EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

2 April 2014

(Dossier evaluation – Compliance check – Substance identity)

Case number	A-008-2012
Language of the case	English
Appellant	Przedsiębiorstwo Produkcyjno - Handlowe UTEX Sp. z.o.o. Poland Represented by: Artur Zając Rybnik Poland
Contested Decision	CCH-D-0000002552-79-03/F of 4 July 2012 adopted by the European Chemicals Agency (hereinafter, the 'Agency') pursuant to Article 41 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; hereinafter the 'REACH Regulation')

THE BOARD OF APPEAL

composed of Mercedes ORTUÑO (Chairman), Andrew FASEY (Technically Qualified Member and Rapporteur) and Mia PAKARINEN (Legally Qualified Member)

Registrar: Sari HAUKKA

gives the following

Decision

RELEVANT LEGISLATION

1. Article 5 of the REACH Regulation provides:

   '*Subject to Articles 6, 7, 21 and 23, substances on their own, in mixtures or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required*.'

2. Article 6(1) of the REACH Regulation provides:

   '*Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to the Agency*.'

SUMMARY OF THE FACTS

Background of the dispute

3. On 24 January 2012, the Agency initiated a dossier compliance check of the Appellant's registration dossier for Product of Semi-Dry Absorption method of Flue Gas Desulphurisation.

4. On 10 February 2012, the Agency notified the draft decision to the Appellant and invited it to provide comments.

5. On 9 March 2012, having previously informally discussed the draft decision with the Agency in a telephone conference on 5 March 2012, the Appellant submitted comments on the draft decision. On 29 March 2012, the Appellant updated its registration dossier. After considering the updated registration dossier and the Appellant's comments, the Agency amended the draft decision (hereinafter the 'amended draft decision').

6. On 25 May 2012, the Agency notified the Competent Authorities of the Member States (hereinafter the 'MSCAs') of the amended draft decision and invited them to submit proposals for amendment. No proposals for amendment were received from the MSCAs.

7. On 4 July 2012, the Agency adopted the Contested Decision which requests, in Section II thereof, the Appellant to provide information on:

   (a) Name or other identifier of the substance (Section 2.1 of Annex VI to the REACH Regulation): a description of the manufacturing process of the Substance of Unknown or Variable composition, Complex reaction products or Biological materials (hereinafter 'UVCB') to identify the name of the registered substance; and

   (b) Composition of the substance (Section 2.3 of Annex VI): information to establish and verify the composition and the name of the registered substance.

8. The Appellant was requested to submit this information in an updated registration dossier by 4 September 2012.

9. The reasoning, regarding the requirement to provide information on the name or other identifier of the substance in accordance with in Section 2.1 of Annex VI to the REACH Regulation), is explained in Section III(a) of the Contested Decision:

'… The naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process. According to the ECHA "Guidance for the identification and naming of substances under REACH and CLP" […] UVCB substances cannot be sufficiently identified by their chemical composition. The main identifier for UVCB substances is the description of the manufacturing process, including the final or most relevant steps for processing. … the Registrant did not provide sufficient and appropriate information on the naming of the registered substance, as required under Annex VI Section 2.1 of the REACH Regulation.

… the Registrant has provided detailed description of the technological processes used for desulphurisation of exhaust gases from coal-fired power plants. Based on this information, the description covers not only the desulphurisation manufacturing process carried out with preliminary dust (ash) extraction step but also the desulphurisation with partial or no dust extraction. As a result, substances referred to as "pure SDA" or the "mixture SDA Product and ash" in the registration dossier can be obtained. … significant differences in the composition of the "pure SDA" and the "mixture SDA Product and ash" can exist depending on whether the preliminary dust extraction step is applied or not...

The preliminary dust (ash) extraction in the manufacturing process having a significant effect on the composition of the substance, ECHA considers that the application or non-application of such step in the process is to be considered as a significant difference in the manufacturing process. In line with chapter 4.3. of the above-mentioned Guidance, any significant changes in the source or technological process are expected to lead to different substances. Accordingly, ECHA regards the substances referred to as "pure SDA" and the "mixture SDA Product and ash" as different substances under REACH, which require separate registrations.
[…]
… in line with the identity of the test material used for documenting the properties of "SDA Product", the substance which is the subject of this registration is manufactured with preliminary dust extraction.

