EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

27 October 2020

(Data and cost-sharing dispute – Opt-out – Access to the joint submission – Error of assessment – Requirements for data and cost-sharing – Every effort)

Case number	A-024-2018
Language of the case	English
Appellant	Symrise AG, Germany
Representatives	Ruxandra Cana, Eléonore Mullier and Hannah Widemann, Steptoe & Johnson LLP, Belgium
Contested Decision	DSH-30-3-D-0207-2018 of 25 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), Uta Jensen-Korte (Technically Qualified Member) and Ángel M. Moreno (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 3-phenylpropan-1-ol (EC No 204-587-6; the 'Substance').

2. The Appellant is the lead registrant of the Substance.

3. Between 21 March 2017 and 26 March 2018, data and cost-sharing negotiations took place between representatives of the Appellant and representatives of another company (the 'Data Claimant').

4. During the course of the negotiations, the Appellant and the Data Claimant discussed an agreement concerning the right for the Data Claimant to refer in its registration dossier to information available in the Appellant's registration dossier (the 'letter of access agreement'). They also discussed the possibility of the Data Claimant purchasing certain data and submitting that information separately (the 'opt-out agreement') pursuant to Article 11(3) of the REACH Regulation (all references to Articles, Annexes and Titles hereinafter concern the REACH Regulation unless stated otherwise).

5. On 26 March 2018, since the Appellant and the Data Claimant did not find an agreement on the sharing of data and costs, 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).

Contested Decision

6. On 25 July 2018, the Agency adopted the Contested Decision.

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

8. In Section C ('*Assessment*') of the Contested Decision, the Agency focuses on three points of the discussions between the Appellant and the Data Claimant:

   (i) Submitting information separately ('opt-out');

   (ii) Transparency of the breakdown of the costs; and

   (iii) Fair cost-sharing among co-registrants.

9. In relation to the discussions on the Data Claimant submitting information separately, the Contested Decision concludes:

   '*By not demonstrating willingness to discuss the [Data Claimant's] proposal to opt-out only from the 1-10 [tonnes per annum], the contractual amendments proposed by the [Data Claimant], and the request for a reimbursement scheme, the [Appellant] effectively blocked the negotiations and thereby the possibility for a common agreement. In doing so, the [Appellant] failed to make every effort to reach an agreement between the Parties*'.

10. In relation to transparency of the breakdown of the costs, the Contested Decision concludes:

    '*…even though both Parties made efforts, the [Appellant] did not make every effort to reach an agreement with the [Data Claimant] regarding the itemisation of the costs, the justification of such costs and the transparency of the cost sharing*'.

11. In relation to fair cost-sharing among co-registrants, the Contested Decision concludes:

    '*…the [Appellant] failed to make every effort to agree on a cost-sharing model which would be fair, transparent and non-discriminatory, and which would include a*

reimbursement mechanism. [The Appellant] did not take into consideration or respond to the [Data Claimant's] concerns on sharing of costs equally among co-registrants. Finally, the [Appellant] rejected the [Data Claimant's] propositions for contractual texts and failed to justify, why the relevant text could not be changed. Consequently, the negotiations reached a standstill'.

12. In the Contested Decision, the Agency concludes overall that:

'*The [Data Claimant] made every effort to reach an agreement on access to the joint submission and the sharing of information. On the other hand, the [Appellant] failed to make every effort to reach an agreement on sharing of data and related costs with the [Data Claimant], and in effect caused the negotiations to reach a standstill'.*

13. The Contested Decision consequently grants the Data Claimant *'access to the joint submission and permission to refer to studies specified in Annex II [to the Contested Decision].'*

14. Annex II to the Contested Decision sets out the '*List of studies subject to permission to refer granted by [the Agency]*'. According to Annex II, in a message of 15 March 2018, the Data Claimant requested *'access to the following vertebrate animal data required according to Annex VIII [to] the REACH Regulation for a registration in the tonnage band 10-100 [tonnes per annum]:*

- *Combined repeated dose toxicity study and reproduction/developmental screening test (following the OECD guideline No. 422)*
- *Acute toxicity to fish test (following the OECD No. guideline 203'*.

15. In the Contested Decision, the Agency grants the Data Claimant access to studies for the following endpoints:

(i) Repeated dose toxicity: Short-term repeated dose toxicity study (28-days) (Section 8.6.1. of Annex VIII);

(ii) Reproductive toxicity: Screening for reproductive/developmental toxicity (Section 8.7.1. of Annex VIII); and

(iii) Short-term toxicity testing on fish (Section 9.1.3. of Annex VIII).

