EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

15 April 2019

(Data-sharing dispute – Article 30 – Assessment of 'every effort' – Requirements for data and cost sharing to be fair, transparent and non-discriminatory)

Case number	A-010-2017
Language of the case	English
Appellants	REACH & Colours Kft, Hungary REACH & Colours Italia S.r.l., Italy
Representatives	Ruxandra Cana, Eléonore Mullier and Hannah Widemann Steptoe & Johnson LLP, Belgium
Interveners	Colorex S.r.l., Italy Codyeco S.p.a., Italy Colortex S.p.a., Italy Triade B.V., the Netherlands Represented by: Ralf Knauf Centro Reach S.r.l., Italy and Claudio Mereu Fieldfisher LLP, Belgium
Contested Decision	DSH-30-3-D-0086-2017 of 20 July 2017 adopted by the European Chemicals Agency 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; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation')

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Sari Haukka (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

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Background to the dispute

1. This appeal concerns a dispute on the sharing of data, and associated costs, related to the substance sodium 4-[(2-hydroxy-1-naphthyl)azo]benzenesulphonate (EC No 211-199-0, CAS No 633-96-5; 'Acid Orange 7' or the 'Substance').

2. This appeal was filed jointly by REACH & Colours Kft and REACH & Colours Italia S.r.l. REACH & Colours Kft is the lead registrant for Acid Orange 7. REACH & Colours Italia S.r.l. represents several consortia which manage the substance information exchange forum ('SIEF') for Acid Orange 7 and also manages SIEFs for over 500 other dyes.

3. Between 9 November 2012 and 12 April 2017, data-sharing negotiations took place concerning Acid Orange 7. These negotiations are reflected in the documents submitted to the Agency during the course of the data-sharing dispute procedure, and to the Board of Appeal in these proceedings. These negotiations took place mainly between the Appellants and Centro Reach S.r.l.

4. Centro Reach S.r.l. informed the Appellants that it was acting on behalf of a group of companies called the '*Dye-Staff Cooperation Group*' and that the Interveners were members of this group (notably, emails and letters of 14 January 2013, 5 November 2015, and 21 December 2016).

5. Two of the Interveners, Colorex S.r.l. and Codyeco S.p.a., also had individual email exchanges with the Appellants.

6. During the course of their negotiations, the Appellants and the Interveners disagreed on the following four aspects of the terms for sharing data and costs:

   - the identification of the studies to which access was being negotiated,
   - the calculation of the costs of gathering and submitting to the Agency the information required for the registration of Acid Orange 7('administrative costs'),
   - an annual surcharge of eight percentage points applied to the price of a letter of access (the '8% annual surcharge'), and
   - a surcharge of 15% (the '15% surcharge'). This is 15% of the value given to each study, regardless of how this value was calculated. In practice, the value of each study was halved on the basis that it could be used for REACH purposes only. The 15% surcharge was then added to the halved study value. The resulting figure – equal to a 35% discount on the value of each study – then formed the basis for the Appellants' calculation of the price of a letter of access.

7. With regard to these four aspects, the data-sharing negotiations developed as follows.

Identification of the studies to which access was being negotiated

8. The Interveners requested the Appellants to identify precisely the information which REACH & Colours Kft had submitted to the Agency in its registration dossier. More specifically, the Interveners requested the Appellants to provide them with the titles and authors of all the studies contained in the registration dossier (notably, emails and letters of 29 October 2015, 28 October 2016 [Colorex S.r.l.], 30 November 2016, 21 December 2016, 27 January 2017, 4 February 2017, 21 February 2017, 22 March 2017, and 12 April 2017).

9. On 14 December 2016, the Appellants provided the Interveners with a table indicating for each study to which access was being negotiated:
   - the Annex and information requirement in the REACH Regulation to which the study relates,
   - the test method used,
   - the reliability of the study (the 'Klimisch score'),
   - whether the study was published or not, and
   - the year in which each study was conducted.
10. On 10 February 2017, the Appellants also provided the Interveners with information on Acid Orange 7 that was already publicly available on the Agency's dissemination website.

Calculation of administrative costs

11. The Interveners requested the Appellants to explain how the administrative costs were calculated, and argued that the Appellants' calculation was not fair because it included costs that were not related to the information needed for the Interveners' own registrations (notably, emails and letters of 28 September 2016 [Colorex S.r.l.], 7 October 2016 [Colorex S.r.l.], 27 October 2016 [Colorex S.r.l.], 28 October 2016 [Colorex S.r.l.], 10 November 2016 [Codyeco S.p.a.], 30 November 2016, 21 December 2016, 27 January 2017, 4 February 2017, 21 February 2017, 22 March 2017, and 12 April 2017).
12. The Appellants explained that they managed the registration of over 500 dyes. It was consequently impracticable to identify administrative costs by study or information requirement (notably, emails and letters of 11 October 2016 [to Colorex S.r.l.], 27 October 2016 [to Colorex S.r.l.], 14 December 2016, and 10 February 2017).
13. The Appellants did however provide the Interveners with a breakdown of the costs incurred for the registration of Acid Orange 7, including a breakdown of administrative costs (two tables shared on 29 April 2016 and 14 December 2016 respectively). The Appellants' cost breakdown listed the activities which the Appellants considered to be administrative, and gave for each activity a description and the number of hours spent. These activities included:
   - '*[f]ace to face meetings, conference calls, mail exchange and discussions among Consortia Members*' and '*Financial management of the Consortia. Financial activities with the SIEF not arising into a LoA [letter of access] sale, including all explanations about costs and cost sharing criteria*',
   - the '*preparation of waiving proposals*' for, amongst others, '*repeated inhalation tox[icity]*' and '*repeated dermal tox[icity]*',
   - the '*[g]eneration of testing proposals if required by the REACH Regulation, contracting the studies in agreement with and on behalf of the companies*', and
   - the '*[p]erformance of a chemical safety assessment (CSA)*'.
14. The Appellants' cost breakdown sent on 14 December 2016 was accompanied by a cover letter. In this cover letter, the Appellants explained that '*the Consortia Members are preparing over 500 dossiers for the 2018 deadline, with all those who were willing to join the Consortia to contribute their work and expertise. The daily work of each lead registrant, of REACH & Colours Italia as consultant as well as the whole administration, is not focused on one substance at a time but several per day; every dossier takes months/years of work before its submission. Several activities concern different endpoints at the same time*'.

