DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

21 September 2020

(Data-sharing dispute – Legal basis – Requirements for data and cost-sharing – Transparency – Every effort – Sharing of costs – Duties of the Agency)

Case number	A-023-2018
Language of the case	English
Appellant	Oxiteno Europe SPRL, Belgium
Contested Decision	DSH-30-3-D-0222-2018 of 24 July 2018 adopted by the European Chemicals Agency (the 'Agency') pursuant to Articles 30(3) and 11 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') and Article 5 of Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with the REACH Regulation (OJ L 3, 6.1.2016, p. 41; 'Implementing Regulation 2016/9').

THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman and Rapporteur), Andrew Fasey (Technically Qualified Member) and Sakari Vuorensola (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. This appeal concerns the sharing of data and costs for the registration of the substance isopentyl acetate (EC No 204-662-3, CAS No 123-92-2; the 'Substance').
2. The Appellant is the lead registrant for the Substance.
3. Between 2016 and 2018, data and cost-sharing negotiations took place between the Appellant and another company (the 'Data Claimant').
4. During the course of those negotiations the Appellant and the Data Claimant disagreed on two elements:
   (i) the costs incurred by the Appellant, as the lead registrant for the Substance, and external consultants in gathering and submitting to the Agency the information required for the registration of the Substance (the 'administrative costs'); and
   (ii) the sharing of the costs of the studies that the Data Claimant intended to submit separately under Article 11(3) of the REACH Regulation (the 'partial opt-out'; all references to Articles hereinafter concern the REACH Regulation unless stated otherwise).
5. By the end of the negotiations, the positions of the Appellant and the Data Claimant on these two elements were as follows.

The administrative costs

6. The Data Claimant agreed that the costs of the studies that are needed to fulfil the information requirements set out in the Annexes of the REACH Regulation (the 'study costs') '*seem reasonable*'. However, the Data Claimant questioned the level of the administrative costs identified by the Appellant. According to the Data Claimant, the level of the administrative costs was '*extremely high*'. The Data Claimant argued that the administrative costs incurred in the preparation of the registration dossier were at least twice what '*can be considered acceptable for a comparable data set*' and the costs incurred by the Appellant as lead registrant were disproportionally high (emails of 12 December 2017, 27 February 2018, 13 March 2018, 3 April 2018 and 11 April 2018).
7. The Appellant explained that all the administrative costs were '*based on actual invoices*'. When the Data Claimant questioned the level of the administrative costs, the Appellant provided an updated overview of the study costs and the administrative costs (emails of 27 February 2018, 13 March 2018, 26 March 2018 and 8 April 2018).
8. The Appellant argued that the costs incurred by it as lead registrant were based on '*appropriate overviews of the time spent*'. The Appellant also argued that the administrative costs incurred in the registration of different substances cannot be compared due to the differences '*in terms of regulatory activity*' related to the substances and their registration dossiers (email of 8 April 2018).

The partial opt-out

9. The Data Claimant stated that it intended to submit separately some of the studies used in the Appellant's registration dossier as these studies were owned by its former parent company. The Data Claimant argued that it already had access to those studies. The Data Claimant argued therefore that it did not require those studies and cannot be

required to pay the Appellant for them (emails of 12 December 2017, 13 March 2018 and 3 April 2018).

10. The Appellant argued that the parent company of the Data Claimant had already been compensated for those studies. Exempting the Data Claimant from paying its share of the costs of those studies would mean that the Data Claimant would be compensated a second time for the same studies. According to the Appellant, this would be unfair vis-à-vis all other co-registrants (emails of 13 March 2018 and 8 April 2018).

Contested Decision

11. On 12 April 2018, the Data Claimant submitted to the Agency an application for permission to refer to the studies involving tests on vertebrate animals contained in the Appellant's registration dossier for the Substance, in accordance with Article 30(3).

12. On 24 July 2018, the Agency adopted the Contested Decision.

13. The Agency based the Contested Decision on Articles 30(3) and 11, and on Article 5 of Implementing Regulation 2016/9.

14. In the Contested Decision, the Agency concluded that the Data Claimant had made every effort to reach an agreement '*on access to the joint submission and the sharing of information*', whilst the Appellant '*could have done more efforts*'.