16. Copies of the robust study summaries are included in Annex III to the Contested Decision.

17. The Contested Decision also states that:

'*As outlined in our previous communication concerning your dispute and the submission of your registration dossier, if [the Agency] grants you access to the joint submission and permission to refer to the requested vertebrate data, you will (i) receive copies of the robust study summaries of the requested vertebrate data, and (ii) be granted reasonable time to gather the additional information that you require in order to submit a complete registration.*

The robust studies summaries mentioned under point (i) are included in Annexes II and III of this decision.

Concerning point (ii), [the Agency] grants you up to ten months from the date of this decision to gather this information. Once you are ready to submit your registration, and at the latest by 27 May 2019, please inform [the Agency]. [The Agency] will then provide you with further instructions how to proceed with your registration. Please note that it would be possible to proceed with your registration at the earliest after the three months appeal period for lodging an appeal against [the Agency's] decision on your dispute claim has elapsed.'

Procedure before the Board of Appeal

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

19. On 21 December 2018, the Agency filed its Defence.

20. On 29 March 2019, the Appellant filed its observations on the Defence.

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

22. On 28 and 29 November 2019 respectively, the Appellant and the Agency responded to questions from the Board of Appeal.

23. On 4 March 2020, Uta Jensen-Korte, alternate member of the Board of Appeal, was designated to replace Andrew Fasey 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').

24. On 11 March 2020, a hearing was held at the Appellant's request. The hearing was held by video-conference in accordance with Article 13(7) of the Rules of Procedure. At the hearing, the Parties made oral submissions and answered questions from the Board of Appeal.

25. On 15 May 2020, Ángel M. Moreno, 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 the Rules of Procedure.

26. On 20 and 26 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. Ángel M. Moreno and the other two members of the Board of Appeal also agreed not to hold the hearing again.

Form of order sought

27. The Appellant requests the Board of Appeal to annul the Contested Decision. The Appellant also requests the Board of Appeal to refund the appeal fee and take such other or further measures as justice may require.

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

Reasons

29. The Appellant raises the following pleas in support of its appeal:

    1. The Agency made an error of assessment and failed to take all information into account in considering that the negotiations had reached a standstill;

    2. The Agency made an error of assessment and failed to take all information into account in its assessment of the efforts of the Data Claimant and the Appellant;

    3. The Agency made an error of assessment and failed to take all information into account in assessing the efforts to itemise non-study costs;

    4. The Agency acted outside the scope of its powers (*ultra vires*) and breached Article 30 by assessing the efforts made by the parties to agree on the sharing of information for submission of information as an opt-out under Article 11(3);

    5. The Agency acted outside the scope of its powers (*ultra vires*) and beyond the Data Claimant's request (*ultra petita*) and breached Article 5 and the principle of legal certainty by granting a '*token*' to the joint submission; and

6. The Agency acted outside the scope of its powers (*ultra vires*) and breached Article 20(2) by granting the Data Claimant a second time line to update its dossier.

30. The Board of Appeal will first examine the Agency's claims that the Appellant's fifth and sixth pleas are inadmissible.

1. Admissibility of the fifth and sixth pleas

31. The Contested Decision, in effect, consists of three separate decisions:

(i) The decision on the permission to refer;

(ii) The decision on access to the joint submission; and

(iii) The decision setting the Data Claimant a time limit to submit the information necessary to complete its registration dossier.

32. The decision to grant access to the joint submission is the subject of the fifth plea and the decision to grant the Data Claimant a time limit to submit the information necessary to complete its registration dossier is the subject of the sixth plea.

1.1. Admissibility of the fifth plea concerning the Agency's decision to grant access to the joint submission

Arguments of the Parties

33. By its fifth plea, the Appellant argues that the Data Claimant submitted a data and cost-sharing dispute to the Agency for failure to share data involving testing on vertebrate animals pursuant to Article 30(3); the Data Claimant did not request access to the joint submission. In granting a '*token*' to the joint submission in the Contested Decision, the Agency acted outside the scope of its powers (*ultra vires*) and beyond the Data Claimant's request (*ultra petita*).

