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-005-2020
Language of the case	English
Appellant	S. Goldmann GmbH & Co. KG, Germany
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 2,5,7,10,11,14-hexaoxa-1,6-distibabicyclo[4.4.4]tetradecane 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-2114499397-27-01/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. ATEG has been registered at the 100 to 1 000 tonnes per year tonnage band. The Appellant is one of the registrants of ATEG.

4. On 20 March 2019, following the substance evaluation of ATEG, the eMSCA 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 ATEG 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) toxicity study in rats, oral route (test method: OECD test guideline ('TG') 408) with ATEG, including additional cardiovascular and toxicokinetic parameters.

6. On the same day, the Appellant and other registrants of ATEG received a separate draft compliance check decision from the Agency under Article 41.

7. On 28 May 2019, the Appellant and other registrants of ATEG 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 ATEG 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 concern.

8. On 19 June 2019, the Appellant and other registrants of ATEG updated their registration dossiers for Sb metal. The dossier update included amendments to the read-across and weight-of-evidence adaptations included in the Appellant's registration dossier for ATEG.

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 ATS, which are the subject of separate appeals in Case A-003-2020, *Campine,* and in Case A-004-2020, *Tribotecc*, 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 (subchronic) toxicity study in rats, oral route (test method: OECD TG 408) with ATEG, including:*

(i) 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

(ii) toxicokinetic assessment covering the test parameter according to test method OECD TG 417 using a satellite group at the high exposure level […]. 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 ATEG under Article 41 requiring the Appellant and other registrants of ATEG to update their registration dossiers by 20 December 2021 with, depending on the tonnage at which they registered the substance, the following information on ATEG:

- *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 421/422) 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 11 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 11 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 11 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-004-2020, 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 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 R18 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 eighteen annexes submitted with the Appellant's observations on the Defence:

    1. Decision of 12 March 2020 on the compliance check regarding Sb metal (Annex R1);
    2. '*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 R2);
    3. '*Scientific opinion, provisional read-across justification, and further research opportunities - Human Health: Genotoxicity*', prepared by the International Antimony Association, dated 31 July 2018 (Annex R3);
    4. '*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 R4);
    5. '*The Migration of Antimony from PET Plastics – Literature Review and Exposure Assessment*', prepared by Blue Frog Scientific Limited, dated 11 December 2020 (Annex R5);
    6. '*Arsenic and Antimony Transporters in Eukaryotes*', Maciaszczyk-Dziubinska *et al.*, International Journal of Molecular Sciences, (2012) 13, pp. 3527-3548 (Annex R6);
    7. '*Cellular and molecular mechanisms of antimony transport, toxicity and resistance*', Tamás, Environ. Chem. (2016) 13, pp. 955-962 (Annex R7);
    8. '*Study plan for dose range finding study*', dated 5 November 2020 (Annex R8);
    9. '*Summary Report on Occupational Exposure to Antimony Metal, Diantimony Trisulphide, and Diantimony Tris(Ethylene Glycolate)*', prepared by EBRC Consulting, dated 12 January 2021 (Annex R9);
    10. '*Derivation of DNELS for Antimony III Compounds*', prepared by C. Boreiko for the International Antimony Association, dated April 2018 (Annex R 10);
    11. '*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 R11);
    12. '*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 R12);
    13. '*The fractions of respiratory tract cells at risk in formaldehyde carcinogenesis*', Miller *et al.*, Inhalation Toxicology (2011), 23(12) pp. 689 to 706 (Annex R13);
    14. '*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 R14);
    15. '*Subchronic feeding study of antimony trioxide in rats*', Hext *et al.,* Journal of Applied Toxicology (1999), 19, pp. 205-209 (Annex R15);
    16. '*Antimony Speciation – Response to ECHA*' prepared by P. Mitchell for the International Antimony Association, dated 14 January 2021 (Annex R16);

17. Quote from a contract research organisation for the performance of the various toxicological studies, dated 7 July 2020 (Annex R17); and
18. Quote from a contract research organisation for analytical/bioanalytical work on antimony substances, dated 9 April 2020 (Annex R18).

40. The Agency argues that the evidence submitted with the Appellant's observations on the Defence as Annexes R1 to R18 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 R18 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 R4, Annex R6, Annex R7, and Annexes R10 to R15), 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 R5, R8 and R9), or because the evidence in question was developed or submitted to specifically address points raised by the Agency in its Defence (Annexes R16, R17 and R18).