Accordingly, the Registrant is required to remove from the dossier any information which does not refer to the registered substance i.e. SDA product, obtained by the desulphurisation process with preliminary dust separation step […].'

10. The reasoning, regarding the requirement to provide information on the composition of the substance in accordance with Section 2.3 of Annex VI to the REACH Regulation, is explained in Section III(b) of the Contested Decision:

'… the registration dossier contains three different compositions: the first one refers to the Substance Identification profile, the second one refers to the composition of "pure SDA Product based on recalculation from Silicate analysis for mixture of Ash and SDA product", the third one … refers to the "mixture of ash and SDA product". … the registered substance ("SDA Product") can be obtained only in the desulphurisation process with preliminary dust separation step. Therefore only the first indication as to the composition refers to the registered substance. However, this composition is not specific to the Registrant, but contains only constituents and their corresponding concentration ranges as they were agreed within the SIEF.

Therefore, the Registrant shall remove composition(s) which do not refer to their registered substance, i.e. obtained only in desulphurisation process with preliminary dust separation step. In addition, the Registrant shall revise the first listed composition and provide information which is specific for the manufactured substance.'

11. According to the Contested Decision the registration dossier contained a description of the technological processes used for desulphurisation of exhaust gases from coal-fired power plants. The Contested Decision states that the description covers the desulphurisation process carried out with preliminary dust (ash) extraction step and the desulphurisation process carried out with partial or no dust extraction. During the appeal proceedings the Parties refer primarily to 'pure SDA' and 'mixture SDA Product and ash'. For the purpose of the present proceedings, and in line with the terminology used by the Parties, the substance obtained by a desulphurisation process with a preliminary dust (ash) extraction step shall be referred to as 'pure SDA'. The substance produced with only partial or no dust extraction shall be referred to as 'mixture SDA Product and ash'. This wording reflects that used by the Parties in the present proceedings and should not be understood in a literal sense nor as prejudging the findings of the Board of Appeal.

Procedure before the Board of Appeal

12. On 2 October 2012, the Appellant lodged the present appeal at the Registry of the Board of Appeal in which it applies for 'a change of the Contested Decision in the section regarding separate registrations for pure SDA and mixture of SDA [Product and ash].'

13. On 3 December 2012, the Agency submitted its Defence. In addition, on 25 February 2013, the Agency responded to a number of questions put to it by the Board of Appeal.

14. On 17 April 2013, the Appellant lodged its observations on the Agency's defence and response of 25 February 2013 to the Board of Appeal's questions.

15. On 8 May 2013, the Parties were notified of the Board of Appeal's decision to close the written procedure. On 17 May 2013, the Appellant requested a hearing to be held. On 22 May 2013, the Agency informed the Board of Appeal that it did not request a hearing to be held.

16. In accordance with Article 13 of Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; hereinafter the 'Rules of Procedure'), following the Appellant's requests for a hearing to be held, the Parties were summoned to a hearing which was held on 3 December 2013. At the hearing, oral presentations were made by the Parties and the members of the Board of Appeal posed questions to the Parties.

REASONS

Claims under examination

17. In the Notice of Appeal the Appellant requests the amendment of the Contested Decision in so far as it requires separate registrations for pure SDA and mixture SDA Product and ash. In support of its claim the Appellant argues in essence that the

registered substance was correctly identified and that mixture SDA Product and ash does not require a separate registration under the REACH Regulation.

18. Before examining the Appellant's arguments the Board of Appeal will firstly examine the Agency's preliminary claim that the appeal is 'unfounded' on the grounds that the Appellant does not contest the operative part of the Contested Decision.

The Agency's claim that the appeal is unfounded on the grounds that the Appellant does not contest the operative part of the Contested Decision

Arguments of the Parties

19. In the Notice of Appeal the Appellant states that it accepts the requirement in the Contested Decision that the registration dossier should only include information regarding pure SDA. The Appellant states further however that it does not agree with the statement that a separate registration of the mixture SDA Product and ash is required in particular as it possesses tests, analyses and expert opinions confirming its position that the mixture SDA Product and ash is only a mixture of two substances which do not react with each other and is therefore not subject to registration.

20. According to the Agency, the appeal is 'unfounded' as the Appellant does not contest the operative part of the Agency's decision requiring the Appellant to update the substance identity information contained in the dossier. The Agency claims that since the Appellant explicitly undertakes to update its registration dossier as required in the Contested Decision, in other words to remove references to mixture SDA Product and ash, the conformity of the Contested Decision with the REACH Regulation is not contested in the present appeal.