34. The Agency argues that the Data Claimant explicitly requested access to the joint submission. The Agency also argues that the Appellant's plea related to the granting of the '*token*' to the joint submission is inadmissible. This is because the Appellant's rights are not affected if another registrant is granted a '*token*' to the joint submission. The Agency argues that the Board of Appeal decided in its decision of 23 March 2018 in case A-011-2017, *REACheck Solutions*, that every registrant has the right to join a joint submission with a full opt-out. It is therefore neither for the Appellant nor the Agency to decide whether such a submission may be made. The Agency must always grant a '*token*' when requested to do so. The lead registrant's position cannot therefore be affected by another registrant joining the joint submission.

35. The Appellant argues that '*aside from new pleas being introduced in later stages of the procedure, there are no conditions of admissibility for pleas to be raised in the Notice of Appeal*'. The rules on admissibility in the REACH Regulation and the Rules of Procedure relate to the appeal as a whole and not to individual pleas. Under Article 12(2) of the Rules of Procedure, the admissibility of pleas is assessed by the Board of Appeal only where they are raised after the first exchange of written pleadings.

36. The Appellant argues that the decision contested in case A-011-2017, *REACheck Solutions,* concerned a dispute to receive only a token for a complete opt-out. Therefore, based on the Board of Appeal's decision, it is only in cases of complete opt-out that the Agency does not have any margin of discretion and that the granting of the token cannot depend on an assessment of every effort of the parties.

37. The Appellant argues that the Agency's plea that the fifth plea is inadmissible is ineffective. The present case concerns an Agency decision whereby both a token and access to the information in the Appellant's dossier were granted; such a decision is therefore certainly one affecting the interests of the Appellant.

Findings of the Board of Appeal

38. The obligation for multiple registrants of the same substance to submit data jointly is set out in Article 11. The Agency's decision to grant access to the joint submission can only therefore be based on that provision. This is irrespective of whether the Data Claimant in the present case intends to submit some, or all, information separately pursuant to Article 11(3) ('opt-out') or is requesting to refer to information in the dossier of another registrant of the same substance.

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

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

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

42. In the present case, since the decision to grant access to the joint submission was not adopted on the basis of any of the Articles listed in Article 91(1), the Board of Appeal is not competent to decide on an appeal against that part of the Contested Decision.

43. Therefore, the appeal is inadmissible in so far as it is directed against the decision to grant the Data Claimant access to the joint submission.

1.2. Admissibility of the sixth plea concerning the deadline for the Data Claimant to provide the information missing from its registration dossier

Arguments of the Parties

44. By its sixth plea, the Appellant argues that the Agency acted outside the scope of its powers (*ultra vires*) and breached Article 20(2) by granting the Data Claimant an additional 10 months by a '*second (extended)*' deadline to update its dossier with non-vertebrate animal data.

45. The Agency argues that the sixth plea is inadmissible as it challenges a measure that has no impact on the legal situation of the Appellant.

46. The Appellant argues that '*aside from new pleas being introduced in later stages of the procedure, there are no conditions of admissibility for pleas to be raised in the Notice of Appeal*'. The rules on admissibility in the REACH Regulation and the Rules of Procedure relate to the appeal as a whole and not to individual pleas. Under Article 12(2) of the Rules of Procedure, the admissibility of pleas is assessed by the Board of Appeal only where they are raised after the first exchange of written pleadings.

47. The Appellant argues that, even if the Board of Appeal decides that the Agency's decision to grant a '*second (extended)*' deadline does not affect the Appellant's legal situation, since the Agency's practice in this respect contradicts the objectives of competitiveness and protection of human health and the environment the Board of Appeal can examine the legality of this practice of its own motion.

48. The Appellant argues that, in accordance with the case-law of the European Court of Justice, it has an interest in '*promoting the Agency to make suitable amendments in the future to the […] procedure if that procedure is found to be incompatible with certain legal requirements*' (for example, judgment of 12 December 2012, *Evropaïki Dynamiki* v *EFSA*, T-457/07, EU:T:2012:671, paragraph 27).

Findings of the Board of Appeal

49. In the Contested Decision, the Agency grants the Data Claimant up to ten months from the date of the Contested Decision to gather the information required to complete its registration dossier (see paragraph 17 above).

50. Article 92(1) provides that '*[a]ny natural or legal person may appeal against a decision addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former*.' The Contested Decision is addressed to the Data Claimant with the Appellant in copy. As the Contested Decision is not addressed to the Appellant, the Board of Appeal will examine whether the part of the Contested Decision granting the Data Claimant up to 10 months to submit the information necessary to complete its dossier is of direct and individual concern to the Appellant.

51. When interpreting the concepts of direct and individual concern in Article 92(1), the case-law of the European Union Courts concerning the interpretation of the fourth paragraph of Article 263 of the TFEU is relevant (see Case A-022-2013*, REACheck Solutions,* Decision of the Board of Appeal of 15 March 2016, paragraphs 69 and 83).

52. Direct and individual concern are cumulative requirements and an appeal is inadmissible if an appellant fails to establish either of these requirements (see, by analogy, judgment of 3 October 2013, *Inuit Tapiriit Kanatami and Others* v *Parliament and Council*, C-583/11 P, EU:C:2013:625, paragraph 76).

53. In order to satisfy the requirement that a contested decision is of direct concern to an appellant who is not the addressee of that decision, two cumulative criteria must be met. First, the contested decision in question must directly affect the legal situation of that appellant and, second, it must leave no discretion to the authorities responsible for implementing it, such implementation being purely automatic and resulting from European Union law alone, without the application of other intermediate rules (see judgment of 27 February 2014, *Stichting Woonpunt and Others* v *Commission*, C-132/12 P, EU:C:2014:100, paragraph 68).

54. To satisfy the first criterion of the direct concern requirement, it must be established that a contested decision directly affects an appellant's legal, rather than factual, situation. The contested decision must produce legal effects with regard to an appellant. It is not sufficient that a contested decision exercises an influence over an appellant's substantive position or causes an appellant adverse economic consequences because they do not affect an appellant's legal situation, only its factual situation (see, to this effect and by analogy, order of 9 November 2016, *Biofa* v *Commission*, T-746/15, EU:T:2016:658, paragraphs 37 and 38). The Court of Justice has also consistently held that the direct effect on an applicant's legal situation cannot consist only of a competitive disadvantage (see, for example, judgment of 17 September 2015, *Confederazione Cooperative Italiane and Others* v *Anicav and Others*, joined cases C-455/13 P, C-457/13 P and C-460/13 P, EU:C:2015:616, paragraphs 48 and 49).

55. The Appellant has not established that its legal situation would be affected and, as a result, the Appellant has not established that it is directly concerned by the Contested Decision.

56. As the requirements of direct and individual concern are cumulative (see paragraph 52 above), there is no need to determine whether the Appellant is individually concerned by the Contested Decision.

57. Therefore, in so far as it is directed against the decision to grant the Data Claimant a time-limit to update its registration dossier, the appeal is inadmissible.

58. Since the appeal is directed against separate decisions contained in the same Contested Decision, the inadmissibility of the appeal in so far as it is directed against one, or more,

of those separate decisions cannot affect the admissibility of the appeal as regards the other separate decisions contained in the same Contested Decision.

59. It is therefore necessary to next examine the appeal in so far as it concerns the Agency's decision on the permission to refer taken in accordance with Article 30.

2. Pleas related to the legality of the Contested Decision in so far as it relates to the data and cost-sharing dispute

60. It is necessary to first examine the Appellant's fourth plea as it concerns the Agency's competence to examine and decide on the permission to refer.

2.1. Fourth plea: The Agency acted outside the scope of its powers (*ultra vires)* and breached Article 30 by assessing the efforts made by the parties to agree on the sharing of information for submission of information as an opt-out under Article 11(3)

Arguments of the Parties

61. The Appellant argues that, at the time the application for permission to refer was submitted, the discussions between the Appellant and the Data Claimant concerned a '*complete opt-out*', that is to say the possibility for the Data Claimant to submit separately all the information required under Article 11(3). As a result, the dispute falls outside the scope of Article 30(3) as, under that provision, the Agency is only entitled to grant permission to refer. The Agency therefore acted *ultra vires* in relation to its findings in Sections C(1) and C(3) of the Contested Decision which include the Agency's assessment of the negotiations regarding the submitting of information separately and the fair cost-sharing among co-registrants.

62. The Appellant argues that the data and cost-sharing negotiations in the present case were not governed by Article 30(3) since the Appellant did not refuse to provide the cost of a study or the study itself.

63. The Appellant argues that it is only under Article 30(3) that the Agency is competent to decide on an application for permission to refer. The negotiations between the Appellant and the Data Claimant were governed by Article 30(1) which imposes data and cost-sharing but for which the legislator did not foresee a role for the Agency.

64. The Agency disputes the arguments of the Appellant.

Findings of the Board of Appeal

65. By its fourth plea, the Appellant argues that the Agency is not competent under Article 30 to examine disputes between registrants of the same substance concerning access to a full-study report for the purposes of submitting information separately pursuant to Article 11(3).

66. For the following reasons, the Appellant's fourth plea must be rejected.

67. First, Article 30 is contained in Title III (Articles 25 to 30), which is entitled as follows: *'Data sharing and avoidance of unnecessary testing'*. According to Article 25, the aim of Title III is to ensure that testing on vertebrate animals for the purposes of the REACH Regulation is undertaken only as a last resort and to avoid the duplication of such testing.

68. At the time of the data and cost-sharing dispute, the Appellant and the Data Claimant were members of the same substance information exchange forum ('SIEF') for the Substance pursuant to Article 29. According to Article 29(2)(a), one of the aims of each SIEF is to '*facilitate, for the purposes of registration, the exchange of the information specified in Article 10(a) (vi) and (vii) between potential registrants, thereby avoiding the duplication of studies*'.

69. Article 30 governs the sharing of information and costs within SIEFs. This provision applies to the sharing of all data and costs related to testing on vertebrate animals and irrespective of whether the registrants are aiming at submitting information separately under Article 11(3), or whether they are negotiating a letter of access for the purpose of the joint submission.

70. Even if the registrant of a substance chooses to submit information separately under Article 11(3), Articles 25, 29 and 30 still apply in their entirety. Article 11(3) does not exclude the requirements for data and cost-sharing set out in Articles 25, 29 and 30. The obligation to share data and costs is always applicable when a registrant seeks access to a study that it requires for its registration. In this respect, it should also be noted that any separate submission, made in accordance with Article 11(3), remains part of the existing registration (see, to this effect, Article 3 of Implementing Regulation 2016/9).

71. Second, if the data and cost-sharing negotiations at issue fell outside the scope of Article 30, there would be legal asymmetry or duality between data and cost-sharing negotiations governed by the REACH Regulation and those falling outside the scope of that Regulation. This would increase the risk of legal uncertainty.

72. In addition, in the present case, from the beginning of the data and cost-sharing negotiations, the parties did not express any intention that they did not want to be governed by the provisions of the REACH Regulation on data and cost-sharing.

73. Third, the Appellant's argument that Article 30 does not apply in the present case because the Appellant did not refuse to provide either proof of the cost of the studies or the studies themselves must also rejected for the following reasons (see also Case A-023-2018*, Oxiteno Europe,* Decision of the Board of Appeal of 21 September 2020, paragraphs 47 to 54).

74. 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).

75. 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)'.*

76. 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.

77. In the present case, the data and cost-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.

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

79. 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*'.

80. In view of the above, Article 30 is applicable in its entirety to the dispute related to the sharing of data and costs in the present case. Therefore, the Agency did not act outside the scope of its powers (*ultra vires*) by assessing and deciding on the efforts made by the parties to agree on the sharing of data and costs, including as part of an opt-out.

81. The Appellant's fourth plea must therefore be rejected.

2.2. First plea: The Agency made an error of assessment and failed to take all information into account in considering that the negotiations had reached a standstill

Arguments of the Parties

82. The Appellant argues that the Agency made an error of assessment and failed to take into account all information in concluding that the data and cost-sharing negotiations had reached a standstill because the Appellant had refused to (i) include a reimbursement mechanism in the agreement, (ii) agree to equal sharing, and (iii) amend the contractual arrangements.

83. The Appellant argues that the scope of the data and cost-sharing negotiations changed on several occasions. The Agency failed to take into account that from 13 March 2018, 10 days before the submission of the application for permission to refer, the negotiations between the parties had focused on allowing the Data Claimant to submit all information separately under Article 11(3). The Agency should have examined whether the negotiations had reached a standstill in relation to this complete opt-out. The application for permission to refer was therefore submitted prematurely as, according to the Agency's guidance on data-sharing (version 3.1, January 2017, page 87; the 'Agency's data-sharing guidance'), such an application should be submitted as a last resort.

84. The Appellant argues that equal sharing and a reimbursement mechanism are not mandatory in a complete opt-out scenario. In addition, equal sharing and a reimbursement mechanism were included in the letter of access agreement previously proposed by the Appellant.

85. The Appellant argues that it was only on 15 March 2018 that the Data Claimant informed the Appellant of the specific studies to which it sought access. This information was essential to put in place the necessary contractual arrangements for data and cost-sharing.

86. The Appellant argues that two days after the Data Claimant had clarified the studies for which it sought to purchase the full-study reports in order to submit its own registration, the Appellant proposed an agreement limited to the four studies requested by the Data Claimant. The new agreement included only the costs of purchasing the four studies.

87. The Appellant argues that, on 21 March 2018, the Data Claimant insisted on equal cost-sharing and a reimbursement mechanism. The Appellant responded that it considered that equal cost-sharing and reimbursement could not apply in this case as the Data Claimant was proposing a complete opt-out.

88. The Agency disputes the arguments of the Appellant.

Findings of the Board of Appeal

89. The Appellant contests the finding in the Contested Decision that the Appellant had:

> '*…failed to make every effort to agree on a cost-sharing model which would be fair, transparent and non-discriminatory, and which would include a reimbursement mechanism. They did not take into consideration or respond to the [Data Claimant's] concerns on sharing of costs equally among co-registrants. Finally, the [Appellant] rejected the [Data Claimant's] propositions for contractual texts and failed to justify, why the relevant text could not be changed. Consequently, <u>the negotiations reached a standstill</u>*' (emphasis added).

90. It is not necessary for the data and cost-sharing negotiations to have formally reached a '*standstill*' before the submission of an application for permission to refer. There is no such requirement in the REACH Regulation nor in Implementing Regulation 2016/9.

91. An application for permission to refer is submitted by a data claimant that considers that no agreement can be reached. In the assessment of the data and cost-sharing dispute, the Agency will analyse the reasons for the failure of the data and cost-sharing negotiations. In doing so, the Agency may refuse to grant a permission to refer because the data claimant did not make every effort and was therefore responsible for the failure of the data and cost-sharing negotiations. In this respect, a premature submission of an application for permission to refer could show a lack of effort of the data claimant.

92. In the present case, it appears that '*all the possible arguments have been exhausted and the negotiations have eventually failed*' within the meaning of Agency's data-sharing guidance. This is because, despite repeated communications, several important issues in the dispute remained unresolved (for example the inclusion of affiliates in the sharing of costs, cost itemisation, and a reimbursement scheme) and the negotiations were becoming circular.

93. To that extent, contrary to the Appellant's claims, the negotiations failed and the submission of the application for permission to refer was not premature. Therefore, the Agency did not make an error of assessment in considering that the negotiations were not making any progress.

94. The first plea must consequently be rejected.

2.3. Second and third pleas: Error of assessment regarding the parties' efforts

Arguments of the Parties

95. The Appellant argues that the Agency committed an error of assessment and failed to take into account all information in assessing both the Data Claimant's efforts and the Appellant's efforts during the data and cost-sharing negotiations.

96. The Appellant argues that the Agency failed to take into account that the Data Claimant constantly changed the scope of its request. These changes were in particular in relation to the extent of the Data Claimant's involvement in the joint submission, which included a complete opt-out, a partial opt-out, as well as involvement in the joint submission with certain waiving. The changes also concerned the scope of the rights the Data Claimant intended to purchase with regard to the studies to which the Data Claimant sought access. The Data Claimant therefore prolonged the negotiations. The Appellant, however, responded quickly to all communications from the Data Claimant, even where the scope of the negotiations frequently changed.

97. The Appellant argues that the Agency failed to take into account the Data Claimant's lack of efforts in responding to the Appellant's proposals and arguments during the negotiations. For example, the Data Claimant merely continued to argue that the costs were too high; this is insufficient to satisfy the every effort requirement.

98. The Appellant argues that the Agency made an error in finding that the Appellant had '*pressured*' the Data Claimant into submitting information separately under Article 11(3) as it was the Data Claimant's initiative to opt-out. The Appellant attempted to accommodate the Data Claimant's request to opt-out, whilst highlighting that this approach is unusual.

99. The Appellant argues that the Agency failed to take into consideration all information in its assessment of the parties' efforts concerning cost itemisation.

100. The Appellant argues that the Agency made an error in finding that the Appellant had '*excluded from the negotiations the question on a reimbursement mechanism*' and only responded late in the negotiations to questions on a reimbursement mechanism. In the negotiations on the letter of access agreement, the Appellant responded immediately that a reimbursement mechanism is included in that type of agreement. The Appellant explained to the Data Claimant that there was, however, no reimbursement mechanism

in an agreement to purchase the studies for the purposes of the Data Claimant's complete opt-out.

101. The Appellant argues that the Agency committed an error of assessment concerning the Appellant's efforts to provide the itemisation of (non-study) administrative costs.

102. The Appellant argues that, throughout the data and cost-sharing negotiations, it provided detailed information on the costs incurred, including in its cost allocation policy and in response to the Data Claimant's specific questions. The Appellant broke down the administrative costs into categories, increasing transparency about the calculation of those costs. Moreover, the Appellant explained that each category of administrative costs are itemised per Annex and divided between the co-registrants accordingly. The invoices for these costs were available upon request and the Data Claimant was able to review them at the Appellant's premises.

103. The Appellant argues that there is no obligation under the REACH Regulation or Implementing Regulation 2016/9 to itemise the non-study costs to the level requested by the Data Claimant; this is in particular the case if, at the time the administrative costs were incurred (prior to the adoption of Implementing Regulation 2016/9), the data owner recorded these administrative costs per endpoint rather than per study.

104. The Appellant argues that the statement in the Contested Decision that the Appellant '*would not provide any further itemisation regarding the costs on the lower tonnage band*' reflects an erroneous assessment of the Appellant's efforts to itemise the costs.

105. The Agency disputes the arguments of the Appellant.

Findings of the Board of Appeal

106. 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 79 above, paragraphs 51 to 56, 76 to 83, 174 and 175 of the decision).

107. As stated in paragraph 4 above, during the course of the data and cost-sharing negotiations, the Appellant and the Data Claimant discussed two possibilities: the opt-out agreement and the letter of access agreement. The Appellant's pleas concern both of those agreements.

2.3.1. Opt-out agreement

108. On several occasions during the data and cost-sharing negotiations, the Appellant and the Data Claimant discussed the opt-out agreement. As part of their contractual freedom, the parties to a data and cost-sharing negotiation are entitled to conclude such an agreement.

109. However, in the present case, the Data Claimant consistently refused to accept the conditions of the opt-out agreement, in particular on the ground that that agreement did not include a reimbursement mechanism. There was therefore no agreement between the parties as regards the exclusion of a reimbursement mechanism and the Appellant was not entitled to impose unilaterally such an exclusion.

110. Contrary to the Appellant's claims during the data and cost-sharing negotiations and the appeal proceedings, a reimbursement mechanism must be included in a cost-sharing model under Article 2(1)(c) of Implementing Regulation 2016/9, unless the parties agree otherwise. In the present case, as stated in the previous paragraph, there was no such agreement to exclude a reimbursement mechanism.

111. Consequently, the Data Claimant's refusal to accept an opt-out agreement without a reimbursement mechanism cannot be seen as the cause of the failure of the negotiations insofar as the Data Claimant insisted on continuing the negotiations within the limits of the mandatory requirements of data and cost-sharing, in particular with the inclusion of a reimbursement scheme.

112. In view of the above, the Agency did not commit an error of assessment in concluding that '*by not demonstrating willingness to discuss the [Data] Claimant's […] request for a reimbursement scheme, the [Appellant] effectively blocked the negotiations and thereby the possibility for a common agreement. In doing so, the [Appellant] failed to make every effort to reach an agreement between the Parties'*.

2.3.2. Letter of access agreement

2.3.2.1. Itemisation of administrative costs

113. The Appellant considers that the Agency committed an error of assessment in concluding that the Appellant did not make every effort to reach an agreement with the Data Claimant with regard to the itemisation of administrative costs in the letter of access agreement.

114. It is necessary to first examine whether, in the light of the Data Claimant's requests and objections, the Appellant complied with the requirement for data and cost-sharing to be transparent.

115. 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 79 above, paragraphs 77 and 78 of the decision).

116. Contrary to the Appellant's claims, the Data-Claimant consistently responded to the Appellant's arguments in detail. Although the parties disagreed about the itemisation of the administrative costs, as stated in the Contested Decision, they explained clearly their positions.

117. The Appellant made some efforts in itemising the administrative costs. However, in this respect, it mainly referred to a '*Cost Allocation Policy*' document (see for example the email of 21 December 2017). The Appellant also asked the Data Claimant to pay a fee (the 'fee') to continue the discussions.

118. The Data Claimant argued that the '*Cost Allocation Policy*' referred to by the Appellant did not sufficiently clarify the administrative costs and did not, for example, specify what was included as '*consulting costs*'. The Data Claimant asked similar specific questions in its email of 22 December 2017.

119. In response to the Data Claimant's requests for clarification, the Appellant stated that no further itemisation was possible (see for example the Appellant's email of 10 January 2018). The Appellant also sent an invoice for the fee stating that no other steps could be taken until the Data Claimant paid the fee (see the Appellant's emails of 15 and 16 January 2018). As shown in the email of 16 January 2018, the Data Claimant reluctantly paid the fee. The Appellant did not further itemise the administrative costs.

120. The requirement to pay the fee before the negotiations could proceed was not justified and constituted an abuse by the Appellant since, if the Data Claimant refused to pay a sum that had not been objectively justified, the negotiations would have been blocked.

121. It follows from the above that, despite the Data Claimant's requests and objections, the Appellant did not comply with the requirement for data and cost-sharing to be transparent.

2.3.2.2. Data and cost-sharing with affiliates

122. In order to comply with the requirements for data and cost-sharing to be non-discriminatory, registrants that are in comparable situations must not be treated differently and registrants who are in different situations must not be treated in the same way unless such treatment is objectively justified (see *REACH & Colours and REACH & Colours Italia*, cited in paragraph 79 above, paragraphs 82 and 83 of the decision).

123. Pursuant to Articles 3(9) and (11), and 6(1), each natural or legal person who manufactures or imports a substance in quantities above one tonne per year is required to submit its own registration for that substance to the Agency. This also applies to legal persons which are affiliates of another registrant of the same substance.

124. Moreover, in accordance with the first subparagraph of Article 4(2) of Implementing Regulation 2016/9, the terms for data and cost-sharing for a substance must apply to all registrants of that substance, including the possibility of future registrants joining at a later stage.

125. The provisions referred to in the previous two paragraphs demonstrate that all present and future registrants of a substance are in a comparable situation as regards data and cost-sharing.

126. Under the Appellant's cost-sharing model in the letter of access agreement, registrants who are affiliates of a previous registrant are not required to bear a share of costs if they submit their own registration dossier to the Agency. This cost-sharing model therefore treats registrants that are in comparable situations differently depending on whether or not they are the affiliates of another registrant (see Joined Cases A-014-2018 to A-021-2018, *Tecnofluid*, Decision of the Board of Appeal of 23 July 2020, paragraphs 62 to 71).

127. This difference in treatment may be objectively justified if there are particular reasons for allowing a specific affiliate to submit its own registration dossier to the Agency without paying a share of the costs of the information required for registration purposes. However, a general and absolute exemption of all affiliates of all registrants from the requirement to pay a share of the costs of the information required for registration purposes is not objectively justified. In the present case, there was not such a justification. The fact that the REACH Regulation and Agency's Guidance does not explicitly prohibit such a difference in treatment does not constitute a justification.

128. By insisting that the Data Claimant accept such a term as part of the letter of access agreement, the Appellant did not make every effort to agree on a cost-sharing model which would be non-discriminatory.

129. The Appellant's cost-sharing model consequently did not comply with the requirements for data and cost-sharing to be non-discriminatory.

2.3.2.3. Conclusion on the letter of access agreement

130. In view of the conclusions in Sections 2.3.2.1. and 2.3.2.2. above, in negotiating the letter of access agreement, the Appellant failed to comply with the requirements for data and cost-sharing to be transparent and non-discriminatory. In addition, the requirement to pay the fee before the negotiations could proceed was not justified and constituted an abuse by the Appellant (see paragraphs 117 to 120 above). The Agency did not therefore commit an error of assessment in concluding that the Appellant '*did not make every effort to agree on a cost-sharing model which would be fair, transparent and non-discriminatory*'.

2.3.3. Conclusion on the Appellant's second and third pleas

131. By proposing two possibilities (the opt-out agreement and the letter of access agreement) that were not in compliance with data and cost-sharing requirements, the Appellant did not comply with the objective obligations imposed on it by Implementing Regulation 2016/9, and therefore did not make every effort and caused the failure of the negotiations.

132. The second and third pleas must consequently be rejected.

Overall conclusion

133. As all the Appellant's pleas have been rejected as either unfounded or inadmissible, the appeal must be dismissed.

Refund of the appeal fee

134. 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