EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

22 March 2022

(Substance evaluation – Error of assessment – Potential risk – Improved risk management measures – Proportionality – Article 25)

Case number	A-004-2020
Language of the case	English
Appellant	Tribotecc GmbH, Austria
Representatives	Claudio Mereu and Simon Englebert Fieldfisher (Belgium) LLP, Belgium
Interveners	(I) The Federal Institute for Occupational Safety and Health, Germany (II) PETA International Science Consortium Ltd. ('PISC'), United Kingdom
Contested Decision	Decision of 12 March 2020 on the substance evaluation of antimony sulphide adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 46 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; the 'REACH Regulation') The Contested Decision was notified to the Appellant under annotation number SEV-D-2114499401-46-01/F.

THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman and Rapporteur), Nikolaos Georgiadis (Technically Qualified Member) and Ángel M. Moreno (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

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Background to the dispute

1. Separate substance evaluations were performed in parallel for the following five antimony compounds:
   - antimony metal (EC number ('No') 231-146-5, CAS No 7440-36-0; 'Sb metal'),
   - diantimony trioxide (EC No 215-175-0, CAS No 1309-64-4; 'ATO'),
   - antimony sulphide, also referred to as diantimony trisulphide, (EC No 215-713-4, CAS No 1345-04-6; 'ATS'),
   - antimony trichloride (EC No 233-047-2, CAS No 10025-91-9; 'ATC'), and
   - 2,5,7,10,11,14-hexaoxa-1,6-distibabicyclo[4.4.4]tetradecane (EC No 249-820-2, CAS No 29736-75-2; 'ATEG').
2. In 2016, the Agency separately included Sb metal, ATO, and ATS in the Community rolling action plan ('CoRAP'). ATC and ATEG were added to the CoRAP in 2018. The CoRAP including Sb metal, ATO, ATS, ATC and ATEG was published on the Agency's website on 20 March 2018 in accordance with Article 44(2) of the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise). The Competent Authority of Germany was appointed as the evaluating Member State Competent Authority (the 'eMSCA') for all five substances.
3. ATS has been registered at the 100 to 1 000 tonnes per year tonnage band. The Appellant is one of the registrants of ATS.
4. On 20 March 2019, following the substance evaluation of ATS, the eMSCAs submitted a draft decision (the 'draft substance evaluation decision') to the Agency.
5. On 18 April 2019, the Agency notified the draft substance evaluation decision to the Appellant and other registrants of ATS and invited them to provide comments pursuant to Article 50(1). According to the draft substance evaluation decision, the Appellant and other registrants were required to provide information on a 90-day (sub-chronic) inhalation toxicity study in rats (test method: OECD test guideline ('TG') 413) with ATS including bronchoalveolar lavage ('BAL'), measurements of lung burden, and additional cardiovascular and toxicokinetic parameters.
6. On the same day, the Appellant and other registrants of ATS received a separate draft compliance check decision from the Agency under Article 41.
7. On 28 May 2019, the Appellant and other registrants of ATS provided comments to the Agency on the draft substance evaluation decision and on the draft compliance check decision. In its comments on those draft decisions, the Appellant argued that the Agency should complete the compliance check on ATS prior to the performance of the substance evaluation. According to the Appellant, the outcome of the compliance check would influence the substance evaluation, especially as regards the number of studies performed to clarify the concerns identified by the Agency.
8. On 19 June 2019, the Appellant and other registrants of ATS updated their registration dossiers for ATS. The dossier update included amendments to the read-across and weight-of-evidence adaptations included in the Appellant's registration dossier for ATS.
9. The eMSCA amended the reasoning in the draft substance evaluation decision to take into account the Appellant's comments on that draft as well as the Appellant's dossier update of 19 June 2019. However, the request for information set out in the draft substance evaluation decision was not amended.
10. On 24 October 2019, the eMSCA notified the Appellant's comments and the amended draft substance evaluation decision to the competent authorities of the other Member States and the Agency in accordance with Article 52(1).

11. On 12 March 2020, as no proposals for amendment were submitted by the competent authorities of the Member States, the Agency adopted the Contested Decision in accordance with Article 51(3).

12. On the same day, the Agency adopted separate substance evaluation decisions concerning Sb metal and ATEG, which are the subject of separate appeals in Case A-003-2020, *Campine,* and in Case A-005-2020, *S. Goldman*, respectively.

13. The Contested Decision requires the Appellant to update its registration dossier by 20 December 2021 with the following information (the 'requested study'):

    '*90-day (sub-chronic) inhalation toxicity study in rats (test method: OECD TG 413) with [ATS], including*

    (i) BAL and measurements of lung burden […], which inform on pulmonary deposition and retention of particles in the lung,
    (ii) cardiovascular effect evaluations, including electrocardiogram, cardiac biomarkers (myoglobin, cardiac troponins, creatine-kinase isoenzyme MB (CK-MB), brain natriuretic peptide (BNP) and N-terminal pro-brain natriuretic peptide (NT-ProBNP)) and histopathology comprising standard HE and histomorphological and quantitative investigations for fibrosis (e.g. Sirius Red/Fast Green Staining) at representative localisations (further specifications see Appendix 1 [of the Contested Decision]) and
    (iii) *toxicokinetic assessment covering the test parameters according to test method OECD TG 417 using a satellite group at the high exposure level (as specified in Appendix 1 [of the Contested Decision]). The toxicokinetic studies shall include quantification of the parent compound and – by means of metal speciation – trivalent (Sb(III)), pentavalent (Sb(V)), and alkylated (e.g. methylated) Sb species, which might be formed from the parent compound.*'

14. On 12 March 2020, the Agency adopted a compliance check decision concerning ATS under Article 41 requiring the Appellant and other registrants of ATS to update their registration dossiers by 20 December 2021 with, depending on the tonnage at which they registered the substance, the following information on ATS:

    - *In vitro* gene mutation study in bacteria (Section 8.4.1. of Annex VII; test method EU B.13/14. / OECD TG 471);
    - *In vitro* cytogenicity study in mammalian cells (Section 8.4.2. of Annex VIII, test method OECD TG 473) or *in vitro* micronucleus study (Section 8.4.2. of Annex VIII; test method OECD TG 487);
    - If the studies referred to in the previous two indents have negative results, *in vitro* gene mutation study in mammalian cells (Section 8.4.3. of Annex VIII; test method OECD TG 476 or TG 490);
    - Screening for reproductive/developmental toxicity (Section 8.7.1. of Annex VIII; test method OECD TG 421 or 422) in rats, oral route; and
    - Pre-natal developmental toxicity study (Section 8.7.2. of Annex IX; test method OECD TG 414) in a first species (rat or rabbit), oral route.

Procedure before the Board of Appeal

15. On 12 June 2020, the Appellant filed this appeal.

16. On 17 September 2020, the Agency filed its Defence.

17. On 23 October 2020, Ángel M. Moreno, alternate member of the Board of Appeal, was designated to act as legally qualified member of the Board of Appeal in this case in accordance with the second subparagraph of Article 3(2) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; the 'Rules of Procedure').

18. On 10 December 2020, the German Federal Institute for Occupational Safety and Health (the 'German competent authority') was granted leave to intervene in support of the Agency.

19. On 10 December 2020, PETA International Science Consortium Ltd. ('PISC') and Cruelty Free Europe ('CFE') were both granted leave to intervene in support of the Appellant.

20. On 10 December 2020, the Board of Appeal rejected an application to intervene submitted by the International Antimony Association.

21. On 15 January 2021, the Appellant filed its observations on the Defence.

22. On 11 February 2021, the German competent authority filed its statement in intervention.

23. On 15 February 2021, PISC filed its statement in intervention.

24. On 15 February 2021, CFE informed the Board of Appeal that it would not be submitting a statement in intervention in the present case.

25. On 4 March 2021, the Agency filed observations on the Appellant's observations on the Defence.

26. On 19 April 2021, the Agency submitted its observations on the statement in intervention lodged by the German competent authority.

27. On 21 April 2021, the Appellant submitted its observations on the statements in intervention lodged by the German competent authority and PISC.

28. On 22 April 2021, the Agency submitted its observations on the statement in intervention lodged by PISC.

29. On 14 June 2021, the Appellant and the Agency replied to questions from the Board of Appeal.

30. On 20 July 2021, CFE informed the Board of Appeal that it no longer wished to intervene in this case.

31. On 21 September 2021, a hearing was held as the Board of Appeal considered it necessary in accordance with Article 13(1) of the Rules of Procedure. The hearing, which was held jointly with appeal Cases A-003-2020 and A-005-2020, took place via video-conference in accordance with Article 13(7) of the Rules of Procedure. At the hearing, the Parties and the German competent authority made oral submissions and answered questions from the Board of Appeal. PISC did not take part in the hearing.

Form of order sought

32. In its written submissions, the Appellant requested the Board of Appeal to annul the Contested Decision. The Appellant also requested the Board of Appeal to order the Agency to pay the costs of the appeal proceedings. PISC supported the form of order sought by the Appellant.

33. At the hearing, following a question from the Board of Appeal, the Appellant clarified that it requests the Board of Appeal to annul the Contested Decision in its entirety. The Appellant also clarified that, in the alternative, it requests the Board of Appeal to partially annul the Contested Decision, in so far as that decision requires the Appellant to include BAL and measurements of lung burden, cardiotoxicity investigations, and toxicokinetic assessments in the requested study.

34. The Agency, supported by the German competent authority, requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

1. Admissibility of the evidence in Annexes R1 to R20 to the Appellant's observations on the Defence

Relevant legislation

35. Under 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.

36. Under Article 15(1) of the Rules of Procedure, the Board of Appeal may prescribe procedural measures at any point in the proceedings.

37. According to Article 15(2)(a) of the Rules of Procedure, one of the purposes of procedural measures is '*to ensure the efficient conduct of the proceedings and to facilitate the taking of evidence*'.

38. Under Article 15(3)(d) of the Rules of Procedure, procedural measures may, for example, consist of asking for documents relating to the case to be produced.