21. The Agency claims that 'only the operative part of the Contested Decision is binding on the registrant'. The Agency argues that the statement in the Contested Decision that it '… regards the substances referred to as pure SDA and mixture SDA Product and ash as different substances under REACH, which require separate registrations' is not binding on the Appellant. The Agency argues that it was simply reminding the Appellant of the obligation set out in Article 6 of the REACH Regulation to register different substances separately. The Contested Decision does not however oblige the Appellant to submit any additional registration dossiers. The Agency considers that an explanation of the Appellant's obligations under the REACH Regulation was necessary for the operative part of the Contested Decision to be understood. The Agency accepts that it is for the Appellant to decide, once it has modified the description of the composition of pure SDA, whether it manufacturers other substances which require registration under the REACH Regulation.

Findings of the Board of Appeal

22. During the proceedings the Agency stated that the operative part of the Contested Decision consists of the requirements set out in Section II of the Contested Decision (see paragraph 7 above).

23. The Board of Appeal observes that the Agency's claim that the operative part of the Contested Decision is not challenged in the present appeal is based on the statement in the Notice of Appeal that the Appellant accepts the Agency's request to provide in the registration dossier information regarding only pure SDA. The Board of Appeal considers however that the Appellant's acceptance of this requirement is conditional on its understanding that a separate registration of mixture SDA Product and ash is

unnecessary, as it considers that mixture SDA Product and ash is not subject to registration under the REACH Regulation. In other words, the Appellant agrees to comply with the requirement to remove certain information from its registration dossier on the understanding that it is not required to make a further and separate registration.

24. In view of the fact that the Appellant's agreement to remove certain information from its registration dossier, in conformity with the Contested Decision, is predicated on its understanding that the statement contained in the Contested Decision that a separate registration should be submitted for mixture SDA Product and ash is incorrect, the Board of Appeal considers that the Appellant has an interest in seeking a decision of the Board of Appeal. The Agency's claim that the appeal is 'unfounded' is therefore dismissed. The Board of Appeal will therefore examine the Appellant's claim.

Appellant's claim regarding the annulment of the Contested Decision in so far as it requires separate registrations for pure SDA and mixture SDA Product and ash

Arguments of the Parties

25. The Appellant seeks the annulment of the Contested Decision in so far as it requires separate registrations for pure SDA and mixture of SDA Product and ash. In support of its claim, the Appellant argues that the information provided in its registration dossier complies with the requirements of the REACH Regulation. According to the Appellant, the registered substance was correctly identified and no mistakes were made in naming the substance and in the analytical data provided to the Agency. The description of the manufacturing process of the substance was very detailed and exact, and should not leave any doubts as to the identity of the substance.

26. The Appellant considers that the REACH Regulation clearly defines that only chemical substances are subject to registration. The Appellant is therefore of the opinion that its documentation is sufficient to cover both pure SDA and mixture SDA Product and ash provided that the companies producing the mixture SDA Product and ash have registered both pure SDA and ash from coal. According to the Appellant, the two substances concerned have been registered separately and, as a result, the mixture SDA Product and ash does not require registration. During the present proceedings the Appellant stated that it accepts the Agency's request to provide, in the registration dossier, information regarding the substance pure SDA only, and undertakes to make changes in the dossier accordingly. However, the Appellant disagrees with the requirement in the Contested Decision to make a separate registration for the mixture SDA Product and ash. The Appellant claims to have studies that confirm that the mixture SDA Product and ash is a mixture of two substances which do not enter into any chemical reaction with each other.

27. According to the Appellant, the production of pure SDA and mixture SDA Product and ash depends only on the time and place of extraction during the desulphurisation process in coal-fired power plants. At the point in a process where mixture SDA Product and ash is obtained, both components of the 'mixture' are only connected by the fact that they are present at the same time and in the same space. According to the Appellant, it is also impossible to isolate these two substances when extracted at that point. Furthermore, if the situation is described using chemical equations, it can be clearly seen that the production of these two substances occurs independently from each other, and that there is no chemical reaction between pure SDA and ash apart from mechanical mixing of their particles.