42. The Appellant argues that, even if the Board of Appeal considers that the evidence submitted as Annexes R1 to R18 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 R18 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 R18 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 Annex R1

46. The Appellant argues that Annex R1 was already known to the Agency and is a document which helps to reconstruct the regulatory history of the ATEG substance evaluation process. The Appellant also argues that it introduced Annexes R1 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.

47. It is unclear to which argument in the Defence Annex R1 is intended to respond. It is also unclear why the Appellant needed to introduce this document to clarify the regulatory history of the ATEG substance evaluation process. 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.

48. In view of paragraphs 46 and 47 above, even though Annex R1 was adopted by the Agency, the delay in introducing that document into the appeal proceedings is unjustified. Annex R1 must therefore be declared inadmissible.

49. The Appellant's argument that the Board of Appeal should request Annex R1 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 present case.

1.2. Admissibility of Annexes R2, R3, and R4

50. The Appellant argues that it introduced Annexes R2, R3 and R4 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.

51. 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.

52. Since Annexes R2, R3 and R4 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 R5

53. The Appellant argues that Annex R5 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 R5 is a review of publicly available literature contracted by the Appellant in the context of the consumer exposure assessment of ATEG. The Appellant argues that Annex R5 is a review of publicly available literature and is related to one of the alleged concerns identified in the Contested Decision. Therefore, the Agency and the eMSCA could have been aware of the reviewed publications had they acted with diligence.

54. Annex R5 responds to arguments raised in the Defence related to the exposure and uses of ATEG. Furthermore, since Annex R5 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 R5 is therefore justified and that evidence is admissible.

1.4. Admissibility of Annexes R6 and R7

55. The Appellant argues that Annexes R6 and R7 are studies available in the public literature and could have been known to the Agency had it acted with diligence. The Appellant argues that, in any event, this Annex was submitted with the observations on the Defence to respond to the Agency's arguments in of the Defence.

56. Annexes R6 and R7 do not specifically respond to arguments raised for the first time in the Defence. In addition, both documents pre-date the adoption of the Contested Decision and could therefore have been submitted with the Notice of Appeal. 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.

57. The delay in introducing Annexes R6 and R7 into the appeal proceedings is therefore unjustified and those documents must be declared inadmissible.

58. The Appellant's argument that the Board of Appeal should request Annexes R6 and R7 under Article 15 of the Rules of Procedure must also be 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 R8

59. The Appellant argues that Annex R8 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 argues that the fact that it was planning to carry out that study was announced in the Notice of Appeal.

60. Since Annex R8 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 R8 is therefore justified and that evidence is admissible.

1.6. Admissibility of Annex R9

61. The Appellant argues that it commissioned Annex R9 to respond to specific arguments raised by the Agency in the Defence and to demonstrate that the exposure of workers to ATEG decreases over time.

62. Annex R9 responds to arguments in the Defence related to exposure to workers. Furthermore, since Annex R9 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 R9 is therefore justified and that evidence is admissible.

1.7. Admissibility of Annex R10

63. The Appellant argues that Annex R10 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 ATEG which was submitted with the registration dossier for ATEG. The Appellant also argues that Annex R10 was submitted to demonstrate how the derived no-effect levels ('DNELs') for ATEG were derived due to the Agency's claims in the Defence that the DNELs derived for ATEG are not appropriate.

64. Although the Agency presents arguments related to DNEL derivation in the Defence, contrary to the Appellant's claims, Annex R10 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 obligations to submit that document in accordance with the Rules of Procedure.

65. In view of paragraphs 63 and 64 above, the delay in submitting Annex R10 is not justified within the meaning of Article 12(1) of the Rules of Procedure. Annex R10 must therefore be declared inadmissible.

66. The Appellant's argument that the Board of Appeal should request Annex R10 under Article 15 of the Rules of Procedure is also rejected. This is because that document is not necessary for the Board of Appeal to decide on the present case.

1.8. Admissibility of Annexes R11, R12, R13, and R14

67. The Appellant argues that Annexes R11, R12, R13, and R14 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.

68. Although Annexes R11, R12, R13, and R14 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.

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. In view of paragraphs 67 to 69 above, the delay in submitting Annexes R11, R12, R13, and R14 is not justified within the meaning of Article 12(1) of the Rules of Procedure. Annexes R11, R12, R13, and R14 are therefore inadmissible.

71. The Appellant's argument that the Board of Appeal should request Annexes R11, R12, R13, and R14 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.

1.9. Admissibility of Annex R15

72. The Appellant argues that Annex R15 is available in the public literature and could have been known to the Agency, had it acted with diligence. The Appellant argues that as Annex R15 refers to the methods used to derive DNELs, it should have been known to the Agency. According to the Appellant, Annex R15 was submitted with the observations on the Defence to respond to the Agency's arguments in the Defence.

73. Annex R15 does not specifically respond to arguments raised for the first time in the Defence. In addition, that document pre-dates the adoption of the Contested Decision and could therefore have been submitted with the Notice of Appeal. However, the document included as Annex R15 to the observations on the Defence is cited in the references to the Contested Decision and is discussed on page 6 of the Contested Decision. The delay in offering Annex R15 is therefore justified and that evidence is admissible.

1.10. Admissibility of Annex R16

74. The Appellant argues that Annex R16 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.

75. Annex R16 is offered to support arguments made in rebuttal of arguments raised in the Defence. Furthermore, since Annex R16 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 R16 is therefore justified and that evidence is admissible.

1.11. Admissibility of Annex R17

76. The Appellant argues that Annex R17 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.

77. Annex R17 is offered to support arguments made in rebuttal of arguments raised by the Agency in the Defence. Furthermore, since Annex R17 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). As a result, the delay in offering Annex R17 is justified and that evidence is admissible.

1.12. Admissibility of Annex R18

78. 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.

79. 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.

1.13. Conclusion on the admissibility of the evidence in Annexes R1 to R18

80. The evidence produced in Annexes R1, R6, R7, R10, R11, R12, 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.

81. 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.

82. The Agency's claim that the evidence produced in Annexes R2, R3, R4, R5, R8, R9, R15, R16, R17, and R18 to the Appellant's observations on the Defence is inadmissible is rejected.

2. Substance

83. 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 ATEG 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

84. 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.

85. 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.

86. 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

87. The Appellant, supported by PISC, argues that the Agency failed to examine, carefully and impartially, all the relevant information on ATEG submitted by the Appellant. The Appellant argues that this information includes its stepwise testing strategy, its proposed read-across and weight-of-evidence adaptations, the comments it submitted during the substance evaluation process, and its comments regarding exposure to ATEG, including its efforts to generate more recent targeted workplace exposure data.

88. The Appellant argues that the Agency acted inconsistently with regards to the use of read-across and adaptations. This is because, in the Contested Decision, the Agency relied on read-across/grouping between ATEG and ATO but in the compliance check decision on ATEG the Agency decided that the antimony compounds cannot be considered as a group of substances and data cannot be read-across from one antimony compound to another.

89. 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.

Clarity of the concern identified by the Agency

90. 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 ATEG or to the other similar trivalent antimony compounds.

91. The Appellant argues that the purpose of the requested study and whether the concerns identified by the Agency relate to consumer exposure, worker exposure or both are unclear.

Potential hazard

92. 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 ATEG 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.

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

94. 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

95. 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.

96. The Appellant argues that the Agency failed to take into account the Appellant's comments during the substance evaluation process regarding exposure to ATEG, 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.

97. The Appellant argues that the measured exposure levels of workers and consumers to ATEG are well controlled below the DNEL and can be considered as insignificant.

98. The Appellant argues that, in relation to consumer exposure, applications in consumer products entail the bonding/embedding of ATEG within a solid matrix and, under normal and foreseeable conditions of use, ATEG will not be released at all or in toxicologically relevant quantities.

99. The Appellant argues that even if the ATEG contained in polymer consumer articles were to migrate from those articles, including into the fluid within polyethylene terephthalate ('PET') bottles, and the total amount originally present in the polymer would be taken up by the consumer, no health risk would be present since the total amounts would be far below any no effect level or maximum tolerable daily intakes of ATEG.

100. The Appellant argues that risk characterisation ratios ('RCR') for consumers are below 0.01 except for the use of personal sanitary products, hygienic paper from PET/PES containing antimony, where the highest RCR is 0.027.

101. The Appellant argues that professional exposure is non-existent. This is because ATEG is not handled by professional workers but is only used by industrial workers as catalyst in PET (films/fibres, resin) production and during handling, moulding and forming of PET articles in industrial settings.

102. The Appellant argues that, regarding professional exposure, good occupational hygiene practices are followed to ensure safe handling of ATEG.

103. The Appellant argues that during the manufacture of PET, ATEG is supplied in a pre-reacted form, which prevents the release of ATEG in the workplace, and is blended with the other ingredients/precursors to form a monomeric unit or pre-polymer consisting of terephthalic acid ('PTA'), monoethylene glycol ('MEG') and ATEG. As such, ATEG is transformed into an antimony-containing monomer, and covalently bound into the polymeric chains that form the PET matrix; the original ATEG containing materials will be no longer present.

104. The Appellant argues that the Agency has not examined the risk management measures currently in place or demonstrated how the requested information will lead to an improvement in those risk management measures. In particular, the Agency failed to demonstrate to what extent the possible improved risk management measure envisaged in the Contested Decision - classification of ATEG as specific target organ toxicity repeated exposure ('STOT RE') 1 or 2 - could lead to improved risk management measures beyond the measures already in place to reduce and control exposure to ATEG, such as Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1). The Appellant also argues that the requested study is an oral study and is therefore not appropriate to determine a STOT RE lung classification already proposed for Sb metal, ATO and ATS.

105. 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

106. 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 and Case A-008-2018, *Taminco and Performance Additives Italy*, decision of the Board of Appeal of 29 January 2020, paragraphs 45 and 46).

107. 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.

108. 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 106 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).

109. 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

110. 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 ATEG (see paragraph 8 above).

111. 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. 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 ATEG and other antimony substances.

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

113. 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.

114. 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.

115. 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 ATEG rejected the read-across approach proposed by the Appellant must also be rejected for the following reasons.

116. 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.

117. Second, the compliance check and substance evaluation decisions for ATEG 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

118. According to the Appellant, it is unclear from the Contested Decision whether the concerns identified by the Agency relate to ATEG or to other similar trivalent antimony compounds.

119. 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 106 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.

120. According to the Contested Decision, the requested study is necessary because '*there is a concern that ATEG may cause systemic toxicity and potentially cancer after prolonged exposure*'.

121. That concern is based on information on structurally similar antimony compounds such as ATO, Sb metal, and potassium antimony tartrate. The Appellant itself acknowledges that ATEG has similar characteristics to Sb metal and other antimony compounds. The Appellant also 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 systemic toxicity and carcinogenicity after prolonged exposure is related specifically to ATEG.

122. In the Contested Decision, the Agency also identified a cardiotoxicity concern related to ATEG. 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 other antimony compounds, such as ATS and sodium antimony gluconate. However, the Agency also explains in the Contested Decision that the available information demonstrates that a form of antimony ('antimony species') is taken up by the organism, is systemically available, and there is concern that ATEG exhibits similar toxicological effects. It is therefore clear that the concern for cardiotoxicity is related specifically to ATEG.

123. It is also clear that the potential regulatory outcome envisaged by the Agency is to regulate, if necessary, ATEG 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 ATEG. Contrary to the Appellant's argument, there is therefore no lack of clarity as to how the requested information will be used.

124. 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

125. As stated in paragraph 106 above, potential risk is a combination of hazard and exposure. These two elements will be examined separately below.

2.1.4.1. Potential hazard

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

127. The Appellant, however, contests the Agency's conclusion that, based on occupational health studies and animal studies, there is a concern that ATEG may cause cardiovascular effects after repeated oral exposure. 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 ATEG because it relates to medical uses of antimony compounds.

128. As noted in paragraph 108 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).

129. 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 106 above, paragraph 89 of the judgment).

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

131. First, 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.

132. 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 106 above, paragraph 458 of the judgment).

133. 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).

134. Second, 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 108 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.

135. 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.

136. Third, 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.

137. Fourth, 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.

138. Fifth, 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 ATEG 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.

139. Sixth, 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 ATEG, 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 ATEG. 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 ATEG.

2.1.4.2. Potential exposure

140. According to the Contested Decision, there is potential worker exposure and, via plastic articles, consumer exposure to ATEG, including exposure of children.

141. The Appellant argues, in essence, that the requested study is not necessary because exposure to ATEG either does not exist or is insignificant. The Appellant also argues that any potential exposure to ATEG is adequately controlled.

142. The examination of exposure for the purposes of demonstrating a potential risk (the first condition referred to in paragraph 106 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 106 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 ATEG. Therefore, 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).

143. With regards to worker exposure, ATEG is used by workers as a catalyst in PET production and during handling, moulding and forming of PET articles in industrial settings.

144. The Contested Decision acknowledges that inhalation exposure to ATEG may be negligible after polymerisation by stating the following:

'*The only use of ATEG as pure substance is in industrial settings as catalyst for the production of polymers (PET) and the further processing and use of PET materials containing ATEG, both in industrial and professional workplaces. As [ATEG] is of low dustiness and mostly used in closed systems there is only limited potential for inhalation exposure. After the polymerisation reaction the catalyst (i.e. ATEG) is bound in the polymer and the potential for inhalation exposure is expected to be negligible*.'

145. However, for the following reasons, the Appellant has not presented any evidence to demonstrate that there is no potential exposure to workers prior to polymerisation, for example in blending to create the pre-reacted, or pre-polymer, form.

146. First, the updated information on exposure to ATEG in the workplace that the Appellant argues will be obtained from a monitoring programme initiated in 2018 is not yet available. The Agency is not required to wait for the Appellant to compile such exposure information which may, or may not, demonstrate an absence of exposure to ATEG in the workplace.

147. Second, the Appellant itself recognises in its submissions in the present proceedings that there is potential worker exposure to ATEG. The Appellant explains for example that workers use ATEG during handling, moulding and forming PET articles in industrial settings. The Appellant also refers to the measures put in place to avoid inhalation and ingestion of ATEG in the workplace. This clearly indicates that there are risks of inhalation and ingestion of ATEG in the workplace, and therefore potential exposure to ATEG by workers. The measures in place to control exposure, such as good occupational hygiene practices, do not mean that there is no potential exposure (see above paragraph 142).

148. In view of paragraphs 143 to 147 above, the Appellant's argument that the Agency failed to demonstrate that there is potential exposure of workers to ATEG for the purposes of demonstrating a potential risk must be rejected.

149. With regard to consumer exposure, the Contested Decision states the following:

'*Consumer exposure via the oral and dermal routes is possible based on the use of ATEG as catalyst in the manufacturing of polymers in particular of PET, which in turn is used in articles for consumers […].*

Due to the long term dermal contact with articles such as textiles and toys and the possibility of oral exposure of children via such articles containing ATEG there is a concern for adverse effects to consumers including children via dermal and oral exposure.'

150. The concern for oral toxicity after repeated exposure identified in the Contested Decision is related to the possibility of oral exposure of children via textiles and toys containing ATEG. In particular, according to the Contested Decision, there is a concern related to the oral exposure of children to ATEG through the mouthing of articles containing PET.

151. For the following reasons, the Appellant has not demonstrated that ATEG does not migrate from PET when handled by consumers.

152. First, it is not disputed that consumers may be exposed to textiles and/or toys containing PET which has been produced using ATEG.

153. Second, much of the evidence relied on by the Appellant to support its claim that there is no, or limited, consumer exposure to ATEG focuses on the possible migration of antimony from PET plastic bottles into the drinking water contained in those bottles, and, to a lesser extent, migration of antimony from PET trays used as food containers and to heat ready-made food. Whilst that evidence is relevant to consumer exposure to ATEG via oral route, the Appellant does not provide evidence related to repeated consumer exposure, in particular of children, through textiles and toys.

154. Third, the evidence presented by the Appellant suggests that there is some release of antimony from PET produced using ATEG as a catalyst. For example, the document entitled '*The Migration of Antimony from PET Plastics – Literature Review and Exposure Assessment*' (Annex R5 to the Appellant's observations on the Defence) states that '*antimony does migrate from PET plastic products.*'

155. Fourth, although some of the evidence presented by the Appellant suggests that the antimony substance migrating from PET is pentavalent Sb(V), the majority of that evidence indicates that the species of antimony released from PET is unknown. For example, as stated in the document attached as Annex 16 to the Notice of Appeal

'*[t]he chemical form of the migrating antimony is unknown, e.g. antimony glycolate, antimony trioxide or antimony acetate*' (Alt *et al.*, '*Diffusion coefficient of antimony catalysts in polyethylene terephthalate (PET) materials*' - Swiss Federal Office of Public Health, Food Safety Division). Likewise, the review of the available literature submitted by the Appellant in Annex R5 to the observations on the Defence acknowledges that there is little information in the available literature on which species of antimony was being measured in drinking water with most of the available evidence simply referring to 'antimony'. The document submitted as Annex 17 to the Notice of Appeal confirms that around 60 % of the total antimony content of PET is available for diffusion and that the migrating species in PET are presumably glycolate complexes ('*Migration of antimony from PET trays into food simulant and food: determination of Arrhenius parameters and comparison of predicted and measured migration data*', Haldimann *et al.*, Food additives & Contaminants: Part A, Federal Office of Public Health, Switzerland). In this respect, it should be noted that ATEG is a glycolate complex.

156. Fifth, the evidence produced by the Appellant in these appeal proceedings suggests that the maximum realistic concentration of antimony which migrates from PET into drinking water is below the regulatory drinking water limits established by the European Union and the World Health Organisation. However, that evidence relates to whether the potential exposure to ATEG is adequately controlled rather than whether there is potential exposure to that substance.

157. In view of paragraphs 149 to 156 above, the Appellant has not demonstrated that the Agency made an error in concluding in the Contested Decision that oral exposure of consumers to ATEG cannot be excluded because ATEG may be released from PET used, for example, in textiles and toys when handled by consumers, in particular children.

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

158. According to the Contested Decision, information from the requested study can be used for deciding on the classification of ATEG 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').

159. The Appellant argues that the Agency failed to demonstrate how a potential classification of ATEG as STOT RE 1 or 2 could lead to improved risk management measures beyond the European Union wide measures already in place to reduce and control exposure to ATEG. The Appellant also argues that, since it is an oral study, the requested study is inappropriate to determine a STOT RE classification for ATEG.

160. For the following reasons, the Appellant's argument that the Agency did not demonstrate how the current risk management measures in place will be improved as a result of the requested study must be rejected.

161. First, a STOT RE classification triggers a certain number of obligations that constitute risk management measures, notably as regards 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.

162. 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.

163. Second, ATEG is not classified as STOT RE. The introduction of a STOT RE classification for ATEG would therefore constitute an improved risk management measure.

164. Third, currently, there is no information on the systemic or the specific target organ toxicity arising from repeated dose exposure to ATEG. The results of the requested study have a realistic possibility of clarifying the target organ toxicity and leading to the obligation to classify ATEG as STOT RE 2, with heart as the main target organ. The results of the requested study might also lead to the establishment of concentration limits under Article 10(1) of the CLP Regulation.

165. Fourth, there is a realistic possibility that the requested study could lead to the ATEG being classified as STOT RE 1, with heart as the main target organ. This would be possible if, for instance, cardiovascular effects are observed in the requested study and they are at or below the guidance values defined in the CLP Regulation.

166. Fifth, 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 ATEG 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.

167. In view of paragraphs 158 to 166 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 ATEG which both constitute improved risk management measures. As a result, it is not necessary to examine the other risk management measures in place for ATEG.

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

168. In view of paragraphs 106 to 167 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

169. 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

170. The Appellant, supported by PISC, argues that the Contested Decision is inappropriate to achieve its objective insofar as it requires the requested study where alleged toxicity is unclear. The Appellant argues that a number of inhalation and oral toxicity-related issues should have been clarified before requiring the requested study. The Appellant argues that the requested study will not address the inhalation concerns identified by the Agency but only oral concerns.

171. The Appellant argues that in the absence of a mechanistic definition of key events associated with antimony systemic and local toxicity and/or carcinogenesis, the requested study would add little or nothing to the classification and risk assessment of ATEG.

172. The Appellant argues that the results of an OECD TG 422 study, requested in the compliance check decision, would reinforce the Appellant's read-across approach for the systemic endpoint and would provide crucial dose selection data for the PNDT test requested in the compliance check decision and the 90-day oral study requested under substance evaluation.

173. The Appellant argues that its systemic/reproductive toxicity testing programme would yield the necessary information and, if the results confirm the need for an OECD TG 408 study, the design of the 90-day study could be structured so as to provide detailed ovarian and testicular pathology and seminology in males. The Appellant argues that this could in turn inform on the need for, and the design of, an extended one generation reproductive toxicity study.

174. The Appellant argues that the Agency should have paid more attention to its stepwise testing strategy since it is more appropriate than the requested study. This is because it allows for the identification of the most appropriate test item, and therefore limits animal testing. The Appellant argues that ATEG may not be the most representative antimony substance to investigate the identified concerns.

175. The Appellant argues that the parameters for the toxicokinetic and cardiovascular effects requested in the Contested Decision are inappropriate.

176. The Appellant argues that the requested toxicokinetic assessment requires extensive method development and validation, would deliver data of limited use, and would not contribute to the determination of the mechanism of action.

177. The Appellant argues that the requested study will be intrinsically limited in its ability to detect or identify an unknown toxophore. The requested toxicokinetic parameters will therefore be unable to achieve the goal of establishing the mechanisms of action.

178. 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 argues that the investigation of cardiovascular effects will provide no benefit for the protection of the exposed populations.

179. The Appellant argues that the Agency has failed to specify why the standard parameters of an OECD TG 408 study, which include histopathology of the heart, are not sufficient to verify the presence or absence of cardiotoxicity.

180. 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. The mode of action and identification of the substance to be tested

181. 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.

182. First, the stepwise testing strategy, which the Appellant claims will clarify the mode of action for genotoxicity 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).

183. Second, the Agency has identified a potential risk in relation to ATEG 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 114 above). Furthermore, the Appellant has not substantiated its claim that ATEG may not be the most representative antimony substance on which to perform the requested study.

184. Third, contrary to the Appellant's arguments, it is not necessary to clarify the mode of action for genotoxicity or await the results of an OECD TG 422 study before performing the requested study. The requested study is intended to clarify a potential hazard related to oral toxicity after repeated exposure. The clarification of the mode of action for genotoxicity or the results of an OECD TG 422 study would not affect the design of the requested study and would not clarify the concern identified in the Contested Decision.

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

2.2.2. Cardiotoxicity parameters

186. For the following reasons, the Appellant's arguments that the additional cardiotoxicity parameters to be included in the requested study are inappropriate to achieve the objective pursued by the Agency and that the Agency has failed to justify why the standard parameters of an OECD TG 408 study are not sufficient to verify the presence or absence of cardiotoxicity must be rejected.

187. First, histopathology of the heart is a parameter foreseen in OECD TG 408. In addition, the section of the Contested Decision entitled '*Considerations on the test method and testing strategy*' clearly sets out why the additional cardiovascular parameters required in that decision, for example the inclusion of the ECG, are necessary.

188. Second, the Appellant did not demonstrate that the requested study cannot be performed with ATEG. 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.

189. 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.

190. Fourth, with regards to the Appellant's argument that the rat is not the most appropriate species for the requested cardiotoxicity parameters, it is sufficient to note that, according to OECD TG 408, '*[t]he preferred species is the rat, although other rodent species (e.g., the mouse) may be used. If the parameters specified within this TG 408 are investigated in another rodent species, a detailed justification for the choice of species should be given, including adaptations to the parameters measure.*'

191. Furthermore, the Appellant did not propose a suitable alternative to the preferred 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.

2.2.3. Toxicokinetic parameters

192. 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.

193. Contrary to the Appellant's claims, OECD TG 417 is suitable 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.

194. 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.

2.2.4. Conclusion on the Appellant's fifth plea

195. In view of paragraphs 181 to 194 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 ATEG prior to the substance evaluation

Arguments of the Parties and the Interveners

196. 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.

197. 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.

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

Findings of the Board of Appeal

199. 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).

200. 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.

201. Furthermore, 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.

202. 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 ATEG 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.

203. It should also be noted that the compliance check decision concerning ATEG (see paragraph 14 above) requests certain *in vitro* mutagenicity studies, a screening study via the oral route, and a PNDT study. However, the tests requested in the compliance check decision are not capable of clarifying the concerns identified in the Contested Decision.

204. 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.

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

206. 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 113 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.

207. In view of paragraphs 199 to 206 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

208. 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.

209. The Appellant argues that its legitimate expectations were based on the inclusion in the CoRAP of ATEG, together with ATC, after the inclusion of Sb metal, ATO and ATS. The Appellant argues that the consequential inclusion of this group of substances in the CoRAP led the Appellant to believe that the Agency intended to assess the substances as a group, and not as five separate and different substances.

210. 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').

211. The Appellant argues that its expectations were also based on 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.

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

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

Findings of the Board of Appeal

214. 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 113 above, paragraph 179 of the decision).

215. 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.

216. 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 214 above, that its grouping and read-across would be accepted.

217. 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.

218. Second, the fact that ATEG was included in the CoRAP at the same time as ATC and after the inclusion of Sb metal, ATO and ATS 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.

219. Third, the Appellant failed to substantiate how the 2020 Report provided precise, unconditional, and consistent assurances that specifically the grouping of ATEG 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 113 above, the Agency is not required to wait for the Appellant to finalise its testing strategy before requesting information under substance evaluation.

220. Fourth, as stated in paragraph 116 above, the information needed to establish structural similarity for the purposes of identifying a potential risk 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.

221. In view of paragraphs 214 to 220 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

222. 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.

223. The Appellant argues that the Agency failed to state reasons regarding the existence of an alleged concern and potential risk, and how the requested study will address the objectives of the Contested Decision.

224. 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.

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

Findings of the Board of Appeal

226. 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).

227. 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).

228. The Appellant's arguments under this plea are related to the Appellant's 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 117 above, paragraph 113 of the decision).

229. 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.

230. 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 ATEG 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.

231. 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 ATEG 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 113 above*,* paragraph 140 of the decision).

232. In view of paragraphs 226 to 231 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

233. The Appellant, supported by PISC, 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.

234. The Appellant argues that conducting the requested study before lower tier (reproductive) oral toxicity studies may result in the duplication of test data, the unnecessary use of vertebrate animals, and the production of equivocal results that cannot be used in the hazard or risk assessment of ATEG and other antimony compounds.

235. The Appellant argues that the Agency should have waited until a OECD TG 422 combined repeated dose screening reproductive study is finalised before requesting any oral sub-chronic studies.

236. The Appellant argues that the performance of the requested study is premature and results in the unnecessary use of vertebrate animals. The Appellant argues that the research strategy, which it proposed in its dossier update of 28 May 2019, would have ensured that the number of animals used in testing is limited to the minimum necessary.

237. The Appellant argues that its stepwise testing strategy would allow the identification of the ideal antimony substance test item(s) to be used in any higher tier oral studies. The Appellant argues that the requested study will not yield more precise results than those achieved through the proposed stepwise testing strategy or the recent read-across from Sb 3^+ and ethylene glycol.

238. The Appellant argues that under Article 13 of the TFEU, Article 25 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), as few animals as possible should be used in testing.

239. The Appellant argues that the Agency breached the principle of proportionality as it requests a 90-day (sub-chronic) oral toxicity study in vertebrate animals in a situation where alleged toxicity is unclear and the parameters of the requested study, including cardiovascular effect evaluations and toxicokinetic assessment, constitute an inappropriate burden for the Appellant.

240. The Appellant argues that the cost of performing the requested study is disproportionate when considering the profits of the companies concerned. The Appellant argues that the cost of the requested study could result in at least one of the two addresses of the Contested Decision inactivating their registration for ATEG. This could in turn result in the cease of supply of ATEG in the European Union. The Appellant argues that the Contested Decision also failed to take into account the fact that ATEG is registered at a low tonnage and has 'intermediate-like' uses.

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

Findings of the Board of Appeal

242. 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).

243. 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 117 above, paragraph 96 of the decision).

244. 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).

245. 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 principles of proportionality because the requested information is unnecessary and inappropriate to achieve the objective pursued by the Agency must therefore be rejected for the same reasons as those set out in Sections 2.1. and 2.5. above.

246. The Appellant's argument that the Agency breached the principles of animal welfare and proportionality because the Appellant's stepwise testing strategy is more appropriate and less onerous than the requested study must also be rejected for the following reasons.

247. As stated in paragraph 215 above, the Agency did not accept the Appellant's read-across adaptation. Furthermore, as stated in paragraph 113 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 121 to 123 above, are specifically related to ATEG.

248. 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 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.

249. For the following reasons, the Appellant's arguments regarding the disproportionate costs related to the requested study (see paragraph 240 above) must also be rejected.

250. First, as set out above, the requested study is necessary and appropriate to clarify whether ATEG causes systemic toxicity and potentially cancer after prolonged exposure, as well as cardiotoxicity. The Appellant has not demonstrated that there are appropriate alternatives to clarify those concerns.

251. Second, the protection of the human health, as one of the primary objectives of the registration and evaluation provisions in the REACH Regulation, takes precedence over economic considerations. The importance of the objectives pursued to clarify a concern related to human health may justify substantial negative economic consequences for certain operators (Case A-004-2014, *Altair Chimica and Others ['MCCP Registrants']*, decision of 9 September 2015, paragraph 81).

252. Third, Article 50(3) enables any addressee of a draft decision to cease the manufacture or import of the substance upon receipt of that draft decision. It can therefore be considered that the legislator has taken into consideration the effect of requests for information on the economic viability of a substance.

253. In view of paragraphs 242 to 252 above, the Appellant's seventh plea must be rejected as unfounded.

2.7. Conclusion on the appeal

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

Claim for the reimbursement of costs

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

256. 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.

257. 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

258. 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

259. 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.

260. 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.

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

[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.

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