Arguments of the Parties

39. The Agency objects to the admissibility of the following twenty annexes submitted with the Appellant's observations on the Defence:

    1. '*Justification Document for the Selection of a CoRAP Substance*' concerning ATO prepared by the German Federal Institute for Occupational Safety and Health, dated 22 March 2016 (Annex R1);
    2. '*Justification Document for the Selection of a CoRAP Substance*' concerning antimony prepared by the German Federal Institute for Occupational Safety and Health, dated 22 March 2016 (Annex R2);
    3. '*Scientific opinion, provisional read-across justification, and further research opportunities - Human Health: Lung toxicity and carcinogenicity*', prepared by the International Antimony Association, dated 31 July 2018 (Annex R3);
    4. '*Scientific opinion, provisional read-across justification, and further research opportunities - Human Health: Genotoxicity*', prepared by the International Antimony Association, dated 31 July 2018 (Annex R4);
    5. '*Scientific opinion, provisional read-across justification, and further research needs - Human Health: Reproductive toxicity*', prepared by the International Antimony Association, dated 31 July 2018 (Annex R5);
    6. '*Derivation of DNELS for Antimony III Compounds*', prepared by Craig Boreiko for the International Antimony Association, dated April 2018 (Annex R6);
    7. '*A Multiple-Path Model of Particle Deposition in the Rat Lung*', Anjilvel and Asgharian, Fundamental and Applied Toxicology (1995), 28, pp. 41 to 50 (Annex R7);
    8. '*Incorporation of particle size differences between animal studies and human workplace aerosols for deriving exposure limit values*', Oller and Oberdörster, Regulatory Toxicology and Pharmacology (2010), 57, pp. 181 to 194 (Annex R8);
    9. '*The fractions of respiratory tract cells at risk in formaldehyde carcinogenesis*', Miller *et al.*, Inhalation Toxicology (2011), 23(12), pp. 689 to 706 (Annex R9);
    10. '*Expert opinion on the biological plausibility of HEC and MPPD*', Kalberlah *et al.*, on behalf of the German Federal Institute for Occupational Safety and Health, dated July 2011 (Annex R10);
    11. '*Summary Report on Occupational Exposure to Antimony Metal, Diantimony Trisulphide, and Diantimony Tris(Ethylene Glycolate)*', prepared by EBRC Consulting, dated 12 January 2021 (Annex R11);

12. '*Exposure to antimony from the use of antimony in ammunition*', prepared by EBRC Consulting, dated 12 January 2021 (Annex R12);
13. '*Occupational Exposure to Metals in Shooting Ranges: A Biomonitoring Study*', Vandebroek *et al.,* Safety and health at Work (2019), 10, pp. 87 to 94 (Annex R13);
14. Decision of the Agency of 12 March 2020 on the substance evaluation of ATO (Annex R14);
15. Letter of 10 April 2018 on the classification of ATS (Annex R15);
16. Letter of 4 September 2019 on the classification of ATS (Annex R16);
17. Proposal for an enforcement project on 'self-classifications' submitted by Eurometaux to the Agency's Forum for Exchange of Information on Enforcement (Annex R17);
18. Quote from a contract research organisation for analytical/bioanalytical work on antimony substances, dated 9 April 2020 (Annex R18);
19. '*Antimony Speciation – Response to ECHA*', prepared by Philip Mitchell for the International Antimony Association, dated 14 January 2021 (Annex R19); and
20. Statement of work dated 7 July 2020 (Annex R20).

40. The Agency argues that the evidence submitted with the Appellant's observations on the Defence as Annexes R1 to R20 is inadmissible under Article 12(1) of the Rules of Procedure because it was introduced after the first exchange of written pleadings and the delay in submitting that evidence is unjustified.

41. The Appellant argues that the delay in offering Annexes R1 to R20 as evidence is justified either because those documents were already known or could have been known to the Agency before the Appellant submitted its observations on the Defence (Annexes R1 to R10, R13, R14, and R17), or because the evidence in question was under development when the Appellant filed the Notice of Appeal and therefore could not have been submitted together with the Notice of Appeal (Annexes R12 and 20), or because the evidence in question was developed or submitted to specifically address points raised by the Agency in its Defence (Annexes R11, R15, R16, R18, and R19).

42. The Appellant argues that, even if the Board of Appeal considers that the evidence submitted as Annexes R1 to R20 to the observations on the Defence is inadmissible, the Board of Appeal should nonetheless request it under Article 15 of the Rules of Procedure. According to the Appellant, this is necessary because that evidence is related to the case, completes the file, and ensures the observance of the right of defence and the rule that both parties should be heard.

Findings of the Board of Appeal

43. Since Annexes R1 to R20 were submitted by the Appellant with the observations on the Defence, that evidence was submitted after the first exchange of written pleadings. In accordance with Article 12(1) of the Rules of Procedure, it is therefore necessary to consider whether the delay in submitting Annexes R1 to R20 as evidence is justified.

44. A delay in offering evidence is justified where, for example, it is presented to support arguments offered to rebut arguments raised for the first time in the defence or where the evidence in question was in preparation at the time of the deadline to submit an appeal and it is clear that the evidence in question could not have been prepared before the deadline to submit the appeal (see, for example, Case A-015-2015, *Evonik Degussa and Others*, decision of the Board of Appeal of 30 June 2017, paragraphs 47 to 52).

45. Where appropriate, it will also be necessary to examine the Appellant's arguments that, should the Board of Appeal decide that any of the evidence is inadmissible, the Board of Appeal should request that evidence to be produced under Article 15 of the Rules of Procedure.

1.1. Admissibility of Annexes R1 and R2

46. The Appellant argues that Annexes R1 and R2 demonstrate that ATO and Sb metal were included in the CoRAP together with ATS at the same time and for the same reasons. According to the Appellant, this indicates that those substances were considered by the Agency as a group of substances. The Appellant argues further that these documents were already known to the Agency and the eMSCA prior to their submission in these proceedings and were needed to respond to arguments in the Defence.

47. In the Notice of Appeal, the Appellant states that ATS was included in the CoRAP in 2016 together with ATO and Sb metal. This statement is a repetition of the statement in the Contested Decision that the substance evaluation for ATS was conducted in parallel to the evaluations for ATO, Sb metal, ATC, and ATEG for which similar initial concerns need to be clarified.

48. Furthermore, contrary to the Appellant's arguments, Annexes R1 and R2 do not respond to arguments in the Defence. In fact, in the Defence, the Agency confirms the statement in the Contested Decision that the substance evaluation of ATS was conducted in parallel to the evaluations of other antimony substances due to similar initial concerns.

49. In its Defence, the Agency did not dispute that the substance evaluations for the various antimony metals were conducted in parallel. There was, therefore, no reason for the Appellant to submit Annexes R1 and R2. As a result, the Appellant's justifications for submitting Annexes R1 and R2 must be rejected. The submission of evidence to establish uncontested facts cannot justify the late submission of new evidence (see, by analogy, judgment of 13 December 2018, *Post Bank Iran*, T-559/15, EU:T:2018:948, paragraph 79). In addition, the fact that Annexes R1 and R2 were known to the Agency does not allow the Appellant to circumvent the requirements of Article 12(1) of the Rules of Procedure.

50. In view of paragraphs 46 to 49 above, the delay in submitting Annexes R1 and R2 is not justified within the meaning of Article 12(1) of the Rules of Procedure. Annexes R1 and R2 must therefore be declared inadmissible.

51. The Appellant's argument that the Board of Appeal should request Annexes R1 and R2 under Article 15 of the Rules of Procedure must also be rejected. This is because the Parties do not dispute that ATS, ATO and Sb metal were included in the CoRAP at the same time and for similar reasons. It is therefore not necessary to consider Annexes R1 and R2 in further detail to decide whether the Appellant is correct in arguing that the Agency treated these substances as a group of substances.

1.2. Admissibility of Annexes R3, R4, and R5

52. The Appellant argues that it introduced Annexes R3, R4 and R5 to rebut the Agency's argument in the Defence that the Appellant developed a read-across in response to the identification of the potential risk by the eMSCA in the substance evaluation process.

53. The Agency states in the Defence that the Appellant responded to the identification of a potential risk by the eMSCA with a proposal to develop a read-across. However, from the information available in the present proceedings, it appears that the Appellant had first submitted a read-across proposal in July 2018, prior to the date of the draft substance evaluation decision, and later amended that proposal on 19 June 2019, after the date the draft substance evaluation decision was notified to it.

54. Since Annexes R3, R4 and R5 support arguments made in rebuttal of arguments raised by the Agency for the first time in the Defence, the delay in offering those Annexes is justified. Therefore, those Annexes are admissible in so far as they are intended to support the Appellant's arguments that its first read-across proposal was submitted in July 2018 and was later amended on 19 June 2019.

1.3. Admissibility of Annex R6

55. The Appellant argues that Annex R6 was known to the Agency and the eMSCA prior to these proceedings as the content of that document was incorporated into the Appellant's Chemical Safety Report (CSR) for ATS which was submitted with the registration dossier for ATS and as Annex 17 to the Notice of Appeal. The Appellant also argues that Annex R6 was submitted to demonstrate how the derived no-effect levels ('DNELs') for ATS were derived due to the Agency's claims in the Defence that the DNELs derived for ATS are not appropriate.

56. Although the Agency presents arguments related to DNEL derivation in the Defence, contrary to the Appellant's claims, Annex R6 does not specifically respond to those arguments. In addition, the fact that a document may be known to the Agency prior to its submission in appeal proceedings does not relieve an appellant of the obligation to submit that document in accordance with the Rules of Procedure.

57. In view of paragraphs 55 and 56 above, the delay in submitting Annex R6 is not justified within the meaning of Article 12(1) of the Rules of Procedure. Annex R6 must therefore be declared inadmissible.

58. The Appellant's argument that the Board of Appeal should request Annex R6 under Article 15 of the Rules of Procedure is also rejected. This is because, according to the Appellant, the content of that document is included in Annex 17 to the Notice of Appeal and is therefore already available in the file.

1.4. Admissibility of Annexes R7, R8, R9, and R10

59. The Appellant argues that Annexes R7, R8, R9, and R10 are studies which are available in the public literature and could have been known to the Agency, had it acted with diligence. The Appellant argues that, as these Annexes refer to the methods used to derive DNELs, they should have been known to the Agency. The Appellant argues that, in any event, these Annexes were submitted with the observations on the Defence to respond to the Agency's arguments in the Defence.