28. The Appellant considers that '… the manufacturing process of a UVCB substance … should be determined by its characteristics [i.e. its physical and chemical, toxicological and ecotoxicological properties] and typical chemical reactions, and not by the place where it is held (if it does not significantly influence the characteristics … of the substance being formed as a result)'. The Appellant also claims that it has studies which prove that the mixture SDA Product and ash has similar toxicological and ecotoxicological properties to pure SDA.

29. The Appellant also considers that the description of the manufacturing process as a determinant of the need to make two separate registrations for the Appellant's substance is an insufficient argument for such a decision. This is especially the case considering that in the description in the registration dossier of how the desulphurisation process in coal-fired power plants works, and the consequent production of pure SDA and mixture SDA Product and ash, it was specifically indicated that in both types of installations (i.e. those with a dust extraction step and those without) the same chemical reaction producing pure SDA occurs. According to the Appellant, the REACH Regulation does not require that, because of parallel processes producing two different substances at the same time and in the same place and with no chemical reaction between them, it is necessary to make an additional registration(s) for a mixture of the two substances.

30. According to the Agency, the Contested Decision correctly concluded that the dossier describes the composition and manufacturing processes of two different UVCB substances, namely pure SDA and mixture SDA Product and ash. The two substances have significantly different compositions which result from different manufacturing processes. Consequently, the two substances could not be considered to be the same. Given that two different substances cannot be registered in the same registration dossier, the Agency considers that it was correct in requiring the Appellant to remove the references to mixture SDA Product and ash from the registration dossier. The Agency considers that its decision that information on mixture SDA Product and ash, rather than for example pure SDA, should be removed from the registration dossier was based on the information contained in the registration dossier itself.

31. The Agency considers that the Appellant's argumentation in the Notice of Appeal seems to be based on two fundamental misunderstandings. Firstly, that the outcome of a chemical reaction could be considered as a mixture (and not a substance). Secondly, that similar hazard profiles could justify registration of two different substances in one registration dossier, even though the information in the registration dossier clearly shows that there are significant differences in the manufacturing process which lead to different substances with different compositions.

32. The Agency claims that according to the definitions of 'substance' and 'mixture' in the REACH Regulation, as further elaborated upon in the 'Guidance for the identification and naming of substances under REACH and CLP' (Version 1.1, November 2011, currently Version 1.3, February 2014; hereinafter the 'Guidance'), a substance is obtained as the result of a manufacturing process generally involving a chemical reaction and defined without separation into component parts, whereas a mixture is a blend of substances, integrated in measured proportions, and which is not the result of a chemical reaction. The mixture SDA Product and ash is isolated and placed on the market without separation into component parts. According to the Agency, mixture SDA Product and ash is therefore a substance in its own right and not a mixture.

33. The Agency contests the Appellant's arguments concerning the similarity of the hazard profiles of mixture SDA Product and ash and pure SDA. Firstly, according to the Agency, the studies and arguments submitted by the Appellant cannot be used to support a claim on the properties of the substances in the present appeal proceedings

as they were not available in the dossier at the time it was assessed by the Agency. Secondly, the substances are clearly different and the REACH Regulation does not allow different substances to be registered in one registration dossier. Thirdly, the studies submitted with the Notice of Appeal fail to support the assertion that the properties of mixture SDA Product and ash are no worse than pure SDA.

Findings of the Board of Appeal

34. The Appellant seeks the amendment of the Contested Decision in so far as it requires separate registrations for pure SDA and mixture SDA Product and ash.

35. The Board of Appeal observes that the Appellant's claim stems in particular from the disagreement with the Agency over which substance or substances should be registered pursuant to Articles 5 and 6 of the REACH Regulation. In view of this disagreement, and as a preliminary step in the analysis of the present case, the Board of Appeal will examine what registrants may be required to register pursuant to Articles 5 and 6(1) of the REACH Regulation and specifically clarify the interpretation of 'substance' and 'mixture' within this context.

36. The Board of Appeal notes firstly that the purpose of registration is to collect information on a substance as manufactured or imported rather than on a hypothetical pure version of the substance. This view is substantiated by the information requirements for registration set out in the REACH Regulation. For example, the information required for substance identification set out in Section 2 of Annex VI includes the composition, the degree of purity, and the percentage of main impurities. This view is also supported, for example, by Recital 19 of the REACH Regulation which provides that '… the registration provisions [of the REACH Regulation] should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures'.