The 8% annual surcharge

15. The Interveners challenged whether there could be an annual surcharge, as well as the fact that it was set at 8%. They argued that the 8% annual surcharge is unfair and discriminatory (notably, emails and letters of 28 September 2016 [Colorex S.r.l.], 7 October 2016 [Colorex S.r.l.], 30 November 2016, 21 December 2016, 27 January 2017, 4 February 2017, 21 February 2017, and 22 March 2017).

16. The Appellants explained the reasons for requiring an annual surcharge, the reasons for setting it at eight percentage points, and that the proposed cost-sharing method included a reimbursement mechanism for the income derived from the 8% annual surcharge, as follows.

17. First, as regards the reasons for requiring an annual surcharge, the Appellants' explanations evolved during the course of the negotiations. Eventually, however, they explained that the annual surcharge was intended to compensate the following five elements (notably in presentations, emails and letters of 9 November 2015, 14 December 2016 and 30 March 2017):

    - the costs of managing and running the SIEF,
    - the costs incurred for meeting obligations under the REACH Regulation,
    - inflation,
    - the cost of money, as calculated on the basis of the rates set by the European Central Bank, and
    - the loss of the profit that would have been made if the money spent to generate, gather and submit to the Agency the information needed for the registration of Acid Orange 7 had been invested instead of being spent in order to comply with the REACH Regulation ('opportunity costs').

18. In addition, in a letter of 30 March 2017, the Appellants explained the reasons for requiring an annual surcharge as follows:

    '*[W]ith the aim to incentive [sic] the financial contribution from all interested parts, we inserted this surcharge which starts only the year after the submission and we redistribute these revenues to all previous co-registrants every year.'*

19. Second, as regards setting the annual surcharge at eight percentage points, the Appellants explained that this rate was, although not directly based on, modelled on the interest rate set out in Directive 2000/35/EC of the European Parliament and of the Council on combating late payment in commercial transactions (OJ L 200, 8.8.2000, p. 35; 'Directive 2000/35/EC'). In a letter of 30 March 2017, the Appellants argued that setting the annual surcharge at eight percentage points was '*consistent with [Directive 2000/35/EC] as it gives a shared, fair and unbiased value to the loss of profit deriving from the necessarily advanced investment in REACH, to be ready within the Tier III deadline in the interest of all co-registrants*'.

20. Third, as regards the reimbursement mechanism for the 8% annual surcharge, in two tables shared with the Interveners on 29 April 2016 and 14 December 2016 the Appellants explained :

    '*Money entering from new SM [SIEF members] will be reshared among previous registrants in the same proportion of what they paid before[.] If new SM will join later on, the next re-sharing will also include previous SM (+ CMs [consortium members]). Eventual 8% yearly surcharge (from 2017) on the [letter of access] value (C32-C35) will be also re-shared among all previous payers (CMs + SMs) – calculated every yea[r].'*

The 15% surcharge

21. The Interveners challenged the 15% surcharge as unfair (notably, emails and letters of 30 November 2016, 21 December 2016, 27 January 2017, 4 February 2017, 21 February 2017, and 22 March 2017).

22. The Appellants explained that the 15% surcharge was intended to achieve the following (notably, presentations, emails and letters of 17 January 2013, 9 November 2015, 14 December 2016, and 1 March 2017):

    - insure against the risk that the results of the studies could affect or prevent the future marketing of Acid Orange 7,
    - cover expenses for work performed in connection with the studies and creating robust study summaries (for example analytical work, monitoring of tests, relations with laboratories and keeping records), and
    - insure against the risk of inconclusive results requiring further work to re-design test protocols or repeat some or all of the studies.

The data-sharing dispute

23. The Appellants and the Interveners did not find an agreement on the sharing of data and costs. On 13 April 2017, having taken the view that the data-sharing negotiations had been unsuccessful, the Interveners filed a data-sharing dispute with the Agency.

24. On 20 July 2017, the Agency adopted the Contested Decision.

Contested Decision

25. The Contested Decision is based on Article 30(3) of the REACH Regulation.

26. In the Contested Decision, the Agency found that the Interveners had made every effort to ensure that data and costs were shared in a fair, transparent and non-discriminatory way, whilst the Appellants had failed to do so.

27. The Agency reached this conclusion primarily on the grounds that, despite repeated requests from the Interveners to that effect, the Appellants did not provide the Interveners with the titles and authors of the studies to which access was being negotiated, and failed to address the Interveners' concerns regarding the calculation of administrative costs, the 8% annual surcharge and the 15% surcharge.

28. The Contested Decision consequently grants the Interveners permission to refer to four studies on vertebrate animals contained in the registration dossier submitted by REACH & Colours Kft.

Procedure before the Board of Appeal

29. On 4 August 2017, the Appellants filed this appeal.

30. On 9 October 2017, the Agency filed its Defence.

31. On 11 December 2017, the Appellants submitted their observations on the Defence and responded to a request for information from the Board of Appeal.

32. On 20 December 2017, the Board of Appeal granted Colorex S.r.l., Codyeco S.p.a., Colortex S.p.a. and Triade B.V. leave to intervene in support of the Agency.

33. On the same date, the Board of Appeal rejected applications for leave to intervene submitted by the Ministry of Health of the Italian Republic and PETA International Science Consortium Ltd ('PISC').