60. Although Annexes R7, R8, R9, and R10 are relevant to the issue of DNEL derivation, which is discussed in the Defence, those Annexes do not specifically respond to arguments in the Defence. In addition, all four documents pre-date the adoption of the Contested Decision and could therefore have been submitted with the Notice of Appeal.

61. The fact that a document is available in the public literature does not allow an appellant to circumvent the requirements of Article 12(1) of the Rules of Procedure.

62. In view of paragraphs 59 to 61 above, the delay in submitting Annexes R7, R8, R9, and R10 is not justified within the meaning of Article 12(1) of the Rules of Procedure. Annexes R7, R8, R9, and R10 are therefore inadmissible.

63. The Appellant's argument that the Board of Appeal should request Annexes R7, R8, R9, and R10 under Article 15 of the Rules of Procedure is also rejected. This is because those documents are not necessary for the Board of Appeal to decide on the present case.

1.5. Admissibility of Annex R11

64. The Appellant argues that it commissioned Annex R11 to respond to specific arguments raised by the Agency in the Defence and to demonstrate that the exposure of workers to ATS decreases over time.

65. Annex R11 responds to arguments in the Defence related to occupational exposure (workers and professionals) to ATS. Furthermore, since Annex R11 was finalised after the deadline to submit the appeal, it could not have been submitted with the Notice of Appeal. In addition, there is no indication that the document could have been finalised before the deadline to submit the appeal (see *Evonik Degussa and Others*, cited in paragraph 44 above, paragraphs 47 to 52 of the decision). The delay in offering Annex R11 is therefore justified and that evidence is admissible.

1.6. Admissibility of Annex R12

66. The Appellant argues that Annex R12 was not available before the deadline to submit the Notice of Appeal and it was therefore not possible for the Appellant to offer that evidence earlier in the written procedure.

67. Since Annex R12 was finalised after the deadline to submit the appeal, it could not have been submitted with the Notice of Appeal. Furthermore, the fact that the document was in preparation was announced in the Notice of Appeal. In addition, there is no indication that the document could have been finalised before the deadline to submit the appeal (see *Evonik Degussa and Others*, cited in paragraph 44 above, paragraphs 47 to 52 of the decision). The delay in offering Annex R12 is therefore justified and that evidence is admissible.

1.7. Admissibility of Annex R13

68. The Appellant argues that Annex R13 is a study available in the public literature and, since it was published in 2018, it could have been known to the Agency, had it acted with diligence. The Appellant argues that, in any event, Annex R13 was submitted to the Board of Appeal only because it was referred to in Annexes R11 and R12.

69. The fact that a document is available in the public literature does not allow an appellant to circumvent the requirements of Article 12(1) of the Rules of Procedure.

70. Furthermore, Annex R13 does not specifically respond to arguments in the Defence and the arguments of the Appellant that this Annex is intended to support in fact respond directly to findings in the Contested Decision. Annex R13 could therefore have been submitted with the Notice of Appeal. The fact that this Annex is referred to in Annexes R11 and R12 does not justify the delay in offering that evidence.

71. In view of paragraphs 68 to 70 above, the delay in submitting Annex R13 is not justified within the meaning of Article 12(1) of the Rules of Procedure. Annex R13 must therefore be declared inadmissible.

72. The Appellant’s argument that the Board of Appeal should request Annex R13 under Article 15 of the Rules of Procedure must also be rejected. This is because that document is not necessary for the Board of Appeal to decide on the case.

1.8. Admissibility of Annex R14

73. The Appellant argues that Annex R14 was known to the Agency and the eMSCA as it is a document adopted by the Agency. According to the Appellant, it was submitted as part of the observations on the Defence to support the Appellant's argument related to the need to consistently apply a grouping approach and to show that studies on ATO are relevant for ATS.

74. However, it is unclear to which argument in the Defence Annex R14 responds. Furthermore, the fact that a document is known to the Agency does not allow an appellant to circumvent the requirements of Article 12(1) of the Rules of Procedure. As a result, even though this document was adopted by the Agency, the delay in introducing it into the appeal proceedings is unjustified. Annex R14 must therefore be declared inadmissible.

75. The Appellant's argument that the Board of Appeal should request Annex R14 under Article 15 of the Rules of Procedure must also be rejected. This is because that document is not necessary for the Board of Appeal to decide on the case.

1.9. Admissibility of Annexes R15 and R16

76. The Appellant argues that Annexes R15 and R16 were introduced to respond to arguments in the Defence and to demonstrate that the self-classification of chemicals has a significance and should not be dismissed as irrelevant.

77. Although the relevance of self-classification is addressed at page 12 of the Contested Decision, the Agency raises further arguments in the Defence on this issue. Annexes R15 and R16 are offered to support arguments made in rebuttal of those further arguments. As a result, the delay in offering Annexes R15 and R16 is justified and that evidence is admissible.

1.10. Admissibility of Annex R17

78. The Appellant argues that Annex R17 was known, or could have been known, to the Agency, as it was a project proposal submitted within the framework of the Agency's Enforcement Forum for Exchange of Information on Enforcement. The Appellant argues that this Annex was submitted with the observations on the Defence to demonstrate that, contrary to the Agency's arguments in the Defence, the self-classification of chemicals has a value and should not be dismissed as irrelevant.

79. Although the relevance of self-classification is addressed at page 12 of the Contested Decision, the Agency raises further arguments in the Defence on this issue. Annex R17 is offered to support arguments made in rebuttal of those further arguments. As a result, the delay in offering Annex R17 is justified and that evidence is admissible.

1.11. Admissibility of Annex R18

80. The Appellant argues that Annex R18 was submitted to respond to the Agency's arguments in the Defence that the study requested in the Contested Decision does not need method development and validation.

81. Annex R18 is offered to support arguments made in rebuttal of arguments raised by the Agency in the Defence. As a result, the delay in offering Annex R18 is justified and that evidence is admissible.

1.12. Admissibility of Annex R19

82. The Appellant argues that Annex R19 was submitted as part of the observations on the Defence because it was commissioned to respond to the arguments raised by the Agency in the Defence.

83. Annex R19 is offered to support arguments made in rebuttal of arguments raised in the Defence. Furthermore, since Annex R19 was finalised after the deadline to submit the appeal, it could not have been submitted with the Notice of Appeal. In addition, there is no indication that the document could have been finalised before the deadline to submit the appeal (see *Evonik Degussa and Others*, cited in paragraph 44 above, paragraphs 47 to 52 of the decision). The delay in offering Annex R19 is therefore justified and that evidence is admissible.

1.13. Admissibility of Annex R20

84. The Appellant argues that Annex R20 was not available before the deadline to submit the Notice of Appeal and it was therefore not possible for the Appellant to offer that evidence earlier in the written procedure. The Appellant also argues that Annex R20 was submitted as part of the observations on the Defence to respond to the Agency's arguments in the Defence that the study requested in the Contested Decision does not need method development and validation.

85. Annex R20 is offered to support arguments made in rebuttal of arguments raised for the first time in the Defence. Furthermore, since Annex R20 was finalised after the deadline to submit the appeal, it could not have been submitted with the Notice of Appeal. In addition, there is no indication that the document could have been finalised before the deadline to submit the appeal (see *Evonik Degussa and Others*, cited in paragraph 44 above, paragraphs 47 to 52 of the decision). The delay in offering Annex R20 is therefore justified and that evidence is admissible.

1.14. Conclusion on the admissibility of the evidence in Annexes R1 to R20

86. The evidence produced in Annexes R1, R2, R6, R7, R8, R9, R10, R13, and R14 to the Appellant’s observations on the Defence is inadmissible and will not, therefore, be taken into account in the examination of the substance of the appeal.

87. The Appellant’s request that those Annexes should be requested by the Board of Appeal under Article 15 of the Rules of Procedure is rejected.

88. The Agency’s claim that the evidence produced in Annexes R3, R4, R5, R11, R12, R15, R16, R17, R18, R19, and R20 to the Appellant’s observations on the Defence is inadmissible is rejected.

2. Substance

89. The Appellant raises the following pleas in law:

    1. The Agency committed an error of assessment by failing to fulfil the conditions for requesting information under Article 46 (first plea);
    2. The Agency infringed an essential procedural requirement of the REACH Regulation as it did not perform a compliance check on ATS prior to the substance evaluation on that substance (second plea);
    3. The Agency breached the principle of the protection of legitimate expectations (third plea);
    4. The Agency committed an error of assessment (fourth plea);
    5. The Contested Decision is inappropriate to achieve the objective pursued by the Agency (fifth plea);
    6. The Agency failed to state reasons for the Contested Decision (sixth plea); and
    7. The Agency breached the principles of proportionality and animal welfare (seventh plea).

2.1. First and fourth pleas: Error of assessment and failure to fulfil the conditions for requesting information under Article 46

90. Under the first plea, the Appellant, supported by PISC, claims that the Agency committed an error of assessment by failing to fulfil the established conditions for requesting information under Article 46.

91. Under the fourth plea, entitled 'error of assessment', the Appellant also raises arguments to support its claim that the Agency failed to establish a potential risk and failed to demonstrate that the requested study will lead to improved risk management measures. As a result, the first and fourth pleas will be examined together.

92. In addition, certain of the Appellant's arguments to support its claim that the Agency failed to demonstrate a potential risk are found under the Appellant's fifth plea related to the appropriateness of requested information. Those arguments will therefore be addressed together with the first and fourth pleas.

Arguments of the Parties and the Interveners

Requesting information under substance evaluation

93. The Appellant, supported by PISC, argues that the Agency failed to examine, carefully and impartially, all the relevant information on ATS submitted by the Appellant. The Appellant argues that this information includes its stepwise testing strategy, its proposed read-across and weight-of-evidence adaptations, as well as the comments it submitted during the substance evaluation process, including its comments regarding exposure to ATS.

94. The Appellant argues that the Agency acted inconsistently as, in the Contested Decision, it relied on data on ATO to demonstrate that ATS could cause toxic effects after inhalation. However, the Agency did not accept the Appellant's proposal regarding the read-across of hazard data from ATO to ATS to assess toxicity. The Appellant argues that this suggests that the Agency selectively used the information available to suit its conclusions in a partial way.

95. The Appellant argues that, under substance evaluation, it is not for the Appellant to prove that there is no risk or that current risk management measures are sufficient to deal with the potential risk. In the present case, according to the Appellant, the Agency failed to demonstrate an actual risk and relied on insufficient and outdated information, for example observations from occupational exposure during mining and smelting of ATS.