15. The Agency based this conclusion on the grounds that the Appellant had failed to itemise the administrative costs, had '*tried to force [the Data Claimant] to pay for all data and refused to grant an opt-out*', and had delayed the negotiations as it '*did not always reply to [the Data Claimant's] requests in a timely manner*'.

16. The Agency therefore granted the Data Claimant '*access to the joint submission*' and permission to refer.

Procedure before the Board of Appeal

17. On 24 October 2018, the Appellant filed this appeal.

18. On 20 December 2018, the Agency filed its Defence.

19. On 15 March 2019, the Appellant filed its observations on the Defence.

20. On 26 July 2019, the Agency filed observations on the Appellant's observations on the Defence.

21. On 6 February 2020, a hearing was held at the Appellant's request. At the hearing, the Parties made oral submissions and answered questions from the Board of Appeal.

22. On 15 May 2020, Sakari Vuorensola, alternate member of the Board of Appeal, was designated to replace Sari Haukka in this case, in accordance with the first 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').

23. On 26 and 27 May 2020 respectively, the Appellant and the Agency agreed, in accordance with the second subparagraph of Article 3(3) of the Rules of Procedure, that the hearing need not be held again. Sakari Vuorensola and the other two members of the Board of Appeal also agreed not to hold the hearing again.

Form of order sought

24. The Appellant requests the Board of Appeal to annul the Contested Decision and order the refund of the appeal fee.

25. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

26. The Appellant raises five pleas in support of its appeal:

- the Contested Decision lacks an appropriate legal basis (first plea);
- the Agency breached Article 30(3) as the conditions triggering the Agency's competence to decide on a data-sharing dispute were not met (second plea);
- the Agency breached Article 5 of Implementing Regulation 2016/9 by misinterpreting the obligations of the previous registrant stemming from Article 2 of that Regulation (first part of the third plea) and by failing to assess comprehensively and impartially the efforts of the parties (second part of the third plea);
- the Agency made several errors of assessment in finding that the Appellant had not made every effort to reach an agreement with the Data Claimant (fourth plea); and
- the Agency breached Article 30(1) by failing to ensure that the Data Claimant pays an equal share of the costs (fifth plea).

27. The Board of Appeal will first examine the first plea, then the second and the fifth, and finally the third and the fourth pleas.

1. First plea: the Contested Decision lacks an appropriate legal basis

Arguments of the Parties

28. The Agency based the Contested Decision on Articles 30(3) and 11, and on Article 5 of Implementing Regulation 2016/9. According to the Appellant, none of these provisions can serve as an appropriate legal basis for the Contested Decision.

29. The Appellant argues, first, that Article 30(3) concerns the sharing of data and costs between participants of a substance information exchange forum ('SIEF'). Under Article 29, SIEFs were operational only until 1 June 2018. Therefore the SIEF for the Substance was not operational at the time of the adoption of the Contested Decision, i.e. 24 July 2018. Consequently, the Appellant and the Data Claimant were not bound by the provisions of Article 30(3) and the Agency no longer had the competence to adopt a decision under that provision.

30. The Appellant argues, second, that neither Article 11 of the REACH Regulation, nor Article 5 of Implementing Regulation 2016/9, are a valid legal basis for the Contested Decision. Article 11 does not give the Agency the competence to grant a potential registrant access to the information in a dossier of a previous registrant or to a joint submission. Article 5 of Implementing Regulation 2016/9 only implements Articles 27(5) and 30(3) of the REACH Regulation and is therefore not a valid stand-alone legal basis for the Contested Decision.

31. The Agency argues that it retained the competence to adopt decisions under Article 30 despite the fact that SIEFs ceased to be operational before the adoption of the Contested Decision.

Findings of the Board of Appeal

32. The Appellant argues that after 1 June 2018 the Agency no longer had the competence to adopt decisions granting potential registrants permission to refer to information in previous registrants' dossiers under Article 30(3). This is because SIEFs ceased to be operational under Article 29 after that date.