34. On 11 January 2018, the Appellants submitted a position paper dated 10 November 2017 in which the Ministry of Health of the Italian Republic proposed to the Competent Authorities of the other Member States a strategy to help small and medium-sized enterprises register dyes such as Acid Orange 7.

35. On 25 January 2018, the Agency submitted its observations on the Appellants' observations on the Defence and responded to a question from the Board of Appeal.

36. On 16 February 2018, the Interveners submitted a statement in intervention.

37. On 26 February 2018, the Agency submitted observations on the position paper submitted by the Appellants on 11 January 2018 (see paragraph 34 above).

38. On 20 and 21 March 2018 respectively, the Appellants and the Agency submitted their observations on the statement in intervention.

39. On 15 May 2018, a hearing was held at the Appellants' request. At the hearing, the Parties and the Interveners made oral submissions and answered questions from the Board of Appeal.

Form of order sought

40. The Appellants request the Board of Appeal to:
    - declare the appeal admissible,
    - annul the Contested Decision,
    - order the refund of the appeal fee, and
    - take such other or further measures as justice may require.

41. The Agency, supported by the Interveners, requests the Board of Appeal to dismiss the appeal.

Reasons

1. Admissibility

42. The Agency argues that REACH & Colours Italia S.r.l. is not entitled to bring proceedings and requests the Board of Appeal to dismiss the case as inadmissible with regard to this Appellant.

43. The Agency does not contest, however, that the appeal is admissible insofar as it was filed by the other Appellant, REACH & Colours Kft.

44. There is consequently no need to examine whether REACH & Colours Italia S.r.l. is also entitled to bring proceedings.

2. Substance

45. The Appellants raise four pleas in law in support of their appeal. They allege that the Agency:

- made several errors in its assessment of the parties' efforts during the data-sharing negotiations,
- exceeded its powers by going beyond the requirements of the REACH Regulation and 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'),
- breached the principle of the protection of legitimate expectations by contravening the Agency's Guidance on data-sharing (version 3.1, January 2017), and
- breached the principle of equal treatment by preventing the Appellants from imposing the 8% annual surcharge and the 15% surcharge.

46. The Board of Appeal will first address the second plea.

2.1. Second plea: the Agency exceeded its powers

Arguments of the Parties

47. The Appellants argue that the Agency should not have assessed whether the terms proposed by the Appellants for sharing data and costs were fair and non-discriminatory. The Agency should have limited its assessment to the efforts of the parties to reach an agreement on sharing data and costs.

48. The Appellants rely, by analogy, on paragraph 111 of the Decision of the Board of Appeal of 4 April 2017 in Case A-001-2016, *Thor*. In that Decision, the Board of Appeal held that '*when assessing the every effort criterion under [Article 63(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1; the 'Biocidal Products Regulation')], the Agency is not entitled to assess the fairness, transparency and non-discriminatory nature of cost calculation methods employed by the parties to a data sharing dispute*'.

49. The Appellants also argue that the Agency exceeded its powers under the REACH Regulation and Implementing Regulation 2016/9 because the Contested Decision effectively obliges the Appellants to:

- disclose to potential registrants the titles and authors of studies,
- record and provide detailed information on administrative costs by endpoint or study,
- use a different method than the one they currently use to share costs among registrants, and
- forego compensation for certain kinds of costs, such as those covered by the 8% annual surcharge and the 15% surcharge.

50. The Agency, supported by the Interveners, argues that the Contested Decision does not create any of the obligations which the Appellants claim is the case.

Findings of the Board of Appeal

51. Article 30(1) of the REACH Regulation provides:

'*Before testing is carried out in order to meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF. If a relevant study involving tests on vertebrate animals is available within the SIEF, a participant of that SIEF shall request that study. If a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study.*

Within one month of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 77(2)(g). If they cannot reach such an agreement, the cost shall be shared equally. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements' (emphasis added).

52. Article 30(3) of the REACH Regulation provides:

'*If the owner of a study as referred to in paragraph 1 which involves testing on vertebrate animals refuses to provide either proof of the cost of that study or the study itself to (an) other participant(s), he shall not be able to proceed with registration until he provides the information to the other participants(s). The other participant(s) shall proceed with registration without fulfilling the relevant information requirement, explaining the reason for this in the registration dossier. The study shall not be repeated unless within 12 months of the date of registration of the other participant(s), the owner of this information has not provided it to them and the Agency decides that the test should be repeated by them. However, if a registration containing this information has already been submitted by another registrant, the Agency shall give the other participant(s) permission to refer to the information in his registration dossier(s). The other registrant shall have a claim on the other participant(s) for an equal share of the cost, provided he makes the full study report available to the other participant(s), which shall be enforceable in the national courts*' (emphasis added).

53. Articles 2 and 4 of Implementing Regulation 2016/9 reiterate that registrants and potential registrants of substances must make every effort to ensure that data and costs are shared on fair, transparent and non-discriminatory terms. Article 2 of Implementing Regulation 2016/9 sets out specific requirements for transparent data and cost-sharing. Article 4 of Implementing Regulation 2016/9 sets out specific requirements for fair and non-discriminatory data and cost sharing.

54. Article 5(1) of Implementing Regulation 2016/9 provides:

'*When settling a data-sharing dispute pursuant to Articles 27(5) and 30(3) of [the REACH Regulation], the Agency shall take account of the parties' compliance with the obligations set out in Articles 2 […] and 4 of this Regulation*.'

55. If the Agency is to take account of the parties' compliance with the requirements for data and cost sharing to be fair, transparent and non-discriminatory, then it must be able to assess whether the parties have complied with those requirements.

56. It therefore follows that under Article 5(1) of Implementing Regulation 2016/9, which implements Article 30(3) of the REACH Regulation, the Agency is competent to assess, following the submission of a data-sharing dispute, whether the proposed terms to share data and costs are fair, transparent and non-discriminatory.

57. The Appellants argue that the Board of Appeal has previously decided to the contrary. In this respect, the Appellants rely, by analogy, on paragraph 111 of the Decision of the Board of Appeal of 4 April 2017 in Case A-001-2016, *Thor* (see paragraph 48 above).

58. In that Decision, which relates to the Biocidal Products Regulation, the Board of Appeal found that it is not for the Agency to prescribe how costs should be calculated or shared in a particular case. This does not mean, however, that the Agency cannot assess whether the proposed terms for calculating and sharing costs are fair, transparent and non-discriminatory.

59. The conclusion at paragraph 56 is also consistent with the Decision of the Board of Appeal of 17 December 2014 in Case A-017-2013, *Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein*. At paragraphs 42 to 45 and 60 of that decision, the Board of Appeal found that the Agency, and the Board of Appeal, can assess whether terms to share data and costs are discriminatory, provided that the terms are sufficiently clear to allow for this assessment.

60. The second plea must consequently be rejected.

2.2. First plea: the Agency made several errors of assessment

Arguments of the Parties

61. The Appellants claim that the Contested Decision is vitiated by several errors of assessment.

62. The Appellants make five arguments in support of the first plea.

63. First, the Appellants argue that the Contested Decision is incorrect in finding that the Appellants failed to identify with sufficient precision the studies to which access was being negotiated.

64. The Appellants argue that, whilst the information provided to the Interveners did not include the titles and authors of the studies to which access was being negotiated, it was nevertheless sufficient to allow the Interveners to understand to which studies access was being negotiated and whether they needed those studies for the purposes of their own registrations.

65. Second, the Appellants argue that the Contested Decision is incorrect in finding that the Appellants failed to address the Interveners' concerns regarding the calculation and sharing of administrative costs.

66. The Appellants explain that the calculation and sharing of administrative costs is particularly challenging in the context of the registration of over 500 dyes, including Acid Orange 7. This is because these substances were registered using a '*group approach*' that involved a number of SIEFs and covered many substances. In these circumstances, it was impracticable for the Appellants to provide the level of detail on administrative costs required by the Interveners.

67. Third, the Appellants argue that the Contested Decision is incorrect in finding that the Appellants failed to address the Interveners' concerns regarding the 8% annual surcharge.

68. The Appellants argue that they have clearly and consistently responded to the Interveners' questions on, and objections to, the 8% annual surcharge. The Appellants also argue that they started preparing the registration of Acid Orange 7 some years in advance of the relevant registration deadline (1 June 2018) and therefore incurred costs that subsequent registrants ought to compensate them for.

69. Fourth, the Appellants argue that the Contested Decision is incorrect in finding that the Appellants failed to address the Interveners' concerns regarding the 15% surcharge.

70. The Appellants argue that they have clearly and consistently responded to the Interveners' questions on, and objections to, the 15% surcharge.

71. Fifth, the Appellants argue that the Agency made several errors in assessing the efforts made by the Interveners during the course of the negotiations.

72. The Appellants argue that the Agency failed to take into account the fact that some of the Interveners had individual exchanges with the Appellants during the course of the negotiations and did not make it clear whether they were negotiating on their own behalf or on behalf of all the Interveners.

73. Additionally, the Appellants argue that the Agency failed to take into account the fact that the Interveners:

- did not provide any justification as to why the precise references of the studies in question were needed,
- complained about the high cost of the letter of access rather than making genuine counterproposals during the negotiations,
- did not accept the Appellants' suggestion to ask a third party consultant to review whether the administrative costs charged were reasonable,
- repeatedly refused to meet with the Appellants, and
- were inconsistent during the negotiations as to whether they were negotiating to share data on Acid Orange 7 only or also on other dyes.

74. The Appellants further argue that the Agency failed to take into account the fact that the Interveners enjoyed support from the Ministry of Health of the Italian Republic throughout the negotiations. In support of this argument the Appellants submitted a position paper in which the Ministry of Health of the Italian Republic proposed to the Competent Authorities of the other Member States a strategy to help small and medium-sized enterprises register dyes such as Acid Orange 7 (see paragraph 34 above).

75. The Agency, supported by the Interveners, argues that it assessed the parties' efforts correctly.

Findings of the Board of Appeal

2.2.1. Legal framework

(a) Requirements for data and cost sharing to be transparent, fair and non-discriminatory

76. The REACH Regulation and Implementing Regulation 2016/9 include a number of requirements that need to be addressed in order to share data and costs in a fair, transparent and non-discriminatory way.

77. First, Article 30(1) of the REACH Regulation and Article 2 of Implementing Regulation 2016/9 indicate the requirements for data and cost sharing to be transparent.

78. It follows from these provisions that a previous registrant must provide clear and comprehensible explanations as to:

- which information is to be shared (in other words, itemisation of data; see Article 30(1), first subparagraph, of the REACH Regulation; Article 2(1)(a) and Article 2(2), second subparagraph, of Implementing Regulation 2016/9),
- how the cost of generating the information is determined (see Article 30(1), second subparagraph, first sentence, of the REACH Regulation; Article 2(1)(a) and Article 2(2), third subparagraph, letters (b) and (c), of Implementing Regulation 2016/9),
- how the cost of gathering and submitting the information to the Agency, including the cost of managing a SIEF, is determined (see Article 2(1)(b) and Article 2(2), third subparagraph, letters (a) and (c), of Implementing Regulation 2016/9), and
- how costs are to be shared among registrants (see Article 2(1)(c) of Implementing Regulation 2016/9).

79. Second, Article 30(1) of the REACH Regulation and Article 4 of Implementing Regulation 2016/9 indicate the requirements for data and cost sharing to be fair.

80. It follows from these provisions that 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 Article 30(1), second subparagraph, of the REACH Regulation; Article 4(1), Article 4(3) and Article 4(4), first subparagraph, of Implementing Regulation 2016/9).