Clarity of the concern identified by the Agency

96. The Appellant argues that, in the Contested Decision, there is a lack of clarity and consistency regarding the concerns identified by the Agency and the expected regulatory outcome. According to the Appellant, it is unclear from the Contested Decision whether the concerns identified by the Agency relate to ATS or to the structurally similar substance ATO.

97. The Appellant argues that the purpose of the requested study and whether the concerns identified by the Agency relate to consumer exposure, worker exposure, professional exposure, or all of these categories, are unclear.

Potential hazard

98. The Appellant argues that, to demonstrate a hazard related to cardiotoxicity, the Agency relied on historical literature and clinical studies which are not relevant to ATS because those studies involved the use of medical antimony compounds at high doses, administered intravenously. The Appellant also argues that the electrocardiogram ('ECG') changes reported in the clinical literature are reversible.

99. The Appellant argues that studies performed via intravenous administration should not be used to regulate substances under the REACH Regulation. This is because the systemic dose achieved via intravenous administration is much higher than the dose which could be available systemically via inhalation. The Appellant also argues that inhalation exposure to ATS in the workplace will not reach the same levels of systemic exposure as that seen in the studies relied on by the Agency.

100. The Appellant argues that the compound for which there is a clear indication of cardiotoxicity - sodium antimony gluconate - is used in medical applications via intravenous administration and is chemically different from the antimony substances investigated by the Agency.

Potential exposure and improved risk management measures

101. The Appellant argues that the Agency has not demonstrated that the requested information is necessary to meet real information needs regarding the protection of human health and the environment.

102. The Appellant argues that the Agency failed to take into account the Appellant's comments during the substance evaluation process regarding exposure to ATS, including the Appellant's recent efforts to generate more information on workplace exposure which will demonstrate the efficiency and efficacy of the existing risk management measures.

103. The Appellant argues that worker exposure is already adequately controlled through ventilation and respiratory protective equipment. The Appellant argues that, for each Process Category ('PROC') mentioned in the Contested Decision, the risk characterisation ratio (RCR') is below 1, demonstrating safe use. In addition, as the tasks are carried out in a controlled industrial environment, worker exposure above levels of concern is excluded.

104. The Appellant argues that, in relation to worker and consumer exposure, the Agency disregarded the Appellant's comments on the draft decision which show that exposure is below the DNEL and that the RCRs demonstrated safe use.

105. The Appellant argues that the Agency has not examined the risk management measures currently in place, such as the good occupational hygiene practices and the ventilation and personal protective equipment used in the ATS industry. The Appellant argues that the Agency also failed to demonstrate how the requested information will lead to an improvement in the existing risk management measures. In particular, the Agency failed to demonstrate to what extent the current self-classification of ATS as specific target organ toxicity repeat exposure ('STOT RE'), level 2 (for lung) and the other European Union wide measures already in place are not appropriate to control exposure to ATS, bearing in mind that its use is primarily industrial and that, when found in consumer/professional products, it is bound into a matrix, preventing exposure. The Appellant argues that the requested information is also unlikely to be accepted as the basis for occupational exposure limits ('OEL') derivation by occupational health professionals.

106. The Appellant argues that once a substance is classified (or self-classified) as STOT RE 2 for lungs, the potential impact of inhalation exposure leading to toxicity upon other organs such as the heart or liver is prevented by the risk management measures necessitated by the classification for lung effects. This is because, according to the Appellant, the protection of lung function requires restrictions upon exposure that will prevent systemic exposure from attaining levels that will impact other potential target organs. As a result, clarifying additional hazards will not improve human health protection.

107. The Agency, supported by the German competent authority, disputes the Appellant's arguments.

Findings of the Board of Appeal

2.1.1. Requesting information under substance evaluation

108. To request information under substance evaluation, the Agency must establish that:

- there are grounds for considering that, based on a combination of exposure and hazard information, a substance constitutes a potential risk to human health or the environment,
- the potential risk needs to be clarified, and
- the requested information, needed to clarify the concern, has a realistic possibility of leading to improved risk management measures (see, for example, judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638, paragraph 276; see also Case A-008-2018, *Taminco and Performance Additives Italy*, decision of the Board of Appeal of 29 January 2020, paragraphs 45 and 46).

109. The Appellant claims that the Agency failed to fulfil each of the three conditions set out in the previous paragraph. The Appellant's arguments that the Agency committed an error of assessment in relation to each of these three conditions will therefore be examined in turn below.

110. To request information under substance evaluation, it is not necessary for the Agency to demonstrate an '*actual risk*', only a '*potential risk*'. The aim of requesting additional information under substance evaluation is to clarify whether the potential risk is an actual risk (see, for example, Joined Cases A-003-2018, A-004-2018, and A-005-2018, *BASF and Kemira*, decision of the Board of Appeal of 17 December 2019, paragraphs 84 to 87). Furthermore, whilst it is the Agency's responsibility to demonstrate that there is a potential risk, it is for an appellant to show that the Agency's conclusion in this respect is erroneous. In assessing the Appellant's pleas that the Agency made errors of assessment, it is therefore necessary to examine whether the arguments put forward by the Appellant are capable of demonstrating that the Agency made errors in concluding that the three conditions referred to in paragraph 108 above are met in the present case (see Case A-007-2019, *Chemours Netherlands*, decision of the Board of Appeal of 12 January 2021, paragraph 40).

111. It is also necessary to examine whether the Agency has examined carefully and impartially all the relevant facts of the individual case, and whether those facts support the conclusions that the Agency drew from them (see, by analogy, judgment of 19 January 2012, *Xeda International and Pace International* v *Commission*, T-71/10, EU:T:2012:18, paragraph 71; see *Chemours Netherlands*, cited in the previous paragraph, paragraph 40 of the decision).

2.1.2. The Appellant's stepwise testing strategy and read-across proposals

112. During the substance evaluation process, the Appellant proposed a stepwise testing strategy to be carried out under the compliance check and substance evaluation processes. The Appellant considered that the stepwise testing strategy would enable it to generate additional data to confirm its read-across proposals which were first submitted in July 2018 and were amended on 19 June 2019, as part of the dossier update for ATS (see paragraph 8 above).

113. Under its stepwise testing strategy, the Appellant aimed, gradually and progressively, to generate information to support its grouping and read-across approach for antimony compounds and for several endpoints, including repeated dose sub-chronic toxicity. According to the Appellant, this testing strategy would limit the number of vertebrate animal tests performed on antimony compounds for the purposes of the REACH Regulation, as testing for the endpoints at issue would be performed on the most representative antimony compound(s), which would constitute source substance(s) in terms of read-across and grouping with target substances. In the Appellant's view, this stepwise testing strategy is the most appropriate method to clarify the potential risk related to ATS and other antimony substances.

114. The Appellant's argument that the Agency made errors in the assessment of its stepwise testing strategy must be rejected for the following reasons.

115. First, the Appellant's stepwise testing strategy has not been completed. The Agency is not required to postpone its decision-making to wait for a registrant to generate information to support potential adaptations (see Case A-005-2016, *Cheminova*, decision of the Board of Appeal of 30 January 2018, paragraph 49). This is especially the case where the date on which that information will become available is unknown or imprecise.

116. Second, before the Appellant finalises its stepwise testing strategy it is not possible to know whether that strategy will be successful in developing an acceptable read-across adaptation. There is no obligation for the Agency to wait for the Appellant to complete its stepwise testing strategy and develop a new read-across adaptation which, ultimately, may not be acceptable.

117. The Appellant's argument that the Agency acted inconsistently because the Contested Decision acknowledges a possible read-across among antimony compounds but the compliance check decision on ATS rejected the read-across approach proposed by the Appellant must also be rejected for the following reasons.

118. First, the information needed to establish structural similarity for the purposes of identifying a potential concern under the substance evaluation process is different from that needed to justify a read-across adaptation for registration purposes under Section 1.5. of Annex XI (see Case A-009-2014, *Albemarle Europe and Others*, decision of the Board of Appeal of 12 July 2016, paragraphs 39 and 78). The Agency did not therefore act inconsistently in this respect.

119. Second, the compliance check and substance evaluation decisions for ATS concerned different information requirements and, in this respect, read-across is endpoint-specific. The fact that a read-across adaptation is accepted for one endpoint does not lead to the conclusion that read-across is plausible for other endpoints (see Case A-006-2012, *Momentive Specialty Chemicals*, decision of the Board of Appeal of 13 February 2014, paragraph 83).

2.1.3. Clarity of the concern identified by the Agency

120. The Appellant argues that there is a lack of clarity in the Contested Decision as to whether the concerns identified by the Agency relate specifically to ATS or to ATO.

121. The clear identification of the substance or substances subject to a request for information under the substance evaluation process constitutes an essential precondition for the application of the three conditions set out in paragraph 108 above. It is in relation to each substance specifically that it is necessary to examine whether a potential risk for human health or the environment exists (see judgment of 15 September 2021, *France* v *ECHA*, T-127/20, EU:T:2021:572, paragraphs 45 and 46). Without clarity on the substance or substances for which there is a potential risk, the whole substance evaluation process in question lacks a clear basis. Without such a clear basis it would not be possible, for example, to assess accurately whether the information requested to clarify the identified potential risk has a realistic possibility of leading to improved risk management measures.

122. According to the Contested Decision, the requested study is necessary because '*there is a concern that ATS may cause respiratory tract and systemic toxicity and cancer after prolonged inhalation exposure*'.

123. That concern is based on information on ATS and on other structurally similar substances, in particular ATO. The Appellant itself acknowledges that ATS has similar characteristics to ATO and Sb metal and argues that those substances should be treated as a group. However, from the wording of the Contested Decision, it is clear that the concern for respiratory tract and systemic toxicity, as well as carcinogenicity is related specifically to ATS.

124. In the Contested Decision, the Agency also identifies a cardiotoxicity concern related to ATS. According to the Contested Decision, there are indications that exposure to antimony compounds may cause cardiovascular toxicity. The Agency demonstrates

the cardiotoxicity concern using data mostly on ATS and sodium antimony gluconate. The Contested Decision also states that '*[t]he available knowledge leads to concerns that ATS may be systemically available and toxic after inhalation*'. It is therefore clear that the concern for cardiotoxicity is related specifically to ATS.

125. It is also clear that the potential regulatory outcome envisaged by the Agency is to regulate, if necessary, ATS itself. This is clear, for example, from the section of the Contested Decision entitled '*What is the possible regulatory outcome?*' which specifies clearly how the requested information may be used specifically in relation to ATS. Contrary to the Appellant's argument, there is therefore no lack of clarity as to how the requested information will be used.

126. The Appellant's argument that the Contested Decision does not clearly set out the substance of concern must therefore be rejected.

2.1.4. Potential risk

127. As stated in paragraph 108 above, potential risk is a combination of hazard and exposure. These two elements will be examined separately below.

2.1.4.1. Potential hazard

128. The Appellant does not dispute the Agency's conclusion that the available information demonstrates that, for ATS, there is a potential hazard related to respiratory tract and systemic toxicity, as well as carcinogenicity. It is therefore not necessary to examine whether the Agency has demonstrated that there is a potential hazard in relation to those concerns.

129. The Appellant, however, contests the Agency's conclusion that, based on occupational health studies and animal studies, there is a concern that ATS may cause cardiovascular effects. According to the Appellant, the Agency failed to demonstrate a potential hazard related to cardiotoxicity because some of the evidence relied on by the Agency is historical and unreliable, and some of that evidence is not relevant to ATS because it relates to medical uses of antimony compounds.

130. As noted in paragraph 110 above, it is the Agency's responsibility to demonstrate, in its decision, that there is a potential risk. This includes the demonstration of a potential hazard. In this respect, the Agency must take into account all the available evidence before deciding, based on that evidence as a whole, that there is a potential risk which requires further investigation (*Evonik Degussa and Others*, cited in paragraph 44 above, paragraph 123 of the decision).

131. Where an appellant challenges the Agency's conclusion that there is a potential risk, including a potential hazard, the appellant must show that that conclusion is erroneous. It is therefore necessary to examine whether the arguments put forward by the Appellant are capable of demonstrating that the Agency made an error in concluding that, based on the available evidence, there is potential hazard related to cardiotoxicity (see *BASF Grenzach* v *ECHA*, cited in paragraph 108 above, paragraph 89 of the judgment).

132. For the following reasons, the Appellant's arguments that the Agency has not demonstrated a potential hazard related to cardiotoxicity must be rejected.

133. First, some of the studies relied on by the Agency in the Contested Decision to demonstrate a concern for cardiotoxicity, for example Brieger *et al.* (1954) and the inhalation tests with ATS in animals (rat, rabbit and dogs) by the same authors, relate specifically to exposure to ATS.

134. Second, the Appellant did not bring forward any studies to contradict the Agency's conclusion that there is a potential hazard related to cardiotoxicity. The Appellant, with the support of expert opinions, rather argues that the Agency made an error in

concluding that the evidence set out in the Contested Decision demonstrates a potential hazard related to cardiotoxicity.

135. In this respect, the Appellant attached an expert opinion to the Notice of Appeal which reviews scientific literature related to cardiotoxicity of antimony compounds and some of the data relied on by the Agency to justify the potential hazard related to cardiotoxicity. Although the expert opinion presents a divergent scientific opinion to that of the Agency and the eMSCA, it does not demonstrate any error of assessment in the Contested Decision. The existence of a diverging scientific opinion is not, in itself, sufficient to demonstrate the existence of an error vitiating the Contested Decision (see, to this effect, *BASF Grenzach* v *ECHA*, cited in paragraph 108 above, paragraph 458 of the judgment).

136. The data available to the Agency in a substance evaluation process may lead to differences of opinion between experts when assessing that data. One of the main purposes of substance evaluation is to clarify potential risks and thereby help resolve the differences of opinions between experts or clarify a potential risk over which there is a consensus (*Evonik Degussa and Others*, cited in paragraph 44 above, paragraph 174 of the decision).

137. Third, it is true that some of the studies relied on by the Agency in the Contested Decision date from the 1950s (Brieger *et al.* (1954) and O'Brien (1959)) and 1960s (Honey (1960)) which may have applied different study designs to those applied in more contemporary studies. Nonetheless, such studies should not be disregarded for those reasons alone and can be sufficient to demonstrate a potential hazard under substance evaluation (*BASF and Kemira*, cited in paragraph 110 above, paragraph 108 of the decision). This is particularly the case where, as in the present case, no studies are submitted to contradict the findings relied on by the Agency. In addition, the Appellant has not offered detailed argumentation or studies to substantiate its claims that the studies and evidence relied on by the Agency are not sufficient to justify the existence of a concern. For example, the expert opinion states that the observational study design does not meet current scientific criteria but does not explain in detail what the deficiencies are and how this would affect the reliability of that study.

138. It must also be noted that the Agency's conclusions were not based solely on historical data. The Agency also relies on more recent data in the Contested Decision, in particular publications based on the US National Health and Nutrition Examination Survey (NHANES) 1999-2010, to conclude that there is a potential hazard related to cardiotoxicity.

139. Fourth, the Appellant is incorrect in arguing that results from studies via intravenous administration are not relevant for establishing a potential hazard under substance evaluation. However, in considering the available studies in a substance evaluation the Agency must take into consideration the route of exposure used in those studies. Whilst this may have an impact on the reliability and relevance of the findings in those studies, they still contribute to the overall evidence establishing a potential hazard related to cardiotoxicity. The Agency's conclusion on the potential hazard is based on the available evidence which shows that after exposure to antimony containing substances an unidentified antimony species, for example $Sb3^{+}$, $Sb5^{+}$, or methylated Sb, becomes systemically available and causes effects independently of the route of exposure.

140. Fifth, contrary to the Appellant's claims, the data relied on in the Contested Decision is not limited to studies involving high doses of antimony metals or the intravenous route only. The exposure level reported in the occupational study by Brieger *et al.* (1954), which reported high incidences of high blood pressure and ECG changes, was 0.58 to 5.5 mg/m³. The Contested Decision also refers to limited inhalation tests with ATS in animals (rat, rabbit and dogs) by the same authors which reported some cardiovascular effects, for example ECG changes and histopathological findings, at a dose of 5.6 mg/m³.

141. Sixth, the Appellant argues that in the studies relied on by the Agency the doses do not reflect current occupational or environmental exposure levels. However, this argument concerns whether the potential exposure to ATS is adequately controlled rather than whether there is a potential hazard which relates to the investigation of the intrinsic properties of the substance at issue.

142. Seventh, with regards to the Appellant's argument that the effects observed in clinical trials were reversible, it must be noted that the aim of substance evaluation is to clarify uncertainty. Currently, there is insufficient information to conclude not only on the cardiotoxicity of ATS, but also on the reversibility of the effects observed in the available data. Furthermore, whether certain effects observed in the studies relied on by the Agency are reversible is not decisive in deciding whether there is a potential hazard related to cardiotoxicity that requires clarification. Even if those effects were reversible, this would not resolve the questions regarding the potential cardiotoxicity of ATS. In addition, even if the ECG changes observed in the clinical literature were reversible, such effects may still require clarification as part of the assessment of the cardiotoxicity potential of ATS.

2.1.4.2. Potential exposure

143. The Appellant argues, in essence, that exposure to ATS is adequately controlled and that, as a result, the requested study is not necessary. The Appellant also argues that the Agency failed to take into account information on exposure to ATS that was included in its registration dossier.

144. The examination of exposure for the purposes of demonstrating a potential risk (the first condition referred to in paragraph 108 above) is not the same as the examination of exposure for the purposes of demonstrating a realistic possibility of improved risk management measures (the third condition referred to in paragraph 108 above). Demonstrating a realistic possibility of improved risk management measures involves an examination of whether the population(s) concerned by the exposure may benefit from further protection through improved risk management measures as a result of the information requested under the substance evaluation process. Examination of potential exposure involves an examination of whether there is potential exposure to a substance irrespective of the controls in place. The Appellant's arguments that the exposure is controlled are therefore not relevant to whether there is potential exposure, and therefore a potential risk, related to ATS. The Appellant's arguments on whether the exposure is controlled will be examined, where necessary, under the part of the Appellant's plea related to improved risk management measures (see Section 2.1.5. below).

145. Furthermore, for the following reasons, it must be concluded that the Appellant has not established that the Agency made an error in concluding that there is potential exposure to ATS.

146. In its submissions during the appeal proceedings, the Appellant explicitly acknowledges that there is potential consumer, worker and professional exposure to ATS which is registered at the 100 to 1 000 tonnes per year tonnage band.

147. With regards to worker exposure, the Appellant argues, for example, that the Contested Decision did not take into account the newer personal protective equipment and better ventilation and cleaning systems that are now available. The Appellant also submitted as evidence a '*Summary Report on Occupational Exposure to Antimony Metal, [ATS], and Diantimony Tris(Ethylene Glycolate)*', dated 12 January 2021 (Annex R11 to the Appellant's observations on the Defence), to support its claim that exposure to ATS is controlled. These arguments and evidence, although not all available to the Agency prior to the adoption of the Contested Decision, demonstrate that the Agency's conclusion that there is potential worker exposure to ATS is correct. This conclusion is irrespective of whether that potential exposure is adequately controlled.

148. With regards to professional exposure, the Appellant argues that exposure to ATS from the removal and replacement of brake pads containing ATS is very low. However, this is nonetheless an indication of potential professional exposure.

149. With regards to both consumer and professional exposure, the Appellant argues that the following statement in the Contested Decision is under review by the registrants of ATS: '*ATS is used in ammunition and therefore exposure of consumers and professionals via dermal, oral (hand-mouth contact), and inhalation route can be expected in shooting ranges*'. Currently, however there is no available data to demonstrate that the Agency made an error in finding that there is potential exposure to professionals and consumers in shooting ranges. Indeed, in its observations on the Defence, the Appellant states '*[w]hile potential exposure of consumers and workers to ATS cannot be excluded, the mere existence of exposure does not imply that exposure is excessive or above any safe levels, and therefore, of concern*'. During the appeal proceedings, the Appellant also submitted a document entitled '*Exposure to antimony from the use of antimony in ammunition*' (Annex R12 to the Appellant's observations on the Defence) to support its argument that exposure to ATS in shooting ranges is limited. However, that document nonetheless indicates potential professional exposure to ATS.

2.1.5. The Appellant's claim that the Contested Decision does not meet real information needs and will not lead to improved risk management measures

150. According to the Contested Decision, information from the requested study can be used for deciding on the classification of ATS for STOT RE 1 or 2 under Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1; the 'CLP Regulation').

151. The Appellant's argument that the requested study will not lead to improved risk management measures and that, as a result, the Agency has not demonstrated that the requested information is necessary to meet real information needs must be rejected for the following reasons.

152. First, a STOT RE classification triggers a certain number of obligations that constitute risk management measures.

153. For example, such obligations relate to the labelling and packaging of the substance concerned. 'Warning' for STOT RE 2 classification and 'danger' for STOT RE 1 classification are examples of labelling requirements. Such labelling serves to improve information for users of the substance concerned as to the risks incurred and therefore must be regarded as a means of enhancing the protection of human health.

154. In addition, a STOT RE classification might lead to the establishment of concentration limits under Article 10(1) of the CLP Regulation.

155. Furthermore, a STOT RE classification must be included in the safety data sheet which the supplier of the substance concerned must provide to the recipients of the substance under Article 31(1)(a) of the REACH Regulation. This obligation to inform the recipients of a substance also constitutes a risk management measure.

156. Second, a change from a self-classification as STOT RE 2 for the lung to a harmonised classification as STOT RE 2 for the lung is in itself an improved risk management measure. A harmonised classification must be uniformly and consistently applied by all registrants of a substance and in the supply chain. However, self-classification can be changed at any time and does not bind either the other registrants of the same substance or other actors in the supply chain. Only harmonised classification has such consequences for all registrants of a substance. In this respect, it must be noted that not all notifiers of ATS currently follow the STOT RE self-classification.

157. Third, a harmonised classification as STOT RE 1 would be possible if, for example, effects are observed in the requested study which are at or below the guidance values defined in the CLP Regulation. A harmonised classification as STOT RE 1 would lead to more stringent measures being applied to ATS than under STOT RE 2. For example, a STOT RE 1 classification will lead to a change of the signal word from 'Warning' to 'Danger' and therefore improve communication of the hazard (see also paragraph 153 above).

158. Fourth, the current self-classification as STOT RE 2 is for the lungs only and the requested study will address effects on other organs. If an effect level for an organ other than the lung, and lower than for the lung, at or below the guidance values defined by the CLP Regulation, is observed in the requested study, it could lead to a more stringent classification, such as STOT RE 1 for that specific organ, and consequently also lead to more stringent risk management measures than those currently in place based on the self-classification as STOT RE 2 for the lung. For example, the information obtained from the cardiotoxicity parameter could lead to a STOT RE 1 or 2 classification for cardiotoxicity, depending on the effect level observed in the requested study.

159. Fifth, it is also clear that the requested information has a realistic possibility of leading to a harmonised classification as, at least, STOT RE 2 and has the potential to strengthen the already available evidence on lung toxicity. This is shown by the fact that the Appellant has already self-classified ATS and argued during the appeal proceedings that there is sufficient data available for a harmonised classification.

160. Sixth, the Appellant's argument that the existing DNEL is sufficient to control the exposure risks must also be rejected. During the DNEL derivation, all valid studies must be taken into account and the results of the study requested in the Contested Decision would contribute possibly to a new DNEL value. This is, in particular, because the current DNEL is based on read-across data from ATO, and not data on ATS itself. Consequently, based on the results of the requested study, a new, more accurate, DNEL could be derived that will in turn lead to improved risk management measures.

161. In view of paragraphs 150 to 160 above, the requested study has a realistic possibility of leading to a harmonised classification as STOT RE 1 or 2 and a revised DNEL for ATS which both constitute improved risk management measures. As a result, it is not necessary to examine the other risk management measures in place for the ATS.

2.1.6. Conclusion on the Appellant's first and fourth pleas

162. In view of paragraphs 108 to 161 above, the Appellant's first and fourth pleas must be rejected as unfounded.

2.2. Fifth plea: The Contested Decision is inappropriate to achieve the objective pursued by the Agency

163. The remainder of the Appellant's arguments under its fifth plea that were not examined in Section 2.1. above will be examined in this Section.

Arguments of the Parties and the Interveners

164. The Appellant, supported by PISC, argues that the Contested Decision is inappropriate to achieve its objective insofar as it requires the requested study to be generated using the rat, which may not be the most sensitive species for that study. The Appellant argues that the rat is not the most appropriate species for inhalation studies as it does not have lung clearance mechanisms comparable to those in humans. The Appellant argues that particles of ATS are poorly soluble and of low toxicity ('PSLT') and would therefore, at certain loading, eventually impair lung clearance by alveolar macrophages.

165. The Appellant argues that the requested study is inappropriate to clarify the concerns identified by the Agency because the mode of action responsible for toxicity is unclear. The Appellant argues that the Agency should have identified the mode of action for lung toxicity before requiring the Appellant to submit the requested study.

166. The Appellant argues that its stepwise testing strategy will allow the mode of action for lung toxicity/carcinogenicity to be clarified and then allow the identification of the most appropriate antimony substance to test. The Agency should therefore have awaited the outcome of that testing strategy.

167. The Appellant argues that the requested toxicokinetic assessment is inappropriate because it would require extensive method development and validation, would deliver data of limited use, and would not contribute to the determination of the mechanism of action.

168. The Appellant argues that the requested cardiotoxicity assessment is not routine for industrial chemicals and will require sophisticated and expensive procedures that are invasive for animals. The Appellant argues that the rat is not the most appropriate species to investigate the cardiotoxicity concerns. The Appellant also argues that the investigation of cardiovascular effects will provide no benefit for the protection of the exposed populations.

169. The Agency, supported by the German competent authority, disputes the Appellant's and PISC's arguments.

Findings of the Board of Appeal

2.2.1. Species to be used in the requested study

170. The Appellant's arguments that the Contested Decision is inappropriate to achieve its objective insofar as it requires the requested study to be generated using the rat must be rejected for the following reasons.

171. First, according to OECD TG 413, '*healthy young adult rodents of commonly used laboratory strains should be employed. The preferred species is the rat. Justification should be provided if other species are used*'. Consequently, unless the use of another species is justified, the rat is the preferred species for the 90-day (sub-chronic) inhalation toxicity study requested in the Contested Decision.

172. Second, although the Appellant presented arguments to support its claim that the rat is not the most appropriate species on which to perform the cardiovascular effects evaluations in the requested study, it did not propose another species that could be used to carry out the OECD TG 413, with the inclusion of the additional parameters. The Appellant did not therefore provide a justification for the use of another species than the preferred species identified in OECD TG 413.

173. Third, the lung overload phenomenon to which the Appellant refers in its submissions can be calculated and prevented. In addition, even if the lung clearance by alveolar macrophages would be impaired at the highest dose, the results of the requested study would still be relevant.

174. Fourth, the Appellant did not substantiate its claim that ATS is a PSLT substance. Nonetheless, according to an article attached by the Appellant to the Notice of Appeal, '*the rat is a sensitive model for PSLT inhalation toxicology'* (*'Expert workshop on the hazards and risks of poorly soluble low toxicity particles*', Driscoll and Borm, Inhalation Toxicology (2020), 32(2) pp. 53 to 62).

2.2.2. Mode of action and identification of the substance to be tested

175. The Appellant's arguments related to the clarity of the mode of action and the identification of the most appropriate antimony substance to test must be rejected for the following reasons.

176. First, the stepwise testing strategy, which the Appellant claims will clarify the mode of action for lung toxicity/carcinogenicity and allow the most appropriate antimony substance to test to be identified, has not been finalised. Therefore, it is not possible to predict the outcome of that testing strategy (see Section 2.1.2. above).

177. Second, the Agency has identified a potential risk in relation to ATS itself which requires clarification (see Section 2.1. above). As a result, the Agency does not have to wait for the Appellant to finalise its stepwise testing strategy before requesting information to clarify the potential risk related to that substance (see paragraph 115 above).

178. Third, the Appellant's testing strategy focuses on lung toxicity but not systemic toxicity. Consequently, it is unclear whether that strategy is capable of clarifying the concerns related to other systemic toxicity effects, such as cardiotoxicity.

2.2.3. Cardiotoxicity parameters

179. The Appellant's arguments that the cardiotoxicity parameters to be included in the requested study are inappropriate to achieve the objective pursued by the Agency must be rejected for the following reasons.

180. First, OECD TG 413 suggests additional optional investigations, such as toxicokinetics, and/or systemic toxicity evaluations (for example the evaluation of immune, hepatic, neurologic and/or cardiovascular effects), to characterise better the overall toxicity of a test chemical.

181. Second, the Appellant did not demonstrate that the requested study cannot be performed with ATS. The Appellant merely argues that the requested cardiotoxicity assessment is not routine for industrial chemicals and will require sophisticated and expensive procedures that are invasive for animals.

182. Third, the Appellant did not provide an alternative to examine the potential risks identified other than arguing that the Agency should await the outcome of its stepwise testing strategy that will, in the Appellant's opinion, identify which substance is the most appropriate on which to perform the study requested in the Contested Decision.

183. Fourth, with regards to the Appellant's argument that the rat is not the most appropriate species for the requested cardiotoxicity parameters, it must be recalled that, according to OECD TG 413, '*healthy young adult rodents of commonly used laboratory strains should be employed. The preferred species is the rat. Justification should be provided if other species are used*' (see Section 2.2.1. above).

184. Furthermore, as stated in paragraph 172 above, the Appellant did not propose a suitable alternative species which could be used in the requested study. The Appellant did not therefore justify the use of another species. In this respect, contrary to the Appellant's arguments, cardiovascular effects have been investigated for a number of years in rats, sufficient experience of such investigations exists, and non-invasive systems/methodologies are available.

2.2.4. Toxicokinetic parameters

185. The Appellant argues that the requested toxicokinetic assessment is inappropriate to achieve the objective pursued by the Agency because it would require extensive method development and validation, would deliver data of limited use, and would not contribute to the determination of the mechanism of action. Those arguments must be rejected for the following reasons.

186. Contrary to the Appellant's claims, OECD TG 417 is suitable for the inhalation route, as well as for the identification of the target tissues and aiding the understanding of the underlying mechanism of toxicity. Furthermore, the requested parameters in the toxicokinetic study do not aim only to understand the mechanism of action; they aim to identify the antimony species responsible for the toxicity ('toxophore') and will

allow it to be determined whether a read-across from the carcinogenicity studies with ATO, which is classified as carcinogenicity category 2 H351 (suspected of causing cancer), can be applied.

187. It must also be noted that the Agency provides some guidance in the Contested Decision as to how the toxophore can be identified by referring to literature on analytical methods used for speciation of antimony. In addition, the Contested Decision does not request the identification of unknown chemical compounds but rather the identification of well-defined antimony species such as trivalent (Sb(III)) and pentavalent (Sb(V)), as well as alkylated (for example methylated), antimony species.

2.2.5. Conclusion on the Appellant's fifth plea

188. In view of paragraphs 170 to 187 above, the Appellant's fifth plea must be rejected as unfounded.

2.3. Second plea: The Agency infringed an essential procedural requirement of the REACH Regulation as it did not perform a compliance check on ATS prior to the substance evaluation

Arguments of the Parties and the Interveners

189. The Appellant, supported by PISC, argues that based on the Board of Appeal's previous decisions, for example in Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others*, as well as the Agency's guidance ('*Registrants' guide – How to act in Substance Evaluation*', April 2020), the Agency should carry out a compliance check of the registrant's dossier prior to a substance evaluation. Therefore, by failing to conduct a compliance check prior to the substance evaluation in the present case, the Agency breached an essential procedural requirement. The Appellant argues that the Agency did not justify a departure from this normal course of action, for example by demonstrating that there is an immediate, relevant and real concern for human health and the environment.

190. The Appellant argues that carrying out a compliance check prior to the substance evaluation in the present case would have allowed the Appellant to reinforce its grouping approach and read-across proposals before any additional information was requested by the Agency. The Appellant argues that, before requesting additional information under substance evaluation, the Agency should have checked the data to be submitted under the compliance check procedure and assessed more thoroughly whether the stepwise testing strategy proposed by the Appellant would have been sufficient to fill any data-gaps in its registration dossier.

191. The Agency, supported by the German competent authority, disputes the Appellant's arguments.

Findings of the Board of Appeal

192. The Agency should not, in principle, use the substance evaluation process to request the standard information listed in Annexes VII to X. Information that could be requested under the compliance check procedure should not, in principle, be requested under substance evaluation. There are circumstances where the Agency may deviate from this normal course of action (see, for example, Case A-023-2015, *S.A. Akzo Nobel Chemicals and Others*, decision of the Board of Appeal of 13 December 2017, paragraph 123 and Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others*, decision of the Board of Appeal of 23 September 2014, paragraph 90).

193. However, contrary to the Appellant's claims, it cannot be read from the REACH Regulation, or the previous decisions of the Board of Appeal, that the Agency must always perform a full compliance check under Article 41, concerning all information contained in a registration dossier for a substance, before performing a substance evaluation on that substance.

194. Furthermore, the Parties agree that the study requested in the Contested Decision, with the inclusion of the additional parameters, is not standard information required under Annexes VII to X. Consequently, the Agency could not have requested that information under the compliance check process. Therefore, contrary to the Appellant's arguments, the Agency was not required to provide a justification as to why it requested the information under the substance evaluation process instead of the compliance check process.

195. Nonetheless, it should be noted that, on 12 March 2020, the Agency sent to the Appellant a letter in which it explained why the Agency had conducted a compliance check process on ATS at the same time as the substance evaluation process that led to the Contested Decision. The Agency stated in that letter, amongst other things, that a compliance check decision is justified by the demonstration of a data-gap whereas a substance evaluation decision is justified by the identification of a potential risk to human health or the environment based on the information available at the time of the evaluation.

196. It should also be noted that the compliance check decision concerning ATS (see paragraph 14 above) requests certain *in vitro* mutagenicity studies and *in vivo* developmental/reproductive toxicity studies. However, the tests requested in the compliance check decision are not capable of clarifying the concerns identified in the Contested Decision.

197. As regards the Appellant's argument that the Agency should have allowed the Appellant to develop its grouping approach and read-across proposals before requesting additional information under substance evaluation, it must be rejected for the following reasons.

198. First, since the Agency has sufficient information to demonstrate that ATS presents potential risks for human health (see Section 2.1. above), it should proceed to request information to clarify those potential risks.

199. Second, the Agency is not required to postpone its decision-making to wait for a registrant to generate information to support or improve potential adaptations (*Cheminova*, cited in paragraph 115 above, paragraph 49 of the decision). This is especially the case where the date on which that information will be available is unknown or imprecise. Waiting to request information where a potential risk has been identified would not serve the main objective of the registration and evaluation provisions in the REACH Regulation, namely the protection of human health and the environment.

200. In view of paragraphs 192 to 199 above, the Appellant's second plea must be rejected as unfounded.

2.4. Third plea: The Agency breached the principle of the protection of legitimate expectations

Arguments of the Parties and the Interveners

201. The Appellant, supported by PISC, states that it had a legitimate expectation that its read-across proposals would be taken into account during the substance evaluation process. The Appellant also states that the Agency breached the Appellant's legitimate expectations insofar as the Contested Decision dismissed the grouping of antimony compounds and the read-across approach relied on by the Appellant for each human health endpoint.

202. The Appellant argues that its legitimate expectations were based on the inclusion of three antimony substances – Sb metal, ATO, and ATS – in the CoRAP at the same time and the subsequent addition of two other antimony substances – ATC and ATEG – to the CoRAP. The Appellant argues that the almost simultaneous inclusion of those substances in the CoRAP led to the expectation that the Agency would treat them as a group.

203. The Appellant argues that the fact that the antimony compounds were considered as a group by the Agency was further demonstrated by the Agency's 2020 annual report on the Integrated Regulatory Strategy ('*Grouping speeds up regulatory action*', Integrated Regulatory Strategy, Annual Report, May 2020; the '2020 Report').

204. The Appellant argues that its expectations were strengthened by the collaborative approach ('COLLA') and Metal and Inorganic Sectoral Approach ('MISA') projects in which it participated and under which the Agency promoted the grouping of substances. The Appellant argues that these projects confirmed its understanding that Sb metal, ATO, ATS, ATC and ATEG would be assessed by the Agency as a group and not as individual substances.

205. The Appellant argues that the Agency relied on data from other antimony compounds, such as ATO, to justify its conclusions on ATS. However, the Agency then refused to do the same to show the absence of a risk related to ATS.

206. The Agency, supported by the German competent authority, disputes the Appellant's and PISC's arguments.

Findings of the Board of Appeal

207. The right to rely on the principle of the protection of legitimate expectations presupposes that precise, unconditional and consistent assurances originating from authorised, reliable sources have been given to the person concerned by the competent authorities of the European Union. That right applies to any individual in a situation in which a European Union institution, body or agency, by giving that person precise assurances, has led that individual to entertain well-founded expectations. Precise, unconditional and consistent information, in whatever form it is given, constitutes such an assurance (see judgment of 13 June 2013, *HGA and Others* v *Commission*, C-630/11 P to C-633/11 P, EU:C:2013:387, paragraph 132; see also *Cheminova* cited in paragraph 115 above, paragraph 179 of the decision).

208. The Agency considered the Appellant's grouping and read-across approach, including the Appellant's stepwise testing strategy, before adopting the Contested Decision. This is clear, for example, from the sections of the Contested Decision entitled '*Explanation of the testing strategy*' and '*Consideration of your comments on the draft decision*' where, amongst other things, the Appellant's stepwise testing strategy is considered by the Agency. However, the Agency did not accept the Appellant's grouping and read-across approach. This is because the Appellant's approach was under development as part of its stepwise testing strategy and there was no certainty that the grouping and read-across approach would clarify the concerns identified in the Contested Decision.

209. Furthermore, for the following reasons, the Appellant has not demonstrated that the Agency or the eMSCA gave it precise, unconditional and consistent assurances, within the meaning of the case-law referred to in paragraph 207 above, that its grouping and read-across would be accepted.

210. First, the fact that the Agency undertook to examine the possibility of grouping in the COLLA and MISA projects does not mean that the Appellant could have legitimate expectations that that grouping of the antimony substances would ultimately be accepted to the extent expected by the Appellant.

211. Second, the fact that ATS was included in the CoRAP at the same time as other antimony metals does not constitute a precise, unconditional, and consistent assurance that the Appellant's grouping and read-across approach would be accepted. The fact that the different antimony compounds were included in the CoRAP separately could also indicate that those substances were intended to be examined individually under separate substance evaluation processes.

212. Third, the Appellant failed to substantiate how the 2020 Report provided precise, unconditional, and consistent assurances that specifically the grouping of ATS with other antimony compounds would ultimately be accepted by the Agency. For the antimony substances to be considered as a group, the Appellant would need to provide an acceptable read-across in accordance with Section 1.5. of Annex XI related to the endpoint in question. However, the Appellant has not yet submitted an acceptable read-across adaptation. The Appellant hopes to develop such a read-across adaptation through its stepwise testing strategy. However, as stated in paragraph 115 above, the Agency is not required to wait for the Appellant to finalise its testing strategy before requesting information under substance evaluation.

213. Fourth, as stated in paragraph 118 above, the information needed to establish structural similarity for the purposes of identifying a potential concern under the substance evaluation process is different from that needed to justify a read-across adaptation for registration purposes under Section 1.5. of Annex XI.

214. In view of paragraphs 207 to 213 above, the Appellant's plea that the Agency breached the principle of the protection of legitimate expectations must be rejected as unfounded.

2.5. Sixth Plea: The Agency failed to state reasons for the Contested Decision

Arguments of the Parties and the Interveners

215. The Appellant, supported by PISC, argues that the Agency failed to state reasons as to why the dossier evaluation was performed in parallel to, rather than before, the substance evaluation and why the Appellant's read-across proposal and its stepwise testing strategy was not acceptable.

216. The Appellant argues that the Agency failed to state reasons regarding the existence of an alleged concern and potential risk, how the requested study will address the various objectives of the Contested Decision, and how carrying out the same study on two substances is beneficial and will better clarify the potential risks identified by the Agency.

217. The Appellant argues that the Agency failed to state reasons as to how the current self-classification of ATS as STOT RE 2 and the other risk management measures in place are not sufficient to control exposure to ATS.

218. The Appellant argues that the Agency failed to demonstrate how the Appellant's comments in the decision-making process and its dossier update were taken into account.

219. The Agency, supported by the German competent authority, disputes the Appellant's and PISC's arguments.

Findings of the Board of Appeal

220. Under Article 130, the Agency must state reasons for all decisions it takes under the REACH Regulation. The duty to state reasons is an essential procedural requirement which is enshrined in the second paragraph of Article 296 of the Treaty on the Functioning of the European Union ('TFEU') and is included in Article 41(2)(c) of the Charter of Fundamental Rights of the European Union as part of the right to good administration (see Case A-001-2020, *SNF*, decision of the Board of Appeal of 29 June 2021, paragraph 134).

221. A statement of reasons must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution, body or agency which adopted the measure in question, in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the Board of Appeal and the European Union judicature to exercise their powers of review (see by analogy judgment of 21 December 2016, *Club Hotel Loutraki and Others* v *Commission*, C-131/15 P, EU:C:2016:989, paragraph 46). Whether a statement of reasons is adequate or not depends on all the circumstances of a case, in particular, the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations (see judgment of 10 March 2016, *HeidelbergCement* v *Commission*, C-247/14 P, EU:C:2016:149, paragraph 16).

222. The Appellant's arguments under this plea are related to its other pleas examined above. Rather than arguing that the Agency failed to state reasons, the Appellant in fact repeats its disagreement with the conclusions reached by the Agency in the Contested Decision. In this respect, the duty to state reasons is an essential procedural requirement which must be distinguished from the question whether the reasoning is well founded, which is concerned with the substantive legality of the measure at issue (judgment of 14 October 2010, *Deutsche Telekom* v *Commission*, C-280/08 P, EU:C:2010:603, paragraph 130; see also *Momentive Specialty Chemicals*, cited in paragraph 119 above, paragraph 113 of the decision).

223. The Appellant argues that the Agency failed to provide a convincing justification for the existence of a potential risk and how the requested study will address the various objectives of the Contested Decision. However, as examined in Section 2.1. above, the Contested Decision clearly provides detailed reasoning on these issues. In particular, in Appendix 1 to the Contested Decision, the Agency clearly sets out its reasons why the requested study is necessary. This includes a clear description of the concerns identified by the Agency, why additional information is necessary and the possible regulatory outcomes of the substance evaluation process.

224. Similarly, the Appellant argues that the Agency failed to explain why the self-classification and other risk management measures in place for ATS are not sufficient to control exposure. However, in the Contested Decision, the Agency clearly sets out why it considers that the self-classification does not eliminate the need to conduct further testing to clarify the concern. In the section of the Contested Decision entitled '*What is the possible regulatory outcome?*', the Agency also clearly identifies how the requested study can lead to risk management measures that are an improvement on those already in place for ATS.

225. The Appellant is also incorrect in arguing that the Agency failed to state reasons as to why it considered that the Appellant's read-across proposal and its stepwise testing strategy are inadequate to address the concerns identified by the Agency. In the section of the Contested Decision entitled '*Consideration of your comments on the draft decision*', the Agency sets out why it considers that the Appellant's testing strategy does not address the concerns related to ATS and why the overall usefulness of the Appellant's strategy is unclear and the outcome uncertain. It is also clear from the Contested Decision that the Agency took into account the Appellant's arguments submitted during the substance evaluation process.

226. With regards to the argument that the Agency failed to state reasons for carrying out the substance evaluation in parallel to a compliance check, it must be recalled that the Agency sent a letter to the registrants of ATS on 12 March 2020 explaining the reasons for following this approach. Consequently, the Appellant was aware of the Agency's reasons for conducting the compliance check process and substance evaluation process in parallel. The letter of 12 March 2020 therefore compensated for the absence of certain reasoning in the Contested Decision (see Case A-023-2015, *S.A. Akzo Nobel Chemicals and Others*, decision of the Board of Appeal of 13 December 2017, paragraph 264; see also *Cheminova,* cited in paragraph 115 above*,* paragraph 140 of the decision).

227. In view of paragraphs 220 to 226 above, the Appellant's sixth plea must be rejected as unfounded.

2.6. Seventh plea: The Agency breached the principles of proportionality and animal welfare

Arguments of the Parties and the Interveners

228. The Appellant, supported by PISC, argues that the Agency breached the principles of proportionality and animal welfare. This is because the Agency requests information that is inappropriate to achieve the objective pursued, will not yield more precise results than the alternatives proposed by the Appellant, and is unlikely to lead to improved risk management measures.

229. The Appellant argues that the performance of the requested study is premature and results in the unnecessary use of vertebrate animals. According to the Appellant, the stepwise testing strategy proposed by the Appellant to first clarify the mode of action would have been the least onerous option to clarify the concerns identified by the Agency.

230. The Appellant argues that, by requesting the 90-day (sub-chronic) inhalation toxicity study for both ATS and Sb metal, the Agency breached the principle of proportionality, placed an unnecessary burden on the registrants of both substances and defied the purpose of grouping and of Article 25(1) of the REACH Regulation and Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33). The Appellant argues that under Article 13 of the TFEU, Article 25 of the REACH Regulation, and Directive 2010/63/EU, as few animals as possible should be used in testing.

231. The Appellant argues that the Agency failed to consider alternatives to animal testing and therefore breached the obligation under Article 25 to ensure that vertebrate animals are used in testing only as a last resort.

232. The Agency, supported by the German competent authority, disputes the Appellant's and PISC's arguments.

Findings of the Board of Appeal

233. In order to respect the principle of proportionality, measures adopted by the European Union institutions and agencies must 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; see also Case A-004-2017, *3v Sigma*, decision of the Board of Appeal of 15 January 2019, paragraph 34).

234. Article 13 of the TFEU provides, amongst other things, that in formulating and implementing the European Union's internal market policies, the Union and the Member States must, since animals are sentient beings, pay full regard to the welfare requirements of animals. The REACH Regulation contains a number of provisions which take into account the welfare of animals. This includes Article 25(1) (see, for example, *Momentive Specialty Chemicals*, cited in paragraph 119 above, paragraph 96 of the decision).

235. The protection of animal welfare is therefore an important consideration in the framework of European Union legislation and the REACH Regulation in particular. 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 a substance evaluation it must ensure that vertebrate animals are used only as a last resort. The Agency's actions should not run counter to the principles of Directive 2010/63/EU (see Case A-004-2014, *Altair Chimica and Others*, decision of the Board of Appeal of 9 September 2015, paragraphs 106 to 108).

236. For the reasons set out above in addressing the Appellant's other pleas, the Appellant has failed to demonstrate that the requested study is unnecessary (see Section 2.1. above) or inappropriate to clarify the concerns identified by the Agency (see Section 2.5. above). The Appellant did not offer any additional arguments under the present plea as to why the requested study is unnecessary or inappropriate to achieve the objective pursued by the Agency. The Appellant's arguments that the Agency breached the principle of proportionality because the requested information is unnecessary and inappropriate to achieve the objective pursued must therefore be rejected for the same reasons as those set out in Sections 2.1. and 2.5. above.

237. The Appellant's argument that the Agency breached the principles of animal welfare and proportionality by requesting the same study under different substance evaluation processes to be performed on both ATS and Sb metal must also be rejected for the following reasons.

238. As stated in paragraph 212 above, the Appellant has not submitted an acceptable read-across adaptation to allow the Appellant to read-across the results of the requested study between Sb metal and ATS. Furthermore, as stated in paragraph 115 above, the Agency is not required to wait for the Appellant to develop or improve a read-across proposal which, eventually, may not be acceptable. It would not serve one of the main objectives of the registration and evaluation provisions in the REACH Regulation – the protection of human health – for the Agency to continue to wait for the Appellant to complete its stepwise testing strategy. This is especially where the outcome of the Appellant's testing strategy is uncertain and there is already evidence of concerns which, as set out in paragraphs 123 and 124 above, are specifically related to ATS.

239. The Appellant's argument that the Agency failed to consider alternatives to animal testing must also be rejected. The Agency clearly stated reasons in the Contested Decision as to why it considered that the Appellant's read-across proposal and its stepwise testing strategy are not adequate to address the concerns identified by the Agency. Furthermore, it is clear in the section of the Contested Decision entitled '*Consideration of alternative approaches*' that the Agency considered the issue of alternative testing methods and decided that there were no alternatives to generate the information requested in the Contested Decision without the use of vertebrate animals.

240. In view of paragraphs 233 to 239 above, the Appellant's seventh plea must be rejected as unfounded.

2.7. Conclusion on the appeal

241. As all the Appellant's pleas have been rejected, the appeal must be dismissed.

Claim for the reimbursement of costs

242. In the Notice of Appeal, the Appellant requests the Board of Appeal to order the Agency to pay the costs of these proceedings.

243. The Rules of Procedure do not provide for the reimbursement of costs that are not, as provided in Articles 17 and 21(1)(h) thereof, related to the taking of evidence. Furthermore, Article 17a of the Rules of Procedure provides that the parties shall bear their own costs.

244. Consequently, and as in the present case no costs arose in relation to the taking of evidence, the Appellant's request for reimbursement of costs is rejected.

Refund of the appeal fee

245. 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 the REACH Regulation (OJ L 107, 17.4.2008, p. 6), the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the appeal is dismissed, the appeal fee is not refunded.

Effects of the Contested Decision

246. The Contested Decision, upheld in the present appeal proceedings, required the Appellant to submit the requested study by 20 December 2021 which is one year, nine months and eight days from the date of that Decision.

247. Pursuant to Article 91(2), an appeal has suspensive effect. The deadline set in the Contested Decision to provide the requested study must therefore be calculated starting from the date of notification of the present decision of the Board of Appeal to the Parties.

248. The Appellant must therefore provide the information requested in the Contested Decision by 30 December 2023[1].

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the information requested in the Contested Decision must be submitted to the Agency by 30 December 2023.**
3. **Rejects the claim for the reimbursement of costs incurred in these proceedings.**
4. **Decides that the appeal fee is not refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal

[1] Under Article 23(6) of the Rules of Procedure, if a time limit ends on a Saturday, Sunday or official holiday of the Agency, it is extended until the end of the first following working day.