33. This argument must be rejected for the following reasons.

34. In accordance with the case-law of the Court of Justice, '*although it is necessary — in order to comply with the principles governing the temporal application of the law and because of the requirements relating to the principles of legal certainty and the protection of legitimate expectations — to apply the substantive rules in force at the date of the facts in issue even if those rules are no longer in force when an EU institution adopts an act, the provision which forms the legal basis of an act and empowers the EU institution to adopt the act in question must, by contrast, be in force when the act is adopted. Similarly, the procedure for adopting that act must be carried out in accordance with the rules in force at the time of adoption*' (judgment of 14 June 2016, *Commission* v *Peter McBride and Others*, C-361/14 P, EU:C:2016:434, paragraph 40).

35. It is therefore necessary to determine whether the Contested Decision (i) applied substantive rules that were in force at the time of the facts at issue and (ii) is based on a valid legal basis that was in force when the Contested Decision was adopted.

36. Under Article 29, SIEFs ceased to be operational on 1 June 2018. This is a consequence of the expiry of the last of the registration deadlines, under Article 23, for phase-in substances.

37. It is not contested that the facts at issue in the present case took place before 1 June 2018. The data and cost-sharing negotiations between the Appellant and the Data Claimant took place between 7 October 2016 and 11 April 2018. Following the failure of those negotiations, the Data Claimant filed a data-sharing dispute on 12 April 2018.

38. Therefore the facts at issue took place before SIEFs ceased to be operational under Article 29. The applicable substantive rules were therefore those of Article 30.

39. The Agency adopted the Contested Decision on the basis of Article 30(3). At the time of the adoption of the Contested Decision, this legal basis had not ceased to be applicable nor had it been repealed or replaced. Therefore, the Agency did not err in law in using this legal basis.

40. The Agency retained its powers to adopt the Contested Decision under Article 30(3) which, at the time of the adoption of the Contested Decision, was a valid legal basis to adopt decisions on data-sharing disputes between SIEF participants.

41. As Article 30(3) is a valid legal basis for the Contested Decision, there is no need to examine the Appellant's arguments that neither Article 11 of the REACH Regulation nor Article 5 of Implementing Regulation 2016/9 are valid legal bases for the Contested Decision.

42. The first plea must consequently be rejected.

2. Second and fifth plea: breaches of Article 30

2.1. Second plea: the Agency breached Article 30(3)

Arguments of the Parties

43. The Appellant argues that, even if the Contested Decision is based on a valid legal basis, the Agency breached Article 30(3).

44. The Appellant argues that under Article 30(3) the competence for the Agency to grant a potential registrant permission to refer is not triggered by the failure to reach an agreement between the previous registrant and the potential registrant. It is triggered by a refusal of the previous registrant to provide either proof of the costs of the requested study or the study itself.

45. According to the Appellant, this condition was not fulfilled. The Appellant had not refused to provide the Data Claimant access to the information on the studies involving tests on vertebrate animals in the Appellant's registration dossier or proof of the costs of that information.

46. The Agency argues that it applied Article 30(3) correctly.

Findings of the Board of Appeal

47. The Appellant's argument is based on an incorrect interpretation of Article 30(3) and must therefore be rejected.

48. Article 30(3) sets out obligations for the sharing of data and costs within a SIEF both before and after a substance has been registered by the first registrant(s).

49. The condition that applies before a substance has been registered by the first registrant(s) is set out in the first sentence of Article 30(3). If the owner of a study refused to share '*either proof of the cost of that study or the study itself*' with the members of its SIEF, he could not '*proceed with registration until he provides the information to the other participant(s)'.*

50. The condition that applies after a substance has been registered by the first registrant(s) is set out in the fourth sentence of Article 30(3). If the information '*has already been submitted*' to the Agency in a dossier of a previous registrant, the Agency can grant a potential registrant of the same substance permission to refer to this information.

51. In the present case, the data-sharing dispute concerned information that the Appellant had already submitted in its registration. Therefore, the condition set out in the fourth sentence of Article 30(3), described in the previous paragraph, applies.

52. Consequently, in the present case, the condition triggering the Agency's competence to adopt a decision on a data-sharing dispute, between a previous registrant (the Appellant) and a potential registrant (the Data Claimant), was fulfilled.

53. The Agency was therefore entitled to either grant or deny the Data Claimant permission to refer (see Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, Decision of the Board of Appeal of 15 April 2019, paragraph 189). The Agency was not required to establish that the Appellant had '*refused*' to share '*either proof of the cost of that study or the study itself*'.

54. The second plea must consequently be rejected.

2.2. Fifth plea: the Agency breached Article 30(1)

Arguments of the Parties

55. The Appellant argues that the Agency breached Article 30(1) as it did not ensure that the Data Claimant pays an equal share of the costs incurred in generating, gathering and submitting information on the requested studies involving tests on vertebrate animals.

56. The Appellant argues that the Agency should have determined in the Contested Decision what constitutes an equal share of those costs and should have ordered the Data Claimant to pay such a share to the Appellant.

57. The Appellant argues that the Agency must ensure a consistent application of the data-sharing provisions of the REACH Regulation at the EU level. Therefore, the Agency cannot rely on decisions of the Member State competent authorities or the national courts on the sharing of costs.

58. The Agency argues that it applied Article 30(1) correctly.

Findings of the Board of Appeal

59. The fourth sentence of the second subparagraph of Article 30(1) states that the costs of a study *'shall be shared equally'* if the members of a SIEF cannot reach an agreement on the sharing of costs incurred in generating, gathering and submitting information on studies involving tests on vertebrate animals. However, Article 30(1) does not specify which authority is competent to decide on what the equal sharing of costs means in practice.

60. Under the fifth sentence of Article 30(3), if the Agency grants permission to refer to the information contained in a previous registrant's dossier, the previous registrant has a claim on a data claimant for an equal share of the costs, and that claim is enforceable in the national courts.

61. Under Article 30(3), it therefore does not fall within the competence of the Agency to determine an equal share of the costs within the meaning of Article 30(1). The competence to determine what the equal sharing of costs means in practice, as well as to assess the amount to be paid by a data claimant, falls within the jurisdiction of national courts.

62. The Agency therefore had no competence to decide how the costs should be shared between the Appellant and the Data Claimant. It follows that the Agency did not breach Article 30(1).

63. The fifth plea must consequently be rejected.

3. Third and fourth pleas: the Agency was incorrect in its assessment of the efforts made by the Appellant and the Data Claimant

3.1. First part of the third plea: the Agency breached Article 5 of Implementing Regulation 2016/9 by misinterpreting the obligations of the previous registrant stemming from Article 2 of that Regulation

Arguments of the Parties

64. The Appellant argues that the Agency did not distinguish between the requirements for itemisation of the costs incurred before and after the entry into force of Implementing Regulation 2016/9.

65. The Appellant argues that Article 2(2)(a) of Implementing Regulation 2016/9 sets out an '*obligation of result*', that is, a previous registrant must itemise costs incurred after the entry into force of Implementing Regulation 2016/9. The Appellant argues that Article 2(2)(c) of Implementing Regulation 2016/9 sets out an *'obligation of mean',* that is, a previous registrant must '*make every effort to provide itemisation*' of the costs incurred before the entry into force of Implementing Regulation 2016/9.

66. According to the Appellant, most of the disputed administrative costs relate to costs incurred before the entry into force of Implementing Regulation 2016/9 and therefore the Appellant was only required to make '*every effort*' to itemise them.

67. The Agency argues that it correctly applied Implementing Regulation 2016/9.

Findings of the Board of Appeal

68. The Appellant argues, in essence, that the Agency breached Article 5 of Implementing Regulation 2016/9 by finding that the Appellant should have itemised all administrative costs, including those that were incurred before the entry into force of Implementing Regulation 2016/9.

69. The costs incurred before the entry into force of Implementing Regulation 2016/9, including administrative costs, can be determined either by proof or by approximation (see *REACH & Colours and REACH & Colours Italia*, cited in paragraph 53 above, paragraph 81).

70. In the Contested Decision, the Agency assessed the efforts made by the Appellant to itemise the administrative costs incurred before the entry into force of Implementing Regulation 2016/9. The Agency explicitly referred to the obligations stemming from Article 2(2)(c) of Implementing Regulation 2016/9.

71. The Agency did not find that the Appellant should have itemised all the administrative costs incurred before the entry into force of Implementing Regulation 2016/9. The Agency limited itself to an assessment of the Appellant's efforts to itemise the costs incurred before the entry into force of Implementing Regulation 2016/9. Therefore, the Agency did not confuse the requirements for itemisation of the costs incurred before and after the entry into force of Implementing Regulation 2016/9.

72. It follows that the Agency did not misinterpret the requirements stemming from Article 2(2) of Implementing Regulation 2016/9 and did not breach Article 5 of that Regulation.

73. The first part of the third plea must consequently be rejected.

3.2. Second part of the third plea and the fourth plea: the Agency made several errors of assessment of the efforts made by the Appellant and the Data Claimant

Arguments of the Parties

74. The Appellant claims that the Agency made several errors of assessment of the efforts made by the Appellant and the Data Claimant in the data and cost-sharing negotiations. The Appellant raises four lines of argument in support of this claim.

75. First, the Appellant argues that the Agency '*breached the margin of discretion it enjoys in the context of Article 30(3)*' as it limited its assessment to the correspondence between the Appellant and the Data Claimant and did not give the Appellant any formal opportunity '*to explain or defend [its] position or to provide other details on the background of the case*'. In order to perform '*an adequate assessment*', the Agency should have asked the Data Claimant and the Appellant to provide further information on the claims that each of them had raised during the data and cost-sharing negotiations.

76. Second, the Appellant argues that the Agency breached Article 5 of Implementing Regulation 2016/9 because it failed to assess '*comprehensively and impartially*' the compliance of both the Appellant and the Data Claimant with the obligations of Implementing Regulation 2016/9.

77. The Appellant further argues that the Agency did not take due account of the Appellant's efforts to collect proof of the administrative costs and put this information at the disposal of the Data Claimant.

78. Third, the Appellant argues that the Agency made an error of assessment in finding in the Contested Decision that the Appellant '*tried to force the [Data Claimant] to pay for all data and refused to grant an opt-out'*.

79. During the negotiations, the Appellant argued that the Data Claimant should pay its share of the costs of the studies that the Appellant had acquired for its registration dossier from the former parent company of the Data Claimant. The Appellant argues that it did not '*oppose*' the Data Claimant's right to opt out, that is, the right to submit some information separately from the joint submission under the conditions set out in Article 11(3). On the contrary, it was the Data Claimant that failed to identify precisely the studies to which it sought access or the studies it intended to submit separately.

80. Fourth, the Appellant argues that the Agency made an error of assessment in finding that the Appellant delayed the negotiations.

81. The Appellant argues that the negotiations were delayed because the Data Claimant questioned the Appellant about '*every single [piece of] information provided*' and '*never made any counter proposal*'. The Appellant argues that the Agency failed to consider the negotiations as a whole and was incorrect in finding that only the Appellant was responsible for the delay.

82. The Agency argues that it was correct in finding that the Appellant had not made every effort to reach an agreement on data and cost-sharing with the Data Claimant.

Findings of the Board of Appeal

83. Under Article 5 of Implementing Regulation 2016/9, when deciding on a data-sharing dispute under Article 30(3), the Agency must take into account the parties' compliance with the obligations set out in Articles 2, 3 and 4 of Implementing Regulation 2016/9.

84. Articles 2, 3 and 4 of Implementing Regulation 2016/9 clarify that registrants and potential registrants of substances must make every effort to ensure that data and the costs incurred in generating, gathering and submitting that data are shared in a fair, transparent and non-discriminatory manner Article 2 of Implementing Regulation 2016/9 sets out specific requirements regarding transparent data and cost-sharing. Article 4 of Implementing Regulation 2016/9 sets out specific requirements regarding fair and non-discriminatory data and cost-sharing. Article 3(3) of Implementing Regulation 2016/9 clarifies the potential registrant's right under Articles 11(3) or 19(2) of the REACH Regulation to opt out from submitting some or all of the data together with the previous registrant.

85. It is necessary to examine the four arguments raised by the Appellant in support of its claim that the Agency made several errors of assessment of the efforts made by the Appellant and the Data Claimant in the data and cost-sharing negotiations (see paragraphs 74 to 81 above).

Breach of Article 30(3)

86. The Appellant argues, in essence, that the Agency committed an error as it limited its assessment to the correspondence between the Appellant and the Data Claimant and did not provide the Appellant with an opportunity to '*explain or defend [its] position or to provide other details on the background of the case*'.

87. The Agency's assessment of whether the parties to a data-sharing dispute have made every effort in the negotiations is based on the exchanges of information between the parties during the data and cost-sharing negotiations. This entails examining the records of the negotiations as provided by the parties to the dispute. When assessing whether the parties to a data-sharing dispute complied with the requirements of Article 5 of Implementing Regulation 2016/9 in the data and cost-sharing negotiations, the Agency cannot take into consideration arguments or justifications that were not made during those negotiations. The Board of Appeal has previously found that the Agency's practice in this regard complies with the right to be heard enshrined in Article 41(2)(a) of the Charter of Fundamental Rights of the European Union (see Case A-017-2013 *Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein*, Decision of the Board of Appeal of 17 December 2014, paragraphs 56, 98 and 99).

88. The Agency's assessment of a data-sharing dispute should centre on those elements on which the parties could not agree during their negotiations, and which therefore led to the filing of the application for permission to refer (see *REACH & Colours and REACH & Colours Italia*, cited in paragraph 53 above, paragraph 88).

89. The Agency's assessment must be carried out on the basis of the negotiations as a whole (see *REACH & Colours and REACH & Colours Italia*, cited in paragraph 53 above, paragraph 86).

90. Before adopting the Contested Decision, the Agency invited the Appellant '*to provide a copy of any correspondence*' between the Appellant and the Data Claimant '*demonstrating the efforts made by both parties to reach an agreement (e.g. [the Appellant's] reply to the request for the conditions of access to the data and the joint submission, any further request(s) for clarification, etc.)*'. The Appellant therefore had the possibility to provide the Agency with all documentation related to the data-sharing dispute. The Agency gave the same opportunity to the Data Claimant.

91. Using the information provided by the Data Claimant and the Appellant, the Agency correctly based the Contested Decision on its assessment of the data and cost-sharing negotiations as a whole. The Agency correctly centred its assessment on those elements of the negotiations upon which the Data Claimant and the Appellant could not agree.

The Agency respected the Appellant's right to be heard and was not required in this case to provide the Appellant with another opportunity to submit further documentation.

92. The Appellant's argument that the Agency '*breached the margin of discretion it enjoys in the context of Article 30(3)*' must therefore be rejected.

Error of assessment with regard to the Appellant's efforts in itemising the administrative costs

93. The Appellant argues that the Agency made an error of assessment in finding that the Appellant had not made every effort in itemising the administrative costs.

94. In light of Article 5 of Implementing Regulation 2016/9, the Agency is required to grant a potential registrant permission to refer if, despite the potential registrant's requests and objections, the previous registrant fails to comply with the requirements for data and cost-sharing to be transparent, fair and non-discriminatory (see, to this effect, *REACH & Colours and REACH & Colours Italia*, cited in paragraph 53 above, paragraphs 51 to 56, 76 to 83, 174 and 175).

95. It is necessary to examine whether, in the light of the Data Claimant's requests and objections, the Appellant complied with the requirements for data and cost-sharing to be transparent, fair and non-discriminatory.

96. This examination must be carried out in a logical sequence. First, it is necessary to assess whether the previous registrant has been transparent and whether the terms it proposes are therefore clear and comprehensible. If so, it is then possible to examine whether the terms proposed by the previous registrant are fair and non-discriminatory (see *REACH & Colours and REACH & Colours Italia*, cited in paragraph 53 above, paragraph 85).

97. In order to comply with the requirement for data and cost-sharing to be transparent, a previous registrant must provide, upon request from a potential registrant, clear and comprehensible explanations as to (i) which information is to be shared, (ii) how the cost of generating the information is determined, (iii) how the cost of gathering and submitting the information to the Agency is determined, and (iv) how costs are to be shared among registrants (see *REACH & Colours and REACH & Colours Italia*, cited in paragraph 53 above, paragraphs 77 and 78).

98. In the course of the data and cost-sharing negotiations, the Data Claimant agreed with the study costs but repeatedly challenged the basis for, and the level of, the administrative costs. The Data Claimant particularly challenged the costs incurred in preparing the registration dossier and the costs incurred by the Appellant as lead registrant (see paragraph 6 above).

99. The Appellant provided the Data Claimant with an overview of the administrative costs and explained that they were '*based on actual invoices*' and '*appropriate overviews of the time spent*' by the Appellant as lead registrant (see paragraphs 7 and 8 above).

100. The overview contained lump sums, amongst other costs, for '*Lead Registrant Costs*', '*[Consortium Manager] Staff Hours*' and '*SIEF Management Costs*'. However, the Appellant failed to provide an itemisation, or proof, of how these costs were incurred by the Appellant as lead registrant and by external consultants. These costs were challenged by the Data Claimant during the data and cost-sharing negotiations. The Appellant could have itemised the costs for example by providing the number of hours worked or proved the costs by providing the invoices. As the Appellant provided neither itemisation nor proof of the challenged costs, it failed to provide the Data Claimant with clear and comprehensible explanations as to how the cost of gathering and submitting the information to the Agency were determined (see point (iii) in paragraph 97 above).

101. The Agency was therefore correct in finding that the Appellant failed to itemise and justify all relevant costs and that this failure prevented the Data Claimant from being able '*to accurately review or contest the costs*'.

102. It follows that the Appellant failed to comply with the requirement for data and cost-sharing to be transparent. As a result, the Appellant failed to make every effort to reach an agreement on the sharing of data and costs.

103. The Appellant's argument that the Agency erred in finding that the Appellant had not made every effort in itemising the administrative costs must therefore be rejected.

Error of assessment with regard to the partial opt-out

104. The Appellant argues that the Agency made an error of assessment when it concluded in the Contested Decision that the Appellant '*tried to force the [Data Claimant] to pay for all data and refused to grant an opt-out*' to the Data Claimant.

105. This conclusion of the Agency does not correctly reflect the fact that the Data Claimant could submit some information separately from the joint submission under the conditions set out in Article 11(3), without being authorised to do so by the Appellant.

106. However, the Agency was correct in concluding that the Appellant tried to obtain from the Data Claimant compensation for studies that the Data Claimant did not require and intended to submit separately in accordance with Article 11(3). The Appellant does not challenge this finding.

107. A potential registrant can only be required to pay a share of the costs of generating, gathering and submitting to the Agency the information that it requires for the purposes of its own registration (see *REACH & Colours and REACH & Colours Italia*, cited in paragraph 53 above, paragraph 80). Therefore, the Agency was correct in concluding that the Appellant should not have sought compensation for studies that the Data Claimant did not require and intended to submit separately in accordance with Article 11(3).

108. The Appellant's argument that the Agency made an error of assessment in concluding that the Appellant '*tried to force the [Data Claimant] to pay for all data'* must therefore be rejected.

Error of assessment with regard to the delays in the negotiations

109. The Appellant argues that the Agency made an error of assessment in concluding that the Appellant caused delays in the negotiations.

110. In the Contested Decision, the Agency underlines a number of factual elements demonstrating that the Appellant did not always reply to the Data Claimant's requests in a timely manner. In its written and oral submissions, the Appellant did not present any evidence capable of contradicting those factual elements.

111. The Appellant argues that the Data Claimant also delayed the negotiations. The Appellant refers to a delay of eight months between April and December 2017. However, during this period of time, the Data Claimant was waiting for the additional information on the administrative costs that the Appellant had promised to provide. The Data Claimant was therefore not responsible for this delay.

112. The Appellant also argues that the unconstructive attitude of the Data Claimant caused delays in the negotiations. This argument replicates the Appellant's arguments on the Agency's assessment of the efforts of the Appellant and the Data Claimant, which have been already addressed and rejected in paragraphs 93 to 103 above.

113. The Appellant's argument that the Agency made an error of assessment when it concluded that the Appellant caused delays in the negotiations must therefore be rejected.

Conclusion

114. In light of paragraphs 83 to 113 above, the Agency did not make an error of assessment in concluding that the Appellant had failed to make every effort to reach an agreement on the sharing of data and costs. The second part of the third plea and the fourth plea must consequently be rejected.

115. As all the pleas and arguments of the Appellant have been rejected, the appeal must be dismissed.

Refund of the appeal fee

116. 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.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the appeal fee is not refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal