EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

23 July 2020

(Article 30(3) of the REACH Regulation – Article 5 of Implementing Regulation 2016/9 – Permission to refer to studies on vertebrate animals – Requirements for data and cost-sharing to be transparent, fair and non-discriminatory)

Case numbers	Joined Cases A-014-2018 to A-021-2018
Language of the cases	English
Appellant	Tecnofluid S.r.l., Italy
Interveners	Quaker Chemical BV, the Netherlands (A-014-2018) Industrial Quimica Lasem, S.A.U., Spain (A-015-2018) Croda Nederland BV, the Netherlands (A-016-2018, A-020-2018) BASF Personal Care and Nutrition GmbH, Germany (A-017-2018) OLEON N.V., Belgium (A-018-2018, A-021-2018) NYCO-STPC, Belgium (A-019-2018) All represented by: Ruxandra Cana, Eléonore Mullier and Filippo Mattioli Steptoe & Johnson LLP, Belgium
Contested Decisions	DSH-30-3-D-0148-2017 (A-014-2018) DSH-30-3-D-0149-2017 (A-015-2018) DSH-30-3-D-0150-2017 (A-016-2018) DSH-30-3-D-0151-2017 (A-017-2018) DSH-30-3-D-0152-2017 (A-018-2018) DSH-30-3-D-0153-2017 (A-019-2018) DSH-30-3-D-0154-2017 (A-020-2018) DSH-30-3-D-0155-2017 (A-021-2018) All adopted by the European Chemicals Agency on 25 May 2018 pursuant to Article 30(3) 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 BOARD OF APPEAL

composed of Antoine Buchet (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Angel-Manuel Moreno (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. These appeals concern the sharing of data and costs for the registration of the following eight substances (the 'Substances'):

   - fatty acids, C16 and C18-unsatd., triesters with trimethylolpropane (A-014-2018, EC No 270-287-7),
   - fatty acids, C16-18 and C18 unsatd., triesters with trimethylolpropane (A-015-2018, EC No 268-092-7),
   - fatty acids, C18-unsatd., diesters and triesters with trimethylolpropane (A-016-2018, EC No 701-042-9),
   - fatty acids, C8-10, triesters with trimethylolpropane (A-017-2018, EC No 293-036-3),
   - fatty acids, C8-10-(even numbered), diesters and triesters with trimethylolpropane (A-018-2018, EC No 812-652-0),
   - pentaerythritol tetraesters of decanoic acid, heptanoic acid, octanoic acid and valeric acid (A-019-2018, EC No 701-020-9),
   - pentaerythritol tetraoleate (A-020-2018, EC No 242-960-5), and
   - 2,2-dimethyl-1,3-propanediyl dioleate (A-021-2018, EC No 255-713-1).

2. The Appellant is a potential registrant of the Substances. The Interveners are the lead registrants for the Substances.

3. The information contained in the Interveners' registration dossiers was gathered and/or generated by a '*consortium*' which '*managed*' the substance information exchange fora ('SIEFs') for a group of 51 substances (the 'Polyol Category') including the Substances. The registration of the Substances is based on a category approach covering the entire Polyol Category, in accordance with Section 1.5. of Annex XI to the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise).

4. Between 2014 and 2017, data and cost-sharing negotiations took place between the Appellant and the Interveners. During the course of these negotiations the Appellant and the Interveners disagreed on two elements, (i) the itemisation of data and costs, and (ii) the status of registrants' affiliates.

5. By the end of the negotiations, the respective positions of the Appellant and the Interveners on these two elements were as follows.

6. First, the Appellant requested the Interveners to provide it with an itemisation of data and costs for the registration of the eight Substances (notably, emails of 9 June 2016 at 11:55 CET; 30 June 2016 at 14:29 CET; 20 July 2016 at 11:06 CET; 2 September 2016 at 11:42 and 15:04 CET; 27 June 2017 at 14:41 CET; 30 June 2017 at 14:55 CET; 13 July 2017 at 15:08 CET; 21 July 2017 at 11:25 CET; 31 July 2017 at 11:56 CET; 5 September 2017 at 15:41 CET; and 28 November 2017 at 15:53 CET).

7. The Interveners provided the Appellant with a list of the studies which they considered relevant for the registration of each of the eight Substances. This list included a figure representing the cost for each information endpoint and an indication of the information requirement in Annexes VII to X to which each of the listed studies applied (notably, document dated 9 June 2016). The Interveners also provided the Appellant with the index and introductory section of a '*category justification document*' setting out the category approach for the registration of the Polyol Category (email of 2 September 2016 at 12:29 CET).

8. Second, the Interveners proposed that the costs of the information required for the registration of the substances in the Polyol Category – including the eight Substances – should be shared among the registrants of all the substances in that category. However, registrants' affiliates would not be required to pay a share of the costs if they submit their own registration dossier to the Agency (notably, emails of 14 July 2017 at 17:11 CET; 24 November 2017 at 16:02 CET; and 30 November 2017 at 17:49 CET).

9. The Appellant objected to the Interveners' proposal on the grounds that it is discriminatory. According to the Appellant, registrants' affiliates should pay a share of the costs if they submit their own registration dossier to the Agency (notably, e-mails of 30 June 2017 at 15:40 CET; 13 July 2017 at 15:27 CET; 5 September 2017 at 15:41 CET; and 11 September 2017 at 15:32 CET).

Contested Decisions

10. On 12 December 2017, the Appellant submitted to the Agency applications for permission to refer to the studies on vertebrate animals contained in the Interveners' registration dossiers for the Substances, in accordance with Article 30(3).

11. On 25 May 2018, the Agency adopted the Contested Decisions.

12. The Contested Decisions are based on Article 30(3), as implemented by 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').

13. In the Contested Decisions, the Agency found that the Appellant had failed to make every effort to find an agreement on data and cost-sharing with the Intervener. The Agency therefore rejected the Appellant's applications for permission to refer.

Procedure before the Board of Appeal

14. On 9 August 2018, the Appellant filed these appeals.

15. On 27 September 2018, the Board of Appeal joined the appeals for the purposes of the written and oral parts of the procedure, and the final decision.

16. On 12 October 2018, the Agency filed its Defence.

17. On 23 January 2019, the Appellant submitted observations on the Defence.

18. On 15 April 2019, Quaker Chemical BV, Industrial Quimica Lasem, S.A.U., Croda Nederland BV, BASF Personal Care and Nutrition GmbH, OLEON N.V., and NYCO-STPC (the 'Interveners') were granted leave to intervene in support of the Agency.

19. On 28 June 2019, the Interveners submitted a statement in intervention.

20. On 29 July 2019, the Agency submitted observations on the Appellant's observations on the Defence.

21. On 22 August and 5 September 2019 respectively, the Appellant and the Agency submitted observations on the statement in intervention.

22. On 27 February 2020, a hearing took place at the Appellant's request. The hearing was held by video-conference in accordance with Article 13(7) 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'). At the hearing, the Appellant, the Agency and the Interveners made oral submissions and answered questions from the Board of Appeal.

23. On 15 May 2020, Mr Angel-Manuel Moreno, alternate member of the Board of Appeal, was appointed to replace Ms Sari Haukka in this case, in accordance with the first subparagraph of Article 3(2) of the Rules of Procedure.

24. 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. Mr Angel-Manuel Moreno and the other two members of the Board of Appeal also agreed not to hold the hearing again.

Forms of order sought

25. The Appellant requests the Board of Appeal to:

- annul the Contested Decisions,
- grant the Appellant permission to refer to the relevant studies,
- order the Agency to require the Interveners to include in their registration dossiers for the Substances any relevant robust study summaries which may be missing from those dossiers,
- order the refund of the appeal fees, and
- take such other or further measures as justice may require.

26. The Agency, supported by the Interveners, requests the Board of Appeal to:

- dismiss the appeals as inadmissible insofar as the Appellant requests the Board of Appeal to order the Agency to require the Interveners to include in their registration dossiers any relevant robust study summaries which may be missing from those dossiers, and
- dismiss the appeals as unfounded for the remainder.

Reasons

1. Admissibility

27. According to the Appellant, the Interveners' registration dossiers do not contain summaries of all the studies that justify and support the category approach applied for the registration of the Polyol Category, including the Substances. The Appellant therefore requests the Board of Appeal to order the Agency to require the Interveners to include in their registration dossiers any relevant robust study summaries which may be missing from those dossiers.

28. The Agency and the Interveners contest the admissibility of this request.

29. Pursuant to Article 93(3), following its examination of a case the Board of Appeal may exercise any power that lies within the competence of the Agency or remit the case to the competent body of the Agency for further action.

30. This provision must, however, be interpreted and applied within the limits of the decision of the Agency that is contested before the Board of Appeal.

31. First, Article 93(3) does not empower the Board of Appeal to take a decision that would go beyond the scope of the decision of the Agency that is contested before it. A decision that, as in the present case, concerns the sharing of data and costs for the registration of a substance, can only be replaced by a decision on the same subject-matter.

32. The inclusion in the Interveners' registration dossiers of any relevant robust study summaries which may be missing from those dossiers does not concern the sharing of data and costs for the registration of the Substances, and therefore goes beyond the scope of the Contested Decisions.

33. Second, Article 93(3) must be read in conjunction with the provision on which a contested decision is based. If – as in the present case – a contested decision is based on Article 30(3), the Board of Appeal may only exercise the powers that the Agency has under that provision.

34. Under Article 30(3), the Agency has no power to require registrants to include in their registration dossiers any relevant robust study summaries which may be missing from those dossiers. Consequently, the Board of Appeal cannot grant the Appellant's request in the present case.

35. The Appellant's request must therefore be rejected as inadmissible.

2. Substance

36. The Appellant raises twelve pleas in support of each of its appeals, namely that the Agency:

- breached an essential procedural requirement because the Contested Decisions were adopted by the Director of Registration of the Agency without a valid delegation of powers from the Executive Director (first plea),
- unlawfully suspended the decision-making process on the Appellant's applications for permission to refer, between December 2017 and March 2018, during an intervention by the Agency's '*Ambassador for small and medium enterprises*' (second plea),
- applied an incorrect test in assessing whether to grant the Appellant's applications for permission to refer (third plea),
- breached Article 5 of Implementing Regulation 2016/9, in conjunction with Articles 2 and 4 of that regulation (fifth and sixth plea),
- committed several errors in its assessment of the facts of the case (fourth, seventh, eighth, ninth, eleventh, and twelfth plea), and
- breached the principle of the protection of legitimate expectations by failing to comply with its own Guidance on data-sharing (Version 3.1, January 2017; tenth plea).

37. The Board of Appeal will first examine the third, fifth and sixth pleas.

Arguments of the parties

38. By its third, fifth and sixth pleas, the Appellant argues, in essence, that the Agency breached Article 5 of Implementing Regulation 2016/9. According to the Appellant, the Agency should have granted the Appellant's applications for permission to refer because the Interveners insisted on terms for data and cost-sharing which were not transparent and were discriminatory.

39. The Agency argues that, when determining whether to grant an application for permission to refer, it is required to assess and balance the efforts of both parties. According to the Agency, on the one hand, the Interveners failed to comply with the requirements for data and cost-sharing to be transparent, and failed to establish that they complied with the requirements for data and cost-sharing to be non-discriminatory. On the other hand, the Appellant's conduct during the negotiations shows that it did not have '*a real intention to find an agreement*'. On balance, when assessing the efforts of the Appellant and the Interveners, the Agency therefore decided to refuse the Appellant's applications for permission to refer.

40. The Interveners argue that they complied with the requirements for data and cost-sharing to be transparent. The Interveners further argue that the terms they proposed for data and cost-sharing with regard to affiliates are non-discriminatory. The Appellant's affiliates, if any, would not be required to pay a share of costs of the information required for registration purposes. Moreover, any difference in treatment between affiliates and registrants who are not affiliates is justified because (i) the Agency's Guidance does not prohibit such a difference in treatment, and (ii) excluding affiliates from sharing in the costs of the information required for registration purposes reduces the administrative burden in the management of the SIEFs for the substances in the Polyol Category.

Findings of the Board of Appeal

41. 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, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, Decision of the Board of Appeal of 15 April 2019, paragraphs 51 to 56, 76 to 83, 174 and 175).

42. This assessment should centre upon 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 the previous paragraph, paragraph 88).

43. In the present case, the Appellant and the Interveners could not agree on (i) the itemisation of data and costs, and (ii) the status of registrants' affiliates.

44. The Board of Appeal will therefore examine whether, in light of the Appellant's requests and objections, the Interveners complied with the requirements for data and cost-sharing to be transparent, fair and non-discriminatory with regard to those elements.

2.1. The itemisation of data and costs

45. The Appellant requested the Interveners to provide it with an itemisation of data and costs (see paragraph 6 above).

46. In order to comply with the requirements for data and cost-sharing to be transparent, a previous registrant must provide, on request from a potential registrant, clear and comprehensible explanations on (i) which information is to be shared and on what basis, (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 41 above, paragraphs 77 and 78).

47. Specifically, as regards the first of these elements, Article 2(1)(a) and (2) of Implementing Regulation 2016/9 requires a previous registrant to provide a potential registrant, on request, with '*[an] itemisation of data to be shared, including the cost of each data item, a description indicating the information requirements in the REACH Regulation to which each cost corresponds and a justification of how the data to be shared satisfies the information requirement*'.

48. First, therefore, the Interveners were required to provide the Appellant with a list of the available information relevant for the registration of the Substances ('*itemisation of data to be shared*').

49. The Interveners provided the Appellant with a list of the key studies which they considered relevant for the registration of the Substances. This was not, however, a complete list of the available information relevant for the registration of the Substances.

50. As a consequence, the Appellant could not verify whether it agreed with the Interveners' selection of the key studies among all the information available for the registration of the Substances.

51. Second, the Interveners were required to provide the Appellant with the cost of each piece of information ('*the cost of each data item*').

52. The Interveners listed an aggregated figure for each information endpoint. They did not, however, list the cost of each available study, or even of each key study.

53. As a consequence, the Appellant could not verify whether the listed figures correspond to the actual cost of the studies needed for registration purposes.

54. Third, as the Substances are registered on the basis of adaptations under Section 1.5. of Annex XI, the Interveners were required to provide the Appellant with a detailed justification for the adaptations, and the information and evidence supporting them ('*justification of how the data to be shared satisfies the information requirement*').

55. The Interveners provided the Appellant with an extract from a '*category justification document*' setting out the category approach for the registration of the Polyol Category. This extract did not, however, contain the detailed justification for the category approach, nor the information and evidence supporting it.

56. As a consequence, the Appellant could not verify whether it agrees with the Interveners' adaptation and the selection of the information required, or whether it wishes instead to rely on opt-outs pursuant to Article 11(3).

57. It follows that the Interveners failed to comply with the requirements for data and cost-sharing to be transparent as regards the itemisation of data and costs.

2.2. The status of registrants' affiliates

58. The Interveners proposed that registrants' affiliates should not be required to pay a share of the costs of the information required for registration purposes if they submit their own registration dossier to the Agency. The Appellant objected to the Interveners' proposal on the grounds that it was discriminatory.

59. The assessment of the terms for data and cost-sharing must be carried out in a logical sequence. First, it is necessary to assess if the previous registrant has been transparent, and the terms it proposes are therefore clear and comprehensible. If so, second, it is 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 41 above, paragraph 85).

60. The Interveners provided clear and comprehensible explanations of their proposed terms or sharing data and costs as regards the status of registrants' affiliates. They therefore complied, to this extent, with the requirements for data and cost-sharing to be transparent.

61. It is therefore possible to assess whether, in light of the Appellant's objections during the data and cost-sharing negotiations, the Interveners' approach to data and cost-sharing as regards the status of registrants' affiliates is non-discriminatory.

62. According to the terms for data and cost-sharing proposed by the Interveners, registrants' affiliates are not required to pay a share of the costs if they submit their own registration dossier to the Agency.

63. 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 41 above, paragraphs 82 and 83).

64. 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.

65. Moreover, pursuant to 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.

66. These provisions demonstrate that all present and future registrants of a substance are in a comparable situation as regards data and cost-sharing.

67. The Interveners therefore proposed to treat registrants that are in comparable situations differently depending on whether they are the affiliates of another registrant or not.

68. 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.

69. 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.

70. First, contrary to the Interveners' arguments, the fact that the Agency's Guidance does not expressly prohibit a difference in treatment between registrants, depending on whether they are the affiliates of another registrant or not, does not constitute a justification.

71. Second, the administrative burden of involving registrants' affiliates in the sharing of costs does not justify the difference in treatment because administrative costs are in themselves subject to compensation among all registrants.

72. The Interveners consequently failed to comply with the requirements for data and cost-sharing to be non-discriminatory as regards the status of registrants' affiliates.

2.3. Result

73. The Interveners failed to comply with the requirements for data and cost-sharing to be transparent and non-discriminatory (see Sections 2.1. and 2.2. above).

74. This is reflected in the Contested Decisions:

'*[W]hilst the [Appellant] repeatedly requested the identification and itemisation of the studies whose costs they were asked to share, the [Interveners] failed to provide this information. [The Agency] considers that the failure of the Other Party to provide this information cannot be justified […].*

[…]

In relation to the affiliates' issue raised by the [Appellant], [the Agency] notes that the [Interveners] did not adequately justify how concretely the participation of affiliates in the cost sharing for the substance complies with the fairness, transparency and non-discrimination criteria.'

75. The Agency did not, however, grant the Appellant's applications for permission to refer in consequence of these findings. Instead, it '*balanced*' or weighed the efforts of the parties against each other. On the one hand, according to the Agency, the Interveners failed to comply the requirements for data and cost-sharing to be transparent and non-discriminatory. On the other hand, according to the Agency, the Appellant's behaviour during the negotiations shows that it did not have '*a real intention to find an agreement*'. On balance, the Agency consequently rejected the Appellant's applications for permission to refer.

76. The Agency's approach is not supported by the relevant legislation for the following reasons.

77. First, 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 paragraph 41 above).

78. Neither the REACH Regulation nor Implementing Regulation 2016/9 contain any provision indicating that, when examining an application for permission to refer, the Agency should '*balance*' a previous registrant's breach of the requirements for data and cost-sharing to be fair, transparent and non-discriminatory against a potential registrant's '*real intention to find an agreement*'.

79. Second, Article 5 provides that a substance may not be placed on the market unless it has been registered, if required, in accordance with the provisions of the REACH Regulation. Articles 10(a) and 25(3) establish a protection period of 12 years during which registrants cannot refer to information submitted by other registrants without first obtaining permission to refer and paying a share of the cost. Articles 25(1), 27(1)(a) and 30(1) require registrants to refer to studies on vertebrate animals, if they exist.

80. These provisions would, on their own, make it possible for previous registrants to impose unfair or discriminatory conditions on potential registrants for the sharing of data and costs, or withhold market access from them.

81. It is clear, therefore, that the objective of the procedure for obtaining permission to refer from the Agency under Article 30(3) is to prevent previous registrants from imposing unfair or discriminatory conditions on potential registrants for the sharing of data and costs, or to withhold market access from them, whilst ensuring that studies on vertebrate animals are not repeated.

82. Following the Agency's approach – the '*balancing*' of efforts – in order to obtain permission to refer a potential registrant must adopt a behaviour that shows '*a real intention to find an agreement*' even if a previous registrant insists on terms which are not transparent, fair and non-discriminatory.

83. This allows previous registrants to draw out the negotiations for a considerable period of time, effectively until the potential registrant has explored every possible avenue to achieve an agreement.

84. As a substance cannot in principle be placed on the market before it is registered, and cannot be registered without permission to refer, the Agency's approach creates an incentive for potential registrants to accept the terms for data and cost-sharing proposed by previous registrants even if those terms are not transparent, fair and non-discriminatory.

85. The Agency's approach – the '*balancing*' of efforts – may therefore make it possible for previous registrants to impose unfair or discriminatory conditions on potential registrants for the sharing of data and costs, or to withhold market access from them. Consequently, the Agency's approach goes against the objective of permissions to refer under Article 30(3).

86. Third, the principle of legal certainty is a general principle of EU law. It requires, amongst other things, that European Union legislation must be applied in a way that is foreseeable by those subject to it (see judgments of 15 September 2005, *Ireland* v *Commission*, C-199/03, EU:C:2005:548, paragraph 69, and of 11 May 2017, *Deza* v *ECHA*, T-115/15, EU:T:2017:329, paragraph 135; see also Case A-006-2016, *SI Group UK and Others*, Decision of the Board of Appeal of 6 June 2018, paragraph 100).

87. Implementing Regulation 2016/9 sets out objective criteria for the Agency's assessment of an application for permission to refer, namely the requirements of transparency, fairness and non-discrimination for any data and cost-sharing agreement. The parties can foresee the outcome of the application of those criteria by the Agency.

88. By contrast, determining whether a potential registrant has '*a real intention to find an agreement*' involves a discretionary assessment of the subjective intention of a potential registrant on the basis of its behaviour. The parties cannot easily foresee the outcome of this assessment by the Agency.

89. If a previous registrant fails to comply with the requirements for data and cost-sharing to be transparent, fair and non-discriminatory, there is no need for the Agency to examine the potential registrant's subjective intention in refusing those terms. By carrying out this assessment, the Agency introduces an element of uncertainty in situations where certainty has been established by the applicable legislation.

90. The Agency's approach – the subjective 'balancing' of efforts even in situations where the terms proposed are objectively incompatible with the legal requirements for data and cost-sharing to be transparent, fair and non-discriminatory – undermines the principle of legal certainty.

91. Fourth, the Board of Appeal has held that the Agency's assessment must be '*balanced*' in the sense that it must be carried out on the basis of the negotiations as a whole, taking into account the actions of both parties to the negotiations and all other relevant circumstances (see *REACH & Colours and REACH & Colours Italia*, paragraph 86).

92. These findings do not mean that the Agency is to '*balance*' the parties' efforts against each other. These findings refer to the case-law of the EU Courts according to which, when exercising its discretion, the Agency must examine carefully and impartially all the relevant aspects of an individual case (see, to this effect, judgments of 6 November 2008, *Netherlands* v *Commission*, C-405/07 P, EU:C:2008:613, paragraph 56, and of 20 September 2019, *PlasticsEurope* v *ECHA*, T-636/17, EU:T:2019:639, paragraph 129, currently under appeal on other grounds).

93. If a previous registrant fails to comply with the requirements for data and cost-sharing to be transparent, fair and non-discriminatory, the Agency should not '*balance*' that failing against other considerations, such as whether the potential registrant had '*a real intention to find an agreement*'.

94. In the present case, the terms for data and cost-sharing proposed by the Interveners were not transparent or non-discriminatory. There was therefore no need for the Agency to examine the Appellant´s subjective intention in refusing those terms.

95. It follows from all of the reasons set out above that the Agency failed to comply with Article 5 of Implementing Regulation 2016/9 because it rejected the Appellant's applications for permission to refer when the Interveners failed to comply with the requirements for data and cost-sharing to be transparent and non-discriminatory.

96. The third, fifth and sixth pleas must therefore be upheld, and the Contested Decisions annulled. There is no need to examine the remaining pleas.

97. Pursuant to Article 93(3), following its examination of a case the Board of Appeal may exercise any power that lies within the competence of the Agency or remit the case to the competent body of the Agency for further action.

98. In the present case there is a degree of uncertainty over which studies are contained in the Interveners' registration dossiers (see paragraph 27 above). In order to adopt a decision granting the Appellant permission to refer, the Board of Appeal would need to examine the content of the registration dossiers in question. However, those dossiers are not available to the Board of Appeal.

99. The present cases must therefore be remitted to the competent body of the Agency, which shall grant the Appellant permission to refer to the relevant studies.

Refund of the appeal fees

100. The appeal fees are refunded pursuant to 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).

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeals as inadmissible insofar as the Appellant requests the Board of Appeal to order the Agency to require the Interveners to include in their registration dossiers any relevant robust study summaries which may be missing from those dossiers.**
2. **Annuls the Contested Decisions.**
3. **Remits the cases to the competent body of the Agency, which shall grant the Appellant permission to refer to the relevant studies.**
4. **Decides that the appeal fees are refunded.**

Andrew FASEY
On behalf of the Chairman of the Board of Appeal

Luca BOLZONELLO
On behalf of the Registrar of the Board of Appeal