81. These costs must moreover be actual in the sense that they can be determined either by proof or by approximation (see Article 30(1), second subparagraph, first sentence of the REACH Regulation; Article 2(2), third subparagraph, and Article 2(3), third subparagraph, of Implementing Regulation 2016/9).

82. Third, Article 30(1) of the REACH Regulation, read in light of the principle of equal treatment, indicates the requirements for data and cost sharing to be non-discriminatory.

83. It follows from this provision that 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.

(b) Assessment of the efforts of the parties

84. Pursuant to Article 5(1) of Implementing Regulation 2016/9, in the event of a data-sharing dispute under Article 30(3) of the REACH Regulation, the Agency assesses whether the potential registrant who filed the dispute has made every effort to ensure that the costs of sharing data are determined in a fair, transparent and non-discriminatory way.

85. The Agency's assessment must be carried out in a logical sequence. It is only if a party proposing certain terms has been transparent, and the terms it proposes are therefore clear and comprehensible, that the Agency is in a position to examine whether those terms are also fair and non-discriminatory (see *Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein*, cited in paragraph 59 above, paragraphs 42 to 45 and 60).

86. 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, by analogy, Case A-007-2016, *Sharda Europe*, Decision of the Board of Appeal of 29 May 2018, paragraph 59; Case A-014-2016, *Solvay Solutions UK*, Decision of 7 March 2018, paragraph 51, and Case A-005-2015, *Thor*, Decision of the Board of Appeal of 23 August 2016, paragraphs 64 and 65).

87. When carrying out its assessment, the Agency must have due regard to all the individual actions and communications of the parties as well as the development of the negotiations over time (see *Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein*, cited in paragraph 59 above, paragraphs 43 and 99).

88. Finally, the Agency's assessment of a data-sharing dispute centres upon those elements on which the parties could not agree during their negotiations, and which therefore led to the filing of the dispute (see *Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein*, cited in paragraph 59 above, paragraph 77, and, by analogy, *Sharda Europe*, cited in paragraph 86 above, paragraph 60).

89. In the present case, during the data-sharing negotiations the Interveners challenged the Appellants on:

- the identification of the studies to which access was being negotiated,
- the calculation of administrative costs,
- the 8% annual surcharge, and
- the 15% surcharge.

90. The Board of Appeal will therefore assess the parties' negotiations on these four elements against the requirements set out in paragraphs 76 to 83 above.

2.2.2. Identification of the studies to which access was being negotiated

91. The Appellants argue that the Contested Decision is incorrect in finding that the Appellants failed to identify with sufficient precision the studies to which access was being negotiated.

92. The Interveners requested the Appellants to provide them with the titles and authors of those studies (see paragraph 8 above).

93. The Appellants provided the Interveners with information which allowed them to determine that they would be able to submit a complete registration dossier based on the information which they could obtain from the Appellants (see paragraphs 9 and 10 above).

94. The Appellants did not, however, provide the Interveners with the titles and authors of the studies.

95. The titles and authors of studies are essential to allow a potential registrant to determine whether it needs to obtain permission to refer to those studies. This is because, for example, the potential registrant may be able to obtain, or already have, legitimate access to a study report from another source. Once the potential registrant is aware of the precise study being referred to, it may also disagree with the previous registrant on the selection and relevance of that study pursuant to Article 11(3)(c) of the REACH Regulation.

96. This information is also essential to help a potential registrant determine whether the cost of the studies, and the proportion of that cost which the potential registrant is expected to pay, has been calculated correctly.

97. In addition, Article 2 of Implementing Regulation 2016/9 requires an '*itemisation of the data to be shared*'. The term '*itemisation*' implies the precise identification of each piece of information in a list. In the case of scientific studies, consistent with the purpose set out in the two preceding paragraphs, an '*itemisation*' must therefore include the title and authors of each study.

98. In the interests of completeness, it should be added that disclosing to a potential registrant the titles and authors of the studies to which access is being negotiated does not entitle that potential registrant to rely on those studies in its own registration dossier. Pursuant to the second subparagraph of Article 10(a), and Article 13(5), both of the REACH Regulation, in order to rely on a study in its registration dossier a potential registrant must either be in legitimate possession of the full study report, or have permission to refer to it for the purpose of registration.

99. It follows that, in the present case, the Appellants failed to make clear which information was to be shared because, despite repeated requests, they did not provide the Interveners with the titles and authors of the studies to which access was being negotiated.

100. The Appellants' argument that the Contested Decision is incorrect in finding that the Appellants failed to identify with sufficient precision the studies to which access was being negotiated must consequently be rejected.

2.2.3. Calculation of administrative costs

101. The Appellants argue that the Contested Decision is incorrect in finding that the Appellants failed to address the Interveners' concerns regarding the calculation of administrative costs.

102. The Interveners requested the Appellants to explain how the administrative costs were calculated, and argued that their calculation was not fair because it included costs that were not related to the information the Interveners needed for their own registrations (see paragraph 11 above). The Interveners did not argue that the calculation of administrative costs was discriminatory.

103. The Board of Appeal will therefore examine, with regard to the calculation of administrative costs, whether the Appellants complied with the requirement for data and cost sharing to be (a) transparent, and (b) fair.

(a) Transparency

104. The Appellants explained during the course of the data-sharing negotiations, and reiterated in these proceedings, that it was impracticable to identify administrative costs by study or information requirement (see paragraphs 12 and 66 above).

105. In the present case, the Appellants were engaged in the concurrent registration of over 500 substances. It was consequently reasonable for them to record administrative costs by activity rather than by substance or endpoint.

106. The Appellants, moreover, provided the Interveners with a breakdown of administrative costs (see paragraph 13 above). This cost breakdown, although rather generic, listed the activities which the Appellants considered to be administrative, and gave for each activity a description and the number of hours spent.

107. It follows that the Appellants complied with the requirement of transparency as regards the calculation of administrative costs.

108. It must therefore be examined, based on the Appellants' explanations, as challenged by the Interveners, whether the calculation of administrative costs was fair.

(b) Fairness

109. 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. These costs must be actual in the sense that they can be determined either by proof or by approximation (see paragraphs 80 and 81 above).

110. An examination of the Appellants' cost breakdown and the cover letter to that cost breakdown (see paragraphs 13 and 14 above) shows that the Appellants' calculation of administrative costs did not comply with these requirements in the following four ways.

111. First, the cost breakdown referred to the costs incurred for managing the consortia for the registration of dyes, including the relationships between the members of these consortia. However, the Interveners were not members of the consortium for Acid Orange 7 and were therefore not required to pay a share of the consortium costs for that substance or for the consortia as a whole. They were only required to pay a share of the SIEF costs for Acid Orange 7.

112. Second, the cost breakdown referred to the preparation of waiving proposals for, amongst others, '*repeated inhalation tox[icity]*' and '*repeated dermal tox[icity]*' as an administrative cost. However, these are not information requirements applicable to the Interveners, who are potential registrants for the tonnage band of 1 to 10 tonnes per year (Annex VII).

113. Third, the cost breakdown referred to the generation of testing proposals as an administrative cost. Registrants in the tonnage band of 1 to 10 tonnes per year (Annex VII) do not, however, need to provide any information for registration purposes that would require the submission of testing proposals to the Agency.

114. Fourth, the cost breakdown referred to the performance of a chemical safety assessment ('CSA') as an administrative cost. Registrants in the tonnage band of 1 to 10 tonnes per year (Annex VII) are not, however, required to perform a CSA.

115. It follows that the Appellants failed to comply with the requirement of fairness in their calculation of administrative costs as their calculation included costs which the Interveners are not required to share.

116. The Appellants' argument that the Contested Decision is incorrect in finding that the Appellants failed to address the Interveners' concerns on the calculation of administrative costs must consequently be rejected.

2.2.4. The 8% annual surcharge

117. The Appellants argue that the Contested Decision is incorrect in finding that the Appellants failed to address the Interveners' concerns regarding the 8% annual surcharge on the price of a letter of access.

118. The Interveners challenged whether there could be an annual surcharge, and also it being set at eight percentage points. They argued that the 8% annual surcharge is unfair and discriminatory (see paragraph 15 above).

119. The Board of Appeal will therefore examine whether the Appellants complied with the requirements for data and cost sharing to be (a) transparent, (b) fair, and (c) non-discriminatory in regard to the annual surcharge and it being set at eight percentage points.

(a) Transparency

120. As regards the reasons for having an annual surcharge, the Appellants explained that the annual surcharge was intended to compensate for the following five elements (see paragraph 17 above):

- the costs of managing and running the SIEF,
- the costs incurred for meeting obligations under the REACH Regulation,
- inflation,
- the cost of money, and
- opportunity costs.

121. The Appellants also explained that they started preparing the registration of Acid Orange 7 some years in advance of the relevant registration deadline (1 June 2018) and therefore needed to incentivise potential registrants to make an early financial contribution towards the registration costs (see paragraph 18 above).

122. As regards setting the annual surcharge at eight percentage points, the Appellants explained that this rate was modelled on the interest rate set out in Directive 2000/35/EC (see paragraph 19 above).

123. By the end of the negotiations, the Appellants had therefore made clear the purpose of the annual surcharge and the reason for it being set at eight percentage points.

124. It follows that the Appellants complied with the requirement of transparency as regards the 8% annual surcharge.

125. It must therefore be examined, based on the Appellants' explanations, as challenged by the Interveners, whether the 8% annual surcharge was fair and non-discriminatory.

(b) Fairness

126. 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. These costs must be actual in the sense that they can be determined either by proof or by approximation (see paragraphs 80 and 81 above).

127. The Appellants identify five elements as being covered by the 8% annual surcharge: the costs of managing and running the SIEF, the costs incurred for meeting obligations under the REACH Regulation, inflation, the cost of money, and opportunity costs (see paragraphs 17 and 120 above).

128. However, even assuming that these are costs that can be included in the calculation of an annual surcharge, the Appellants have neither quantified any of these costs, nor established that there is any relation between their amount and setting the overall annual surcharge on the price of a letter of access at eight percentage points.

129. The Appellants explain setting the overall annual surcharge at eight percentage points solely by reference to Directive 2000/35/EC.

130. Leaving aside the fact that it was repealed with effect from 16 March 2013, Directive 2000/35/EC provided for the introduction by Member States of a statutory interest rate to deter late payments in commercial transactions. Such an interest rate is entirely unrelated to the actual costs of generating, gathering and submitting information to the Agency for the purposes of a registration under the REACH Regulation.

131. It follows that the 8% annual surcharge required by the Appellants was set without regard to the actual costs of generating, gathering and submitting to the Agency the information required for the registration of Acid Orange 7.

132. The 8% annual surcharge is consequently unfair.

(c) Non-discrimination

133. 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 paragraph 83 above).

134. All SIEF participants are in a comparable situation in so far as they have to submit information for registration purposes and are subject to the same rules and obligations for the sharing of data and costs (see, to this effect, *Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein*, cited in paragraph 59 above, paragraph 46).

135. For the purposes of this appeal, with regard to the rules and obligations for the sharing of data and costs, it must therefore be examined whether the 8% annual surcharge treats registrants in the Acid Orange 7 SIEF differently.

136. In the present case, the rate of the annual surcharge on the price of a letter of access was set higher than the rate of inflation. The 8% annual surcharge therefore increased the price in real terms of a letter of access over time.

137. Such an increase in price in real terms can be offset by a reimbursement mechanism which eventually re-calculates and reimburses costs among all registrants concerned, for example after each registration deadline (see *Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein*, cited in paragraph 59 above, paragraphs 50 and 53).

138. In the present case, the Appellants did propose a reimbursement mechanism according to which, on an annual basis, the income derived from the 8% annual surcharge paid by all new registrants is to be distributed among previous registrants (see paragraph 20 above).

139. Such a mechanism does not however reimburse costs among all registrants concerned and cannot therefore be considered to be a full reimbursement mechanism. For example, it benefits the early registrants of a substance as they obtain cumulatively a share of the surcharge paid by all later registrants, whereas the later registrants only get a share of the surcharge from the even later registrants but not from the previous registrants. Ultimately, all other things being equal, the price in real terms of a letter of access will be higher for later registrants than earlier ones.

140. It follows that, in the circumstances of the present case, the 8% annual surcharge treats registrants who are in a comparable situation, as participants in the SIEF for Acid Orange 7 who are covered by the same rules and obligations for the sharing of data and costs, differently.

141. It must therefore be examined, based on the Appellants' explanations, whether this difference in treatment was objectively justified.

142. First, the Appellants explain that they needed to incentivise potential registrants to make an early financial contribution towards the registration (see paragraphs 18 and 68 above).

143. Under Article 30 of the REACH Regulation, however, 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. These costs must be actual in the sense that they can be determined either by proof or by approximation (see paragraphs 80 and 81 above).

144. Incentivising potential registrants to make an early financial contribution by applying an annual surcharge on the price of a letter of access that is set higher than the rate of inflation is not a cost within the meaning of Article 30 of the REACH Regulation.

145. That aim cannot, therefore, justify a difference in treatment between registrants who require the same information for the purposes of their own registration.

146. Second, the Appellants claim that they incurred the five cost elements listed in paragraphs 17 and 120 above during the time between the submission to the Agency of their own registration and the Intervener's later registration of Acid Orange 7. These are the costs of managing and running the SIEF, the costs incurred for meeting obligations under the REACH Regulation, inflation, the cost of money and opportunity costs. According to the Appellants, the 8% annual surcharge compensates for these costs.

147. The Appellants, however, have neither quantified any of these elements, nor established that there is any relation between their amount and setting the overall annual surcharge on the price of a letter of access at eight percentage points.

148. Therefore, the Appellants cannot rely on the elements listed in paragraphs 17 and 120 to justify a difference of treatment between SIEF participants.

149. It follows that the 8% annual surcharge treats registrants who are in a comparable situation differently without an objective justification.

150. The 8% annual surcharge is consequently discriminatory.

151. The Appellants' argument that the Contested Decision is incorrect when finding that the Appellants failed to address the Interveners' concerns regarding the 8% annual surcharge must therefore be rejected.

2.2.5. The 15% surcharge

152. The Appellants argue that the Contested Decision is incorrect in finding that the Appellants failed to address the Interveners' concerns regarding the 15% surcharge.

153. The Interveners challenged the existence of the 15% surcharge as unfair (see paragraph 21 above). They did not challenge the 15% surcharge as discriminatory.

154. The Board of Appeal will therefore examine whether the Appellants complied with the requirements for data and cost sharing to be (a) transparent, and (b) fair in regard to the existence of the 15% surcharge.

(a) Transparency

155. The Appellants explained (see paragraph 22 above) that the 15% surcharge was intended to:

- insure against the risk that the results of studies could affect or prevent the future marketing of Acid Orange 7,
- cover expenses for work performed in connection with the studies and creating robust study summaries, and
- insure against the risk that tests might produce inconclusive results.

156. By the end of the negotiations, the Appellants had therefore made clear the purpose of the 15% surcharge.

157. It follows that the Appellants complied with the requirement of transparency as regards the 15% surcharge.

158. It must therefore be examined, based on the Appellants' explanations, as challenged by the Interveners, whether the 15% surcharge was fair.

(b) Fairness

159. 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. These costs must be actual in the sense that they can be determined either by proof or by approximation (see paragraphs 80 and 81 above).

160. None of the elements to which the Appellants refer in support of the 15% surcharge (see paragraphs 22 and 155 above) fulfil these conditions.

161. First, the risk that the results of studies could affect or prevent the future marketing of Acid Orange 7 is not a cost within the meaning of Article 30 of the REACH Regulation, and is, moreover, entirely hypothetical.

162. Second, the costs of work performed in connection with the studies and creating robust study summaries are costs incurred for generating, gathering and submitting information to the Agency. Including them in the calculation of a surcharge therefore leads to possible double counting.

163. Third, the information required for the registration of Acid Orange 7 had already been generated (mostly before the entry into force of the REACH Regulation), gathered and submitted to the Agency. There was consequently no risk that tests might produce inconclusive results. In addition, any future costs arising from the registration of Acid Orange 7 can and should be shared among registrants when and if they arise (see Article 4(2) and Article 4(4), second subparagraph, of Implementing Regulation 2016/9).

164. The 15% surcharge is consequently unfair.

165. The Appellants' argument that the Contested Decision is incorrect in finding that the Appellants failed to address the Interveners' concerns regarding the 15% surcharge must consequently be rejected.

2.2.6. Efforts made by the Interveners

166. The Appellants argue that the Agency made several errors in assessing the efforts made by the Interveners during the course of the negotiations.

167. First, the Appellants argue that some Interveners had individual exchanges with the Appellants during the course of the negotiations and did not make it clear whether they were negotiating on their own behalf or on behalf of all the Interveners (see paragraph 72 above). This argument must be rejected for the following reason.

168. Centro Reach S.r.l. informed the Appellants that it was acting on behalf of a group of companies called the '*Dye-Staff Cooperation Group*' and that the Interveners were members of this group (see paragraph 4 above). The identity of the participants in the negotiations should therefore have been clear to the Appellants. If uncertainties remained, the Appellants could have asked for further clarifications.

169. Second, the Appellants highlight specific actions and inactions on the part of the Interveners, and argue that these actions and inactions show that the Interveners did not make every effort to achieve an agreement (see paragraph 73 above). This argument must be rejected for the following reason.

170. When deciding on a data-sharing dispute, the negotiations must be assessed as a whole, taking into account not only the parties' individual actions, but the

development of the negotiations over time (see paragraphs 86 and 87 above).The negotiations as a whole show that the Interveners consistently challenged the Appellants, to no avail, as regards the identification of the studies to which access was being negotiated, the calculation and sharing of administrative costs, the 8% annual surcharge, and the 15% surcharge.

171. Third, the Appellants argue that the Interveners enjoyed support from the Ministry of Health of the Italian Republic (see paragraph 74 above). This argument must be rejected for the following reason.

172. The Appellants have not established that the Ministry of Health of the Italian Republic supported the Interveners during the course of the negotiations. In any event, such support would be irrelevant to whether the Interveners made every effort in this case.

173. The Appellants' arguments that the Agency made several errors in assessing the efforts made by the Interveners during the course of the negotiations must consequently be rejected.

2.2.7. Conclusion on the first plea

174. The Appellants failed to be transparent as regards the identification of the studies to be shared, and insisted on unfair and/or discriminatory terms as regards the calculation of administrative costs, the 8% annual surcharge and the 15% surcharge.

175. In the circumstances of the case, and taking into account the failings summarised in the previous paragraph, the Interveners made every effort by consistently challenging the Appellants on the identification of the studies to which access was being negotiated and on the calculation of administrative costs, the 8% annual surcharge and the 15% surcharge. Whilst the Appellants did respond to the Interveners' questions, this did not lead to any changes to the proposed terms.

176. The Agency was therefore correct in finding in the Contested Decision that the Interveners made every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way.

177. The first plea must consequently be rejected.

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

Arguments of the Parties

178. The Appellants argue that the Agency disregarded its own Guidance on data-sharing (version 3.1, January 2017), according to which administrative costs can be recorded by activity rather than by substance or endpoint.

179. The Agency, supported by the Interveners, argues that the Appellants had no legitimate expectations that their way of calculating administrative costs would be accepted.

Findings of the Board of Appeal

180. The principle of the protection of legitimate expectations is a fundamental principle of European Union law. The right to rely on that principle extends to any person with regard to whom an institution of the European Union has given rise to justified hopes (see judgment of 14 March 2013, *Agrargenossenschaft Neuzelle*, C-545/11, EU:C:2013:169, paragraph 23 and 24).

181. In whatever form it is given, information which is precise, unconditional and consistent and comes from an authorised and reliable source constitutes assurances capable of giving rise to such hopes (see *Agrargenossenschaft Neuzelle*, cited in the previous paragraph, paragraph 25).

182. The Appellants argue that the Agency contravened the Guidance on data-sharing.

183. Contrary to the Appellants' argument, the Contested Decision does not state that administrative costs cannot be recorded by activity rather than by substance or endpoint. Rather the Contested Decision correctly finds that the Appellants have failed to address the Interveners' concerns as regards the calculation of administrative costs.

184. In any event, the Guidance on data-sharing states at pages 117 and 118:

'*Type and details of the itemisation exercise (in particular the level of itemisation) will possibly differ from case to case. They may depend,* inter alia*, on the form of cooperation chosen and its structure (e.g. whether it evolved from an existing form of cooperation or it was set up specifically for REACH purposes) and whether the tasks have been allocated to single substances or group(s) of substances (hence deriving a fully substance-specific cost itemisation could be difficult).*

The distinction between study and administrative costs, and the possible relevance of the latter for a specific information requirement, may vary from one [registration] to another. What is important is that costs are transparently recorded and their sources clear to the co-registrants.'

185. This part of the Guidance is couched in very generic language. It is not precise and unconditional within the meaning of the case-law referred to in paragarphs 180 and 181.

186. The third plea must therefore be rejected.

2.4. Fourth plea: the Agency breached the principle of equal treatment

Arguments of the Parties

187. The Appellants argue that the Contested Decision breaches the principle of equal treatment because it prevents them from imposing the 8% annual surcharge and the 15% surcharge on the Interveners. This, in turn, allows the Interveners to benefit from the fact that the Appellants prepared and submitted a registration earlier than the Interveners despite being subject to the same registration deadline (1 June 2018).

188. The Agency, supported by the Interveners, argues that the Contested Decision does not breach the principle of equal treatment.

Findings of the Board of Appeal

189. When deciding on a data-sharing dispute pursuant to Article 30(1) and (3) of the REACH Regulation, as implemented by Article 5(1) of Implementing Regulation 2016/9, the Agency can either grant or deny permission to refer to information submitted by a previous registrant.

190. In the present case, the Agency was correct in finding in the Contested Decision that the Interveners made every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way (see Section 2.2. above).

191. Having reached this conclusion, the Agency was obliged to grant the Interveners permission to refer to the four studies on vertebrate animals contained in the registration dossier submitted by REACH & Colours Kft. The Agency had no margin of discretion in this regard. It cannot, therefore, have breached the principle of equal treatment by granting a permission to refer through the Contested Decision (see, by analogy, Case A-004-2015, *Polynt*, Decision of the Board of Appeal of 19 October 2016, paragraph 140).

192. In any event, the Contested Decision does not prevent the Appellants from recovering the costs which, they claim, are covered by the 8% annual surcharge and the 15% surcharge. When determining the amount of costs to be shared pursuant to the fifth sentence of Article 30(3) of the REACH Regulation, a national court is not bound to follow the reasoning set out in an Agency decision granting permission to refer. A national court may, within its own discretion, decide which costs should be included in its determination of the cost that should be paid to the previous registrant.

193. It follows that the fourth plea must be rejected.

194. As all the Appellants' pleas and arguments have been rejected, the appeal must be dismissed.

Refund of the appeal fee

195. 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 is refunded if the appeal is decided in favour of an appellant.

196. As the appeal is dismissed, the appeal fee will not be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

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

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal