded its competence by requesting information on '*forms*' of SAS is therefore dismissed.

2. Appellants' plea alleging an error of assessment with regards to the request for inhalation toxicity testing on pyrogenic SAS

Arguments of the Parties

226. The Appellants claim that the request to submit specific toxicological information is unlawful because the Agency erred in concluding that further inhalation toxicity information is needed based on the results the 1991 Reuzel *et al.* publication.

227. The arguments of the Parties in relation to the alleged error of assessment are summarised in paragraphs 125 to 143 above.

Findings of the Board of Appeal

228. The Board of Appeal has found, in see paragraphs 161 to 184 above, that the Agency was justified in concluding, primarily through the conclusions of the Reuzel *et al.* study, that pyrogenic SAS presents a potential inhalation toxicity concern.

229. The Appellants claim that the Agency erred in concluding that further inhalation toxicity information on pyrogenic SAS is needed based on the results the 1991 Reuzel *et al.* publication must therefore be dismissed.

3. Alleged breach of the principle of proportionality with regards to the request for inhalation toxicity testing on pyrogenic SAS

Arguments of the Parties

230. The Appellants submit that the second request is disproportionate because, in addition to being unnecessary, the required inhalation studies are not the least onerous measure that could have been adopted by the Agency. In particular, the Appellants claim that the Agency could have adopted a '*step-wise*' approach involving, as a first step, a re-evaluation of all lung sections originating from the Reuzel *et al.* study. The Appellants consider that the Agency should have awaited the results of the re-evaluation of the Reuzel *et al.* study which they were in the process of conducting themselves (i.e. the PWG review). The Appellants argue alternatively that the Agency should have awaited the submission of the physicochemical information requested in the Contested Decision before requesting the additional inhalation toxicity data.

231. The Appellants also claim that the second request is disproportionate because it requires the test to be performed on the same '*form*' of pyrogenic SAS twice. According to the Appellants, *'[t]his is because there is a linear correlation between surface area and the number of hydroxyl groups. High surface area correlates with a high number of hydroxyl groups, and low surface area correlates with a low number of hydroxyl groups*'.

232. The Agency states that the request for toxicological information is limited to the SAS type which, according to the findings of the Reuzel *et al.* study, is '*suspected of posing a risk*'. The second request is restricted to the pyrogenic type of SAS and the information requested is therefore proportionate.

Findings of the Board of Appeal

233. As stated in paragraph 210 above, the principle of proportionality requires that European Union measures do not exceed the limits of what is appropriate and necessary in order to achieve the objectives legitimately pursued by the measure in question. When there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.

234. The objective pursued by the requested testing is to clarify a potential inhalation toxicity concern for pyrogenic SAS from repeated exposure. The Board of Appeal notes that the '*forms*' that need to be tested are clearly defined in relation to surface area and degree of hydroxylation. The Board of Appeal also observes that the requested testing only considers two possible drivers of toxicity, hydroxylation and surface area, when it could potentially have included many more variables in the testing requirements.

235. The Board of Appeal also observes that, as only one commercial product of pyrogenic SAS was tested in the Reuzel *et al.* study, it is unclear whether the effects identified are relevant to all '*forms*' of pyrogenic SAS. Information on the inhalation toxicity potential of different '*forms*' of pyrogenic SAS is potentially relevant for the purpose of establishing risk management measures. The Board of Appeal also observes that the results of the testing requested should provide information on whether the effects observed in the Reuzel *et al.* study are reversible and whether the effects are due to particle overload or the toxicity of pyrogenic SAS (see paragraphs 170 to 179 above).

236. The Board of Appeal finds that it is not appropriate to perform inhalation toxicity testing on only one '*form*' as this will not help the Agency in identifying the potential drivers for toxicity nor will it assist the Agency in clarifying potentially different properties of different '*forms*' of pyrogenic SAS. For this information requirement the Agency has identified two physicochemical properties – number of hydroxyl groups and surface area - as potential drivers for toxicity. The Board of Appeal finds that it is proportionate to require testing that looks at two potential drivers of toxicity.

237. The Board of Appeal further finds that whilst the PWG review, which was submitted to the Board of Appeal on 10 August 2016, provides further valuable insight into the results of the Reuzel *et al.* study, it is not capable of clarifying the potential concern identified with regards to pyrogenic SAS. The PWG review is another expert opinion which may come to a different conclusion to that reached by the Agency but does not remove the potential inhalation toxicity concern identified by the Agency. Furthermore, in light of the challenges in re-testing the slides from the Reuzel *et al.* study and bearing in mind that the study in question was scored as Klimisch 1, there was no reason for the Agency to anticipate that re-examining the results from the Reuzel *et al.* study would satisfy the objective pursued. The PWG review also does not answer the questions pertaining to reversibility and whether the observed effects in the Reuzel *et al.* study are due to particle overload or the toxicity of pyrogenic SAS. The Board of Appeal finds that it is

therefore appropriate for the Agency to request sub-chronic inhalation testing on pyrogenic SAS.

238. The Appellants' claim that the Agency should have awaited the submission of the results on the physicochemical properties of SAS (the first request) before requesting the inhalation toxicity studies. However, since the Board of Appeal has annulled the first request, it is not necessary to decide on this argument.

239. The Appellants also argue that the Contested Decision is disproportionate as it allegedly requests the Appellants to perform the study on the same '*form*' of pyrogenic SAS twice due to the linear correlation between surface area and the number of hydroxyl groups. The Appellants stated further at the hearing that, whilst they contest the need to perform the tests at all, if they are required to perform them it would make sense to perform them only on the first and the fourth '*forms*' identified in the Contested Decision.

240. This issue of the '*forms*' to be tested was discussed between the eMSCA and the registrants of SAS and was addressed in the Contested Decision and in the submissions in this appeal.

241. According to the Contested Decision:

'*To address the concern, information on the most potent forms of SAS is required. Therefore, additional inhalation information on the four indicated forms is requested to ensure that the most potent forms are studied. It cannot be ruled out that another form of SAS than the ones currently tested may be more potent and induce fibrosis at a lower concentration, resulting in a lower DNEL. Therefore, it is highly relevant to perform the requested 90-day toxicity study with the requested forms*'.

242. In the same vein the minutes of the 39th Meeting of the MSC on 8-11 December 2014 state that:

'*The proposed decision contains requests to test on only four of these forms, i.e. testing on the most relevant forms. The eMSCA expressed concern that the differences in surface area clearly indicated by the Registrants could lead to differences in toxicity hence they are requesting for a 90-day inhalation study on four SAS forms*'.

243. The Board of Appeal observes that there is a disagreement on the link between surface area and number of hydroxyl groups, whether there is a linear correlation between the two, and whether this correlation covers the full range of surface areas and hydroxylation states for the registered '*forms*' of SAS. The Board of Appeal, in the absence of detailed information on the '*forms*' to be tested, as identified in the Contested Decision, cannot say which Party is correct in this regard. However, the Board of Appeal observes that if, in practice, the four different '*forms*' identified in the Contested Decision only result in two different samples for testing purposes then only the two samples will have to be tested. If this is the case, the Appellants should provide a clear justification to this effect in the registration dossier update.

244. The Board of Appeal finds that in light of the objective legitimately pursued, the evidence from the Reuzel *et al.* study, and the limitations of the PWG review, it is both appropriate and necessary to require a 90-day sub-chronic toxicity study in rats via the inhalation route on four pyrogenic SAS '*forms*'. Furthermore, the PWG review or another re-evaluation of the Reuzel *et al.* study was not an appropriate measure to clarify fully the potential concern identified. The Appellants' claim that the second request, the sub-chronic toxicity testing on four '*forms*' of pyrogenic SAS, is disproportionate must therefore be dismissed.

4. Alleged breach of Article 25 regarding the request for inhalation toxicity testing on pyrogenic SAS

Arguments of the Parties

245. The Appellant claims that the second request is unlawful because the Agency did not respect its duty under Article 25 to require testing on vertebrate animals only '*as a last resort*'. In this regard, the Appellants claim that there are no references to possible alternatives to animal testing in the Contested Decision.

246. PISC argues that a short-term (five-day) study could provide equivalent results and therefore by requesting a 90-day study the Agency breached Article 25(1). PISC also argues that the Agency should have conducted a step-wise, or tiered, approach whereby no testing on animals was requested before the physicochemical information on '*forms*' requested in the Contested Decision was provided.

247. The Agency argues that the Contested Decision addresses the issue of alternatives to animal testing. As the effects from inhalation exposure were not seen before a 13-week exposure duration, a 28-day repeated dose toxicity study was not an option. Therefore, '*the Agency reflected on possible means to reduce unnecessary testing in the Contested Decision*'. The Agency adds that there is no alternative to testing on vertebrate animals in order to investigate inhalation toxicity from repeated exposure. It can therefore not be decisive whether Article 25 was explicitly referenced or not in the Contested Decision because its objective was met during the decision-making procedure and reflected in the Contested Decision.

Findings of the Board of Appeal

248. At the outset, it should be recalled that Article 13 of the TFEU provides that:

> '*in formulating and implementing the Union's agriculture, fisheries, transport, internal market […] policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions […].*'

249. Article 25(1) provides that '*in order to avoid animal testing, testing on vertebrate animals for the purposes of [the REACH] Regulation shall be undertaken only as a last resort […]*'.

250. The protection of animal welfare is therefore an important consideration in the framework of European Union legislation and the REACH Regulation in particular. The Board of Appeal notes that, under the REACH Regulation, the Agency has a legal obligation to consider animal welfare in its decision-making. Where the Agency requires additional testing pursuant to substance evaluation it must ensure *inter alia* that vertebrate animals are used only as a last resort (Case A-004-2014, *Altair Chimica and Others*, Decision of the Board of Appeal of 9 September 2015, paragraphs 106 to 108).

251. It is in the light of these considerations that the arguments put forward by the Appellants and by PISC must be examined.

252. The Board of Appeal notes that the Agency has requested information on four, and potentially only two, '*forms*' of pyrogenic SAS. The Board of Appeal also observes that the information request in the Contested Decision only considers two possible drivers of toxicity, hydroxylation and surface area, when it could potentially have included many more variables in the testing requirements. Consequently, unlike the other requests in the Contested Decision, the Appellants are not required to provide test data on all '*forms*' of SAS nor does the testing address a wide variety of variables requiring the sacrifice of many more vertebrate animals.

253. The Board of Appeal has also found above (see paragraph 173) that the PWG review was not appropriate to clarify the potential inhalation toxicity concern identified in the Contested Decision. There was no requirement for the Agency to wait for the conclusions of that review nor to require the conduct of such a review prior to requesting any tests on vertebrate animals (see paragraph 237 above). The Board of Appeal considers that, if the opposite was the case, the delays inherent in having to wait for previous tests on animals to be re-assessed every time a concern is identified, before conducting additional testing, would be incompatible with the primary objective of the REACH Regulation, that is to achieve a high level of protection of human health and the environment.

254. The Board of Appeal also finds that, in light of the pattern of effects shown in the Reuzel *et al.* study over 13 weeks, a 28-day study would not be of sufficient duration to examine the potential inhalation toxicity concern identified and in particular the effects caused by repeated exposure over a sustained period of time, the reversibility of effects and the relevance and importance of particle overload. The Board of Appeal also notes that there is currently no alternative to testing on vertebrate animals that would allow the assessment of sub-chronic inhalation toxicity.

255. The Board of Appeal also finds that a five day study, as proposed by PISC, would be insufficient to clarify the objective pursued, the potential inhalation toxicity concern from repeated exposure. In particular it could not clarify whether the observed effects in the Reuzel *et al.* study are reversible and whether they are due to particle overload or the toxicity of pyrogenic SAS.

256. The Board of Appeal also finds that the Appellants' argument that the Contested Decision makes no reference to the consideration of alternatives to animal testing is incorrect. The Contested Decision states in this regard:

'*As an alternative, in case for one of the identified forms a sub-chronic toxicity study (90-day, via inhalation) is available (taking into account the modifications to OECD 413 indicated above), and the tested form […] is fully characterised according to [first request] of [the Contested Decision], this information may be provided to cover the information request for this one form*'.

257. The Appellants' claim that the Agency breached Article 25 is therefore dismissed.

5. Alleged breach of the duty to state reasons as regards inhalation toxicity testing on pyrogenic SAS

Arguments of the Parties

258. The Appellants argue that in attempting to justify the concern that would be addressed by requesting information related to '*forms*' of SAS the Agency infringed its duty to state adequate reasons by misquoting several documents, in particular the European Parliament Resolution of 24 April 2009 on '*Regulatory aspects of nanomaterials*' and the Reuzel *et al.* study.

259. The Appellants argue that no document quoted by the Agency in the Contested Decision proposes, or even suggests, that information on '*forms*' - within the meaning of the Contested Decision - would be needed to establish the safety of nanomaterials merely because a substance would meet the non-legally binding definition of nanomaterials.

260. The Appellants argue that the Contested Decision fails to provide an explanation of how information related to '*forms*' of SAS would address the concern identified and why the information provided in the registration dossier is not sufficient.

261. The Appellants submit that the generation and submission of additional data under Article 46 is not an end in itself, but can only be requested if a concern has been identified. The mere lack of information is not a concern which justifies the generation and submission of that information.

262. The Agency argues that the Contested Decision complies with Article 130 regarding the duty to state reasons. In particular, the Agency argues that it was not required to address in the Contested Decision all the issues of fact and of law which have been raised by the Appellants during the substance evaluation process. The Agency can limit itself to the elements of law and fact which have decisive importance in the context of the decision.

263. According to the Agency, the statement of reasons includes '*the legal basis, the factual background and purposes of the substance evaluation for SAS*'. The Appellants, as diligent operators involved in the decision-making procedure as well as the substance evaluation process could understand and follow the rationale of the Contested Decision including its information requests. The fact that the Appellants are of a different opinion on the conclusions to be drawn from the available information does not mean that there is a flaw in the Contested Decision in this regard.

Findings of the Board of Appeal

264. Pursuant to Article 130, the Agency shall state the reasons for the decisions it takes under the REACH Regulation. The Board of Appeal considers that this duty to state reasons has the same scope as that under paragraph 2 of Article 296 of the TFEU. According to the case-law of the European Courts, pursuant to that provision, the reasons given in the Contested Decision must show in a clear and unequivocal manner the reasoning of the Agency so that the persons concerned by the act are able to ascertain whether the measure is well founded and to enable the legality of the act to be reviewed. Furthermore, the requirements to be satisfied by the statement of reasons depend on the circumstances of each case. In addition, the question of whether a statement of reasons complies with Article 296 TFEU must be assessed with regards not only to its wording but also to its context and to all the legal rules governing the matter (for example, judgment of 2 April 1998, *Commission* v *Sytraval and Brink's France*, C-367/95 P, EU:C:1998:154, paragraph 63).

265. The Board of Appeal observes that, where the persons concerned are involved in the process by which a measure comes about, the requirement to state reasons may be circumscribed since those persons acquire information through their involvement (for example, judgment of 12 June 1997, *Tiercé Ladbroke* v *Commission*, T-504/93, EU:T:1997:84, paragraph 52).

266. The Board of Appeal also highlights that, according to the case-law of the European Courts, the duty to state reasons in decisions is an essential procedural requirement which must be distinguished from the question of whether the reasoning is well founded, which is concerned with the substantive legality of the measure at issue. The reasoning of a decision consists of a formal statement of the grounds on which that decision is based. If those grounds are vitiated by errors, those errors will vitiate the substantive legality of the decision, but not the statement of reasons in it, which may be adequate even though it sets out reasons which are incorrect (judgment of 10 July 2008, *Bertelsmann and Sony Corporation of America* v *Impala*, C-413/06 P, EU:C:2008:392, paragraph 181).

267. In this case, the Appellants were involved throughout the substance evaluation process and the subsequent decision-making procedure. As discussed above, the issues raised by the Appellants throughout the substance evaluation process and the decision-making

procedure have been addressed with the involvement and knowledge of the Appellants. The fact that the Appellants disagree with the conclusions in the Contested Decision does not alter the fact that the grounds for that decision were adequately set out in the Contested Decision.

268. The Board of Appeal also considers that the Agency has adequately explained how the second request will contribute to clarifying the concern related to inhalation toxicity of pyrogenic SAS.

269. The Appellants' plea is therefore dismissed as unfounded.

6. Breach of the principle of legal certainty in the request for inhalation toxicity testing on pyrogenic SAS

Arguments of the Parties

270. The Appellants argue that whilst the Contested Decision defines '*forms*' as '*all individual size grades and trade names that can be identified separately per SAS type, based on differences in characteristics*', it fails to define the terms '*all individual size grades and trade names*', '*differences in characteristics*', or '*characteristics*'. By using these terms, the Contested Decision imposes obligations that are expressed through undefined and uncertain terms, thereby placing the Appellants in a situation in which the actions to be undertaken to ensure compliance with such obligations are uncertain.

271. The Agency states that the Appellants consistently and repeatedly refer to nanomaterial '*forms*' of SAS in the Notice of Appeal and have not been able to propose or use a better term to qualify this concept. The Agency claims that Annex I to the Contested Decision defines the term '*form*' in relation to the substance specifically at issue. The Agency argues that this definition is precise and aims at ensuring that the term is clearly understood.

272. The Agency states that with '*regard to an assumed uncertainty towards the interpretation of terminology used in the Contested Decision […] the Appellants as diligent operators can be expected to interpret the request*'. The Agency states further that it has '*an established practice of providing contextual information on how to implement evaluation decisions after they have been taken*'.

Findings of the Board of Appeal

273. The principle of legal certainty requires that every act 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 (judgment of 1 October 1998, *Langnese-Iglo* v *Commission*, C-279/95 P, EU:C:1998:447, paragraph 78, and judgment of 30 November 2009, *France and France Télécom* v *Commission*, T-427/04 and T-17/05, EU:T:2009:474, paragraph 300; see also Case A-008-2015, *Evonik Degussa*, Decision of the Board of Appeal of 12 October 2016, paragraph 36).

274. '*SAS forms*' are defined in Annex I to the Contested Decision as '*all individual size grades and trade names that can be identified separately per SAS type, based on differences in characteristics*'.

275. In relation to the second request the Appellants are requested to perform the test on the following '*four pyrogenic SAS forms as manufactured that represent:*

i. the lowest specific surface area with the lowest number of hydroxyl groups,

ii. the lowest specific surface area with the highest number of hydroxyl groups,

iii. the highest specific surface area with the lowest number of hydroxyl groups,

iv. the highest specific surface area with the highest number of hydroxyl groups […]'.

276. The Board of Appeal finds that in the second request the '*forms*' of SAS to be tested are clearly defined by reference to surface area and the degree of hydroxylation. Consequently the Appellants are able to clearly and precisely know which '*forms*' should be tested with regards to this particular information requirement.

277. The Appellants' plea is therefore dismissed as unfounded.

278. The Appellants' pleas in relation to the second request are therefore dismissed in their entirety.

D - Appellants' pleas related to the uses of pyrogenic SAS only (third request)

279. By way of the third request the Appellants are requested to provide '*[i]nformation on the uses of each individual form of SAS […] that is manufactured, imported and/or placed on the market.*' As the Board of Appeal has already annulled the third request insofar as it applies to precipitated SAS, silica gel and colloidal SAS, the Board of Appeal will examine this plea with regards to the uses of pyrogenic SAS only.

Arguments of the Parties

280. The Appellants claim that the request to provide information on the uses of SAS is unlawful because the information is unnecessary as the registration dossier already contains this information and the Agency has failed to identify a valid concern to be addressed by the requested information. The Appellants also claim that such a level of detail is not required by the REACH Regulation and therefore was not provided by the Appellants in their registration dossiers.

281. The Appellants also argue that the request is disproportionate in that it requires the Appellants to submit information on the uses of each individual '*form*' of SAS (manufactured, imported and/or placed on the market) without targeting those 'forms' suspected of being hazardous. The Appellants claim that '*if the hazard is alleged to apply to SAS in general, information on the uses of each and every form is superfluous because certain uses of SAS will necessitate the development of a safety assessment and exposure scenarios. By choosing a non-targeted approach, the Contested Decision does not meet the proportionality test which consists of establishing that the measure is necessary and that it imposes the least onerous burden on its addressees*'.

282. The Appellants argue that whilst the Contested Decision defines '*forms*' as '*all individual size grades and trade names that can be identified separately per SAS type, based on differences in characteristics*', it fails to define the terms '*all individual size grades and trade names*', '*differences in characteristics*', or '*characteristics*'. By using these terms, the Contested Decision imposes obligations that are expressed through undefined and uncertain terms, thereby placing the Appellants in a situation in which the actions to be undertaken to ensure compliance with such obligations are uncertain.

283. The Agency states that the Appellants consistently and repeatedly refer to nanomaterial '*forms*' of SAS in the Notice of Appeal and have not been able to propose or use a better term to qualify this concept. The Agency claims that Annex I to the Contested Decision defines the term '*form*' in relation to the substance specifically at issue. The Agency argues that this definition is precise and aims at ensuring that the term is clearly understood. The Agency claims that the definition in Annex I refers to the morphology characteristics relevant for hazard assessment.

284. The Agency states that with '*regard to an assumed uncertainty towards the interpretation of terminology used in the Contested Decision […] the Appellants as diligent operators can be expected to interpret the request*'. The Agency states further that it has '*an established practice of providing contextual information on how to implement evaluation decisions after they have been taken*'.

285. The Agency argues that if the suspected risk is confirmed by new toxicological data, risk management measures, taking into account the difference in toxicity of types of SAS and corresponding '*forms*', may have to be adopted in a timely manner. However, such measures would only be proportionate if the actual uses per type and '*form*' are known to the authorities, and measures can take account of the actual exposure to various types and '*forms*' of SAS.

286. The Agency claims further that a request for information on uses only after the toxicity profile of the types, '*forms*' and surface-treated '*forms*' of SAS has been determined would entail a second, or even third, round of substance evaluation decision-making. The Agency states that as the information on uses should normally already be available to registrants of SAS based on the existing information requirements for registration purposes, the request only requires a clarification as to which type or '*form*' of SAS corresponds to the uses identified.

Findings of the Board of Appeal

287. The Board of Appeal notes that the Contested Decision states: '*in the registration dossier, a list of uses of SAS by industrial workers, professional workers and consumer is included*'. The Contested Decision also states that:

'*no information is provided on the uses of each individual SAS type or each SAS form. Based on the toxicity of SAS and the potential high exposure, there is a concern about the risk of SAS and information on the exposure of SAS is therefore in demand.*'

288. The Board of Appeal finds that the term '*SAS form*' is not clearly defined in the Contested Decision, in particular in Annex I thereof, or relevant guidance. Whilst the Board of Appeal understands that the request for use information relates to each '*form'* that is manufactured, imported or placed on the market, it is not clear from the definition cited in paragraph 274 above at what point one SAS '*form*' should be considered, for the purposes of the Contested Decision, to be a different SAS '*form*'. For example, it is unclear what differences in characteristics require one SAS '*form*' to be identified separately from another and what exact characteristics are being referred to. Similarly, it is unclear what is meant by an individual size grade. It is also not clear to the Board of Appeal what the difference is between '*individual size grades and trade names*' in this regard. This lack of clarity means that the Appellants cannot be certain what constitutes a '*form*' and therefore what information they are required to provide. As a result, it is not possible for the Appellants to identify uses per '*form*'.

289. The Board of Appeal also observes that, in the absence of information about the inhalation toxicity of pyrogenic SAS, the request for further information on uses is premature. Furthermore, whilst information on uses may be relevant for the introduction of appropriate risk management measures, without some understanding of the drivers of toxicity, if any, it is not possible to identify which characteristics may be relevant for the identification of '*forms'* and the uses thereof for risk management purposes.

290. In the interests of clarity, the Board of Appeal recognises that information on uses may be relevant information to request pursuant to a substance evaluation. However, it must be clear how information on uses will be used to clarify the concern, particularly with regards to improved risk management measures.

291. The Appellants' plea that the third request breaches the principle of legal certainty is therefore upheld.

292. In view of the above, the Board of Appeal finds that the third request must be annulled in its entirety.

Refund of the appeal fee

293. 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.

294. In the present case, four of the five information requirements set out in the Contested Decision have been annulled. The Board of Appeal finds in the circumstances of the current case that the appeal must be considered as having been decided in favour of the Appellants.

295. The appeal fee shall therefore be refunded.

Effects of the Contested Decision

296. According to Article 91(2), an appeal has suspensive effect.

297. The Contested Decision, which is partially annulled in the present appeal proceedings, required the registrants, now the Appellants, to submit the required information by 20 March 2017, which is two years and nine days from the date of adoption of the Contested Decision. The Board of Appeal considers however that, because of the duration of the present appeal proceedings, the deadline set in the Contested Decision should be interpreted, in the light of the principle of suspensive effect laid down in Article 91(2), as if it referred to two years and nine days from the date of notification of the final decision of the Board of Appeal.

298. Consequently, the information required by the parts of the Contested Decision which are not annulled, namely a sub-chronic toxicity study (90-day; OECD 413), in rats via the inhalation route with four pyrogenic SAS '*forms*' (Section II, point 2 of the Contested Decision), shall be submitted within two years and nine days from the date of notification of this Decision of the Board of Appeal.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Agency's Decision of 11 March 2015 on the substance evaluation of silicon dioxide in so far as it requests:**
   - **information on seven physicochemical properties of each individual SAS '*form*' that is manufactured, imported and/or placed on the market (the first request),**
   - **information on the uses of each individual '*form*' of SAS that is manufactured, imported and/or placed on the market (the third request),**
   - **information on eight physicochemical properties of each individual surface-treated SAS '*form*' that is manufactured, imported and/or placed on the market (the fourth request), and**
   - **all toxicological information on surface-treated SAS as manufactured, imported and/or placed on the market as available to the Registrant(s) of SAS (the fifth request).**
2. **Dismisses the appeal as regards the request for information on a sub-chronic toxicity study (90-day; OECD 413), in rats via the inhalation route with four pyrogenic SAS '*forms*' (the second request). This information shall be provided by 9 July 2019.**
3. **Decides that the appeal fee shall be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Marc GOODACRE
On behalf of the Registrar of the Board of Appeal

Annex

List of Appellants

Evonik Degussa GmbH, Germany
Evonik Resource Efficiency GmbH, Germany
Evonik Aerosil France Sarl, France
Evonik Silquilmica SA, Spain
Evonik Degussa Antwerpen NV, Belgium
Akzo Nobel Pulp and Performance Chemicals AB, Sweden
Akzo Nobel Finland OY, Finland
Akzo Nobel Chemicals GmbH, Germany
Albemarle Europe Sprl, Belgium
Albermarle Catalysts Company B.V., the Netherlands
BASF SE, Germany
Cabot Aerogel GmbH, Germany
Cabot Carbon Limited, United Kingdom
Cabot GmbH, Germany
Clariant Production (France) S.A.S., France
Clariant Produkte (Deutschland) GmbH, Germany
Deltagran Europe srl, Italy
Grace Silica GmbH, Germany
Hellenic Petroleum SA, Greece
IQESIL S.A., Spain
Instituto Suizo Para el Fomento de la Seguridad Swissi-España, S.L.U, Spain
J.M. Huber Finland OY, Finland
Johnson Matthey Chemicals GmbH, Germany
LSR Associates Ltd., United Kingdom
Merck KGaA, Germany
Merck Performance Materials SAS, France
PPG Industries Chemicals BV, the Netherlands
Rhodia Operations SAS, France
SCAS Europe S.A./N.V., Belgium
Silysiamont SpA, Italy
Specialty Chemicals Coordination Center SA/NV, Belgium
Solvay Solutions Italia SpA, Italy
Wacker Chemie AG, Germany
PQ Silicas UK Ltd., United Kingdom
PPG CENTRAL (UK) Ltd., United Kingdom