37. In addition, the Guidance specifically identifies three broad categories of substance. In general terms, and for the purposes of the present Board of Appeal Decision, the first is a mono-constituent substance where a single substance is the major constituent with other constituents being present in relatively small percentages. The second is a multi-constituent substance which consists of two or more constituents being present in significant percentages with other constituents being present in relatively small amounts. The third, as mentioned in Recital 45 of the REACH Regulation, is a UVCB which typically consists of many constituents, some of which may not be identified and/or where it is difficult or impossible to identify the exact composition of the substance.

38. The Board of Appeal observes that in this particular case pure SDA and mixture SDA Product and ash, if subject to registration, would both be considered to be UVCBs in their own right.

39. During the proceedings the Appellant described how SDA and ash are produced in different combinations depending on the manufacturing process (i.e. desulphurisation in coal-fired power plants with or without a preliminary dust (ash) extraction step) and the point in that process where they are extracted. Where there is no dust (ash) extraction step before desulphurisation the output is a combination of SDA and ash. The Board of Appeal observes that the output, made up primarily of two constituents, namely SDA and ash, is the result of the same process and would therefore be considered to be a single substance for registration purposes. This view is supported by the fact that the two substances cannot be physically separated. Furthermore, as

clarified at the hearing, there is no attempt to measure or blend the two substances as the output of the process, mixture SDA Product and ash, is a by-product of the desulphurisation process and there is no attempt to control the composition of the mixture SDA Product and ash. In light of the above, the Board of Appeal concludes that the output from the desulphurisation process without a dust extraction step, namely mixture SDA Product and ash, must be considered to be a single UVCB (which could be considered to be analogous to a multi-constituent substance where the two main constituents would be UVCBs in their own right) if subject to registration under the REACH Regulation.

40. In the process where there is a dust extraction step before desulphurisation the output of the dust extraction step is ash. The Board of Appeal observes that the ash must therefore be considered to be a single substance if subject to registration under the REACH Regulation. Subsequently, the output of the desulphurisation process following a dust extraction step is SDA with a very low percentage of ash remaining (<0.001% according to the Appellant at the hearing and which may be considered to be an impurity for registration purposes). The Board of Appeal concludes that the output from the desulphurisation process with a dust extraction step, pure SDA, must therefore be considered to be a single substance if subject to registration under the REACH Regulation.

41. The Appellant stated during the proceedings that the ash and SDA, extracted separately from the desulphurisation process with dust extraction, are subsequently mixed to form a mixture of SDA and ash. The Board of Appeal considers that this is the intentional mixing of two substances and is not the result of a single production step but of at least two (e.g. the dust extraction step and the desulphurisation step). The Board of Appeal concludes that this mixture of SDA and ash is not therefore a single substance requiring registration but a mixture the separate components of which may be subject to registration under the REACH Regulation.

42. In view of the above, the Board of Appeal considers that, from the information made available to it, the Appellant's registration dossier may have contained information on more than one substance which is subject to the registration obligations set out inter alia in Articles 5 and 6 of the REACH Regulation.

43. The Board of Appeal observes that the analysis above clarifies what, in accordance with the REACH Regulation, is a substance and what is a mixture in this particular case. This analysis does not however specify what the Appellant is required to register in order to comply with the registration requirements set out in the REACH Regulation as there are a number of factors which the Appellant may need to consider before arriving at a conclusion in this regard.

44. With the above in mind, the Board of Appeal will now examine whether the Agency acted correctly in requesting the Appellant to remove from its registration dossier any information which does not relate to pure SDA.

45. As a preliminary remark, the Board of Appeal considers that the Agency was correct in concluding that each registration dossier must relate to only one substance. This is clear, for example, from the wording of several provisions of the REACH Regulation, including Articles 6(1) and 10 thereof. Consequently, two different substances cannot be registered in the same registration dossier regardless of whether they have the same hazard properties. The Appellant's arguments based on the similarity of the toxicological and ecotoxicological properties of two substances must also therefore be dismissed. As a result, it is not necessary for the Board of Appeal to examine the evidence provided by the Appellant to support its contention that the two substances have similar properties, or the admissibility thereof.

46. As part of the analysis of the present case, the Board of Appeal considers it necessary to briefly clarify the roles of the various actors in the registration process.

47. The Board of Appeal observes that pursuant to Article 6(1) of the REACH Regulation, unless otherwise provided for in that Regulation, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to the Agency. Furthermore, it is clear inter alia from Article 1(3), read in conjunction in particular with Recital 19, that the decision on which substance or substances to register lies with the manufacturer or importer concerned.

48. It is therefore the duty of every registrant to identify the substances they need to register to comply with the REACH Regulation. The Board of Appeal observes that from the Appellant's submissions in the present case it would appear that the Appellant has gone to significant lengths to try to clarify its registration responsibilities with regard to SDA, ash, mixture SDA Product and ash, SDA Product, and other possible substances in its portfolio. For example, the Appellant stated at the hearing that it has consulted its national helpdesk, the Agency's helpdesk, experts, and Agency staff at stakeholder days in this regard.

49. If a manufacturer or importer fails to register a substance in accordance with Article 6(1), Article 126 of the REACH Regulation foresees that the Member States shall have in place provisions on penalties applicable to such infringements. It is therefore the responsibility of the Member State enforcement authorities concerned to take action if they consider that a manufacturer or importer has failed to register a substance in accordance with the REACH Regulation. As stated by the Agency during the proceedings, this task is performed in the context of enforcing Article 5 of the REACH Regulation, in other words in ensuring that substances on their own, in mixtures or in articles, subject to Articles 6, 7, 21 and 23 of the REACH Regulation, are not manufactured in the European Union or placed on the market unless they have been registered.

50. Following the registration of a substance, the compliance check procedure conducted by the Agency pursuant to Article 41 of the REACH Regulation is intended to verify the registration dossier's compliance with the information requirements specified in the REACH Regulation for registration purposes. The Board of Appeal considers that the Agency is not competent however to instruct a particular company to register a particular substance or substances. The Agency is also not competent to check whether a particular company is complying with the REACH Regulation with regard to registering all the substances that it is required to register. As stated above, this is the responsibility of the Member State enforcement authorities.

51. The Board of Appeal observes that in the present case the Agency claims that it was faced with a registration dossier apparently covering at least two different substances. In these circumstances, the Agency decided that the substance addressed in the dossier most closely corresponded to the substance pure SDA and therefore instructed the Appellant to remove from the dossier all information concerning other substances.

52. Regarding the Agency's decision on which substance should be the subject of the registration dossier, the Contested Decision states that the Agency '… notes that, in line with the identity of the test material used for documenting the properties of "SDA product", the substance which is the subject of this registration is manufactured with preliminary dust extraction. Accordingly, the [Appellant] is requested to remove from the dossier any information which does not refer to the registered substance, i.e. SDA product, obtained by the desulphurisation process with preliminary dust separation step.'

53. The Agency also stated during the proceedings that it reached its decision on which substance the Appellant intended to include in the registration dossier on several grounds. Firstly, the Agency states that in the dossier header the substance is named 'Semi Dry Absorption (SDA) Product' which is also the chemical name indicated for the registered substance. According to the Agency this shows the closest proximity with the description of the composition of SDA without ash, in other words pure SDA which is described in the first composition in the dossier. According to the Agency, the composition described as mixture SDA Product and ash is significantly different to the name of the substance described in the dossier. Furthermore, as set out in the Contested Decision and repeated by the Agency during the present proceedings, according to the Appellant's statements in the chemical safety report, the test material used corresponds to pure SDA. In other words, the dossier describes the hazards of pure SDA.

54. The Board of Appeal finds however that where a dossier potentially contains information on more than one substance the Agency cannot unilaterally dictate, based on assumptions, no matter how persuasive, which of those substances should be the subject of the registration dossier in question. In doing so the Board of Appeal considers that the Agency would be encroaching on the Appellant's right, as set out in paragraphs 47 and 48 above, to decide which substances to register. In other words, the Agency would be acting outside the powers accorded to it by the REACH Regulation.

55. The Board of Appeal notes that during the present proceedings the Agency stated that the Appellant '… cannot register the two different substances in one registration dossier. The registration is thus incompliant with REACH, and [the Agency] was correct in seeking clarification as to which substance shall be covered by the registration'. The Board of Appeal agrees with the approach set out in this statement. However, the Board of Appeal points out that, rather than seeking to clarify which substance the Appellant wished to include in the registration dossier, the Agency in effect took that decision on behalf of the Appellant on the basis of assumptions made from the information contained in the registration dossier.

56. Furthermore, the Board of Appeal considers that such a practice may lead to situations where a registrant feels compelled to register a substance which it does not wish, or does not need, to register. Whilst the Agency stated during the proceedings that registrants can register substances that they do not manufacture or import the Board of Appeal considers that such a situation cannot be the result of decisions taken by the Agency.

57. During the proceedings the Agency also claimed that in its Notice of Appeal the Appellant explicitly accepts that the dossier should only cover pure SDA. As stated above in paragraphs 23 and 24, however, the Board of Appeal considers that the Appellant's indication in the Notice of Appeal that it would update its dossier so that it includes information only on pure SDA is predicated on its understanding that it is not required to register mixture SDA Product and ash. Furthermore, the Board of Appeal considers that the Appellant's undertaking cannot be taken as an explicit acknowledgment that pure SDA is the substance that it is required, or intends, to register pursuant to Articles 5 and 6 of the REACH Regulation. Indeed, in the present case, the Board of Appeal observes that despite several attempts at clarification by the Board of Appeal, it was not fully clear which substance or substances the Appellant is in fact required to register pursuant to Article 6(1) of the REACH Regulation as a result of its commercial activities.

58. Furthermore, it became apparent at the hearing that the substances that are the subject of this appeal may in fact be recovered from waste generated in power production plants by other legal entities. The Agency stated that it was unaware of this information. The Agency acknowledged however that this new information may have implications for the naming of a substance for registration purposes as the recovery stage of the manufacturing process may be relevant for that purpose. The Board of Appeal also observes that this information may impact on the identity of the substance(s) the Appellant is required to register. It is possible therefore that the compliance check and the resulting Contested Decision are based on a false premise. The Board of Appeal considers that this further highlights the dangers of the Agency compelling the registration of certain substances.

59. The Board of Appeal considers that the Agency could have, consistent with its legal powers, stated in the Contested Decision that the registration dossier appears to contain information on more than one substance. To this the Agency could have added that, since registration dossiers may only cover one substance, the Appellant should remove all information which does not relate to the substance which the Appellant intended to register in a particular dossier. This would have avoided the Agency exceeding its powers by unilaterally selecting which substance is covered by a specific registration dossier.

60. As indicated by the Agency at the hearing, there needs to be a clear distinction between the legal requirements that need to be met to comply with the registration requirements for a particular substance (i.e. the information needed to make a compliant registration) and the decisions a company takes with regard to the substances it is required to register (i.e. its registration strategy).

61. In situations where it is not clear which substance is intended to be covered by a particular registration dossier, the Board of Appeal encourages the Agency to help registrants, especially when examining the dossiers of small and medium sized enterprises ('SMEs'), to understand their duties with regard to the registration of substances and the content thereof. As indicated for example in Article 77(2)(j) of the REACH Regulation, the Agency should provide advice to help companies to comply with their registration responsibilities, including helping them to identify their registration strategy as well as the information required to meet registration requirements.

62. As stated above, in this particular case, the Contested Decision could be read as directing the Appellant with regard to its registration strategy in addition to identifying what was required to make the registration compliant. The Board of Appeal considers that the Agency should continue providing advice to companies with regard to their registration strategy where it is appropriate to do so but this advice must be clearly differentiated from placing a requirement on the registrant, for example following a compliance check decision.

63. In view of the fact that the Agency exceeded its powers by selecting which of the substances contained in the registration dossier should be the focus of that dossier the Board of Appeal annuls the Contested Decision and remits the case to the competent body of the Agency for re-evaluation of the Appellant's registration dossier that is current at the time of that re-evaluation.

64. The Board of Appeal also considers that, based on the Board of Appeal's findings above, the Appellant should re-examine its registration strategy with regard to which substances it is obliged to register pursuant to the REACH Regulation.

Refund of the appeal fee

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

66. As the Board of Appeal has decided the appeal in favour of the Appellant in the present case, the appeal fee shall be refunded on that basis.

ORDER

On those grounds,

THE BOARD OF APPEAL

hereby:

Annuls Decision CCH-D-0000002552-79-03/F adopted by the European Chemicals Agency on 4 July 2012.

Remits the case to the competent body of the Agency for re-evaluation of the registration dossier that is current at the time of that re-evaluation.

Orders the refund of the appeal fee.

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal