

**DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

15 December 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 – Itemisation of data and costs)*

Case number	A-005-2019
Language of the case	English
Appellants	Codyeco S.p.A., Italy Colorex S.r.l., Italy Colortex S.p.A., Italy Farbotex Fast Solutions S.p.A., Italy Gammacolor S.r.l., Italy H.B. S.r.l., Italy Neocolor S.r.l., Italy Ve.Co.Tex. S.r.l., Italy Triade B.V., the Netherlands; all represented by Centro Reach S.r.l., Italy
Representative	Claudio Mereu Fieldfisher (Belgium) LLP, Belgium
Intervener	REACH & Colours Kft, Hungary Represented by: Ruxandra Cana, Eléonore Mullier and Hannah Widemann Steptoe & Johnson LLP, Belgium
Contested Decision	DSH-30-3-D-0213-2018 of 18 December 2018, adopted by the European Chemicals Agency pursuant to Articles 11 and 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') and Article 5 of Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH (OJ L 3, 6.1.2016, p. 41; 'Implementing Regulation 2016/9')

THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Katrin Schütte (Technically Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. This appeal concerns the sharing of data and costs for the registration of numerous dyes (the 'Substances').
2. Data and cost-sharing negotiations for the registration of the Substances took place between Centro REACH S.r.l. and the Intervener.
3. Centro REACH S.r.l. (the 'Appellants' representative') represented the Appellants, each of whom is a potential registrant for some or all of the Substances, in the negotiations.
4. The Intervener is the lead registrant for some of the Substances. During the negotiations, the Intervener represented, in addition to those Substances for which it was the lead registrant, the lead registrants for the remaining Substances, and the data owners for all the Substances.
5. Data and cost-sharing negotiations between the Appellants' representative and the Intervener started in November 2012 on another substance, 'Acid Orange 7'. The negotiations on Acid Orange 7 led to a data and cost-sharing dispute and subsequently to a decision of the Agency on 20 July 2017. The decision of the Agency was then appealed before the Board of Appeal, which adopted a decision on 15 April 2019 in Case A-010-2017, *REACH & Colours and REACH & Colours Italia*. The data and cost-sharing negotiations on the Substances took place partly alongside and partly after the negotiations on 'Acid Orange 7'.
6. During the course of the data and cost-sharing negotiations on the Substances, the Appellants' representative requested the Intervener to provide it with an itemisation of the information available for the registration of the Substances, and the related costs (notably, emails of 25 and 27 July 2017, 15 September 2017, 16 and 28 November 2017, 3 and 21 December 2017, 30 January 2018).
7. The Intervener refused to provide that itemisation, unless the Appellants' representative (i) provided a '*universal unique identifier*' for each Appellant (potential registrant at the time of the negotiations), (ii) provided a '*confirmation of substance sameness*' for each substance for which each Appellant was a potential registrant, and (iii) confirmed pre-registration of each substance for which each Appellant was a potential registrant (notably, emails of 27 July 2017, 9 and 11 August 2017, 9 and 10 October 2017, 21 December 2017). This information would have allowed the Intervener to determine precisely which of the Appellants intended to register which of the Substances.
8. The Appellants' representative provided the Intervener with a list of the Appellants' names, and a list of the Substances for which the Appellants were potential registrants with the relevant tonnage band per substance. It did not, however, provide the specific information requested by the Intervener (notably, emails of 27 July 2017, 13 September 2017, 2 and 5 October 2017, 10 and 15 November 2017, 13 March 2018).
9. In addition, the Appellants' representative disagreed with the Intervener's proposal as to how the costs should be shared among registrants (the 'cost-sharing model'; notably, emails of 21 December 2017, 22 December 2017, 13 February 2018, 13 March 2018, 23 March 2018).

Contested Decision

10. On 30 March 2018, the Appellants' representative submitted to the Agency, on behalf of the Appellants, an application for each of the Appellants to obtain permission to refer to the studies on vertebrate animals contained in the registration dossiers for the Substances, in accordance with Article 30(3) of the REACH Regulation.
11. On 18 December 2019, the Agency adopted the Contested Decision.
12. The Contested Decision is based on Articles 11 and 30(3) of the REACH Regulation, and Article 5 of Implementing Regulation 2016/9.
13. In the Contested Decision, the Agency found that the Appellants' representative had failed to make every effort to reach an agreement on data and cost-sharing with the Intervener.
14. According to the Contested Decision, the Appellants' representative '*never justified [its] refusal to share the requested [universal unique identifier and confirmation of substance sameness], in spite of [the Intervener] consistently asking for the reasons for this refusal and justifying the need to have this information*'.
15. Furthermore, according to the Contested Decision, the Appellants' representative '*expressed [its] disagreement with the [Intervener's] cost-sharing model only in generic terms, labelling it 'disproportionate' and threatening the Other Party with a dispute filing, rather than engaging in the negotiations*'.
16. The Agency therefore rejected the Appellants' applications for permission to refer.

Procedure before the Board of Appeal

17. On 15 March 2019, the Appellants filed this appeal.
18. On 23 May 2019, the Agency filed its Defence.
19. On 27 September 2019, REACH & Colours Kft was granted leave to intervene in this case in support of the Agency.
20. On 18 November 2019, the Appellants submitted their observations on the Defence.
21. On 25 November 2019, the Intervener submitted its statement in intervention.
22. On 20 December 2019, the Agency submitted its observations on the Appellants' observations on the Defence.
23. On 24 January 2020, the Appellants and the Agency submitted their respective observations on the statement in intervention.
24. On 15 May 2020, the Appellants and the Intervener submitted their respective replies to questions from the Board of Appeal.
25. On 18 May 2020, the Agency submitted its reply to questions from the Board of Appeal.
26. On 18 June 2020, Katrin Schütte, alternate member of the Board of Appeal, was designated to replace Sari Haukka in this case, in accordance with the first subparagraph of Article 3(2) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; the 'Rules of Procedure').
27. On 30 September 2020, a hearing took place at the Appellants' request. The hearing was held by video-conference in accordance with Article 13(7) of the Rules of Procedure. At the hearing, the Parties and the Intervener made oral submissions and answered questions from the Board of Appeal.

Form of order sought

28. The Appellants request the Board of Appeal to annul the Contested Decision and order the Agency to pay the costs incurred by these proceedings.
29. The Agency, supported by the Intervener, requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

30. The Appellants raise two pleas in support of their appeal, namely that the Agency:
 - committed a manifest error in its assessment of the case (first plea), and
 - breached the principle of the uniform application of European Union law (second plea).

1. First plea: Manifest error of assessment**Arguments of the Parties and Intervener**

31. The Appellants argue, in essence, that the Agency erred in finding that the Appellants' representative failed to make every effort by refusing to provide the information requested by the Intervener (for each of the Appellants, a '*universal unique identifier*', '*confirmation of substance sameness*', and confirmation that each of the Appellants had pre-registered the relevant Substances). According to the Appellants, the information in question does not need to be provided by a potential registrant to a previous registrant as a pre-requisite for data and cost-sharing negotiations.
32. The Agency, supported by the Intervener, disputes the Appellants' arguments. According to the Agency, in order to obtain permission to refer under Article 30(3), a potential registrant must have made '*every effort*' to reach an agreement with the previous registrant. The Appellants' representative did not make every effort because (i) it failed to respond to the Intervener's '*legitimate request*' to provide a '*universal unique identifier*', '*confirmation of substance sameness*', and confirmation of pre-registration for each Appellant and substance, and (ii) it did not negotiate in a constructive manner.
33. In addition, according to the Intervener, knowing which of the Appellants intends to register which of the Substances is an essential element for the conclusion of a data and cost-sharing agreement in the present case.

Findings of the Board of Appeal

34. 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 Case A-024-2018, *Symrise*, Decision of the Board of Appeal of 27 October 2020, paragraph 106; Case A-023-2018, *Oxiten Europe*, Decision of the Board of Appeal of 21 September 2020, paragraph 94; Case A-013-2018, *Tecnofluid (I)*, Decision of the Board of Appeal of 23 July 2020, paragraph 29; Joined Cases A-014-2018 to A-021-2018, *Tecnofluid (II)*, Decision of the Board of Appeal of 23 July 2020, paragraph 41 of the decision; and 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).

35. Specifically, in order to comply with the requirement 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 the costs are to be shared among registrants (see *Tecnofluid (II)*, cited in the previous paragraph, paragraph 47 of the decision).
36. 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 and costs.
37. The Appellants' representative requested the Intervener to provide it with an itemisation of data and costs, and the Intervener did not do so (see paragraphs 6 to 8 above).
38. In order to determine whether this constituted a breach, on the part of the Intervener, of the obligation to provide an itemisation of data and costs under Article 2(1)(a) and (2) of Implementing Regulation 2016/9, it is necessary, first of all, to determine whether the request by the Appellants' representative was sufficient to give rise to such an obligation.
39. The Appellants' representative requested the Intervener to provide it with an itemisation of data and costs without indicating precisely which of the Appellants intended to register which of the Substances by means of the information requested by the Intervener ('*universal unique identifier*', '*confirmation of substance sameness*' and confirmation of pre-registration).
40. Knowing which of the Appellants intended to register which of the Substances – for example by means of the information requested by the Intervener (see the previous paragraph) – is part of the essential elements of a data and cost-sharing agreement. Therefore, the conclusion of such an agreement is impossible without this information being disclosed.
41. However, in the present case, the Appellants and the Intervener were not at the stage of the conclusion of a data and cost-sharing agreement; they were still at a stage where the negotiations had not actually started. For the following reasons, data and cost-sharing negotiations cannot be prevented from starting because the information requested by the Intervener (see paragraph 39 above) is missing.
42. First, the Appellants' representative provided the Intervener with the names of the companies concerned (the potential registrants), and a list of the substances in question with the relevant tonnage band per substance (see paragraph 8 above).
43. Although that information did not show which of the Appellants intended to register which substance, it was sufficient to allow the Intervener to verify, in its capacity as lead registrant and representative of the lead registrants (see paragraph 4 above), which of the Appellants was a member of which substance information exchange forum ('SIEF') and therefore a potential registrant of which substance.
44. Second, pursuant to Article 2(1)(a) of Implementing Regulation 2016/9, an itemisation of data and costs includes '*the cost of each data item, a description indicating the information requirements [...] to which each cost corresponds and a justification of how the data to be shared satisfies the information requirement*'.
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45. The itemisation of data and costs therefore concerns only the nature of the information available for the registration of a substance, and the cost of that

information. The itemisation of data and costs does not depend on the identity, or even the number, of potential registrants of a substance.

46. Consequently, not knowing which Appellant intended to register which substance did not prevent the Intervener from providing an itemisation of data and costs in accordance with Article 2(1)(a) and (2) of Implementing Regulation 2016/9.
47. Third, a potential registrant may not know, when beginning data and cost-sharing negotiations, whether it will eventually register a substance. A potential registrant's decision on whether to register a substance may depend on the cost of the registration, which in turn will be informed by the itemisation of data and costs, and the cost-sharing model proposed by the previous registrant.
48. It follows that the request made by the Appellants' representative was sufficient to trigger the Intervener's obligation, under Articles 2(1) and (2) of Implementing Regulation 2016/9, to provide an itemisation of data and costs. The Intervener was not entitled to refuse the request, made by the Appellants' representative, for an itemisation of data and costs. The Intervener therefore failed to comply with the requirements for data and cost-sharing to be transparent.
49. The Contested Decision does not contain any reference to this failure on the part of the Intervener. On the contrary, the Contested Decision states:

'Making every effort means that the existing and potential registrants must negotiate as constructively as possible and in good faith. They must make sure that the negotiations move forward in a timely manner, express their arguments and concerns, ask questions and reply to each other's arguments, concerns and questions. Making every effort also means that the parties need to be consistent in their negotiating strategy. They should raise their concerns in a timely manner and behave in a consistent and predictable manner as reliable negotiators. When they face dissent on an aspect, the parties must explore alternative routes and make suitable attempts to unblock the negotiations. As the potential and existing registrants themselves bear the obligation to make every effort to find an agreement, they need to exhaust all possible efforts before submitting a dispute to ECHA with the claim that negotiations have failed. [...] Part of making every effort is also making clear requests and explaining one's position. This entails identifying oneself and detailing the requests made, so as to enable the development of the negotiations on a shared understanding. [...] [The Appellants' representative] never justified [its] refusal to share the requested company [universal unique identifiers] and sameness confirmation, in spite of the [Intervener] consistently asking for the reasons for this refusal and justifying the need to have this information. [...] [The Appellants' representative] thus did not make every effort in this regard.'
50. The Contested Decision therefore relies on the subjective intention of the Appellants' representative and the Intervener as expressed through their behaviour in the negotiations, rather than examining their compliance with objective requirements of transparency, fairness, and non-discrimination.
51. Furthermore, the Contested Decision denies the Appellants' applications for permission to refer on the grounds that the Appellants' representative did not make clear to the Intervener which Appellant intended to register which substance (by means of a combination of a 'universal unique identifier', 'confirmation of substance sameness' and confirmation of pre-registration). However, this information is not a pre-requisite for a potential registrant seeking and obtaining an itemisation of data and costs (see paragraphs 40 to 47 above).
52. The Agency consequently erred in finding that the Appellants' representative failed to make every effort by refusing to provide the information requested by the

Intervener (by means of a combination of a '*universal unique identifier*', '*confirmation of substance sameness*' and confirmation of pre-registration).

53. The first plea must therefore be upheld, and the Contested Decision annulled. There is no need to examine the remaining plea.

2. Result

54. Pursuant to Article 93(3) of the REACH Regulation, 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.
55. The Intervener failed to comply with the requirements for data and cost-sharing to be transparent. Each Appellant must consequently be given permission to refer to the relevant studies on vertebrate animals contained in the registration dossiers of the relevant substances.
56. However, in order to adopt a decision granting the Appellants permission to refer to the relevant studies on vertebrate animals in the relevant registration dossiers for the Substances, the Board of Appeal would need to examine the content of the dossiers in question. Those registration dossiers are not available to the Board of Appeal.
57. Furthermore, before granting each Appellant permission to refer in accordance with Article 30(3) of the REACH Regulation, it is necessary to verify that each Appellant was, at the time of filing of the applications for permission to refer, a potential registrant for the relevant substances within the meaning of Articles 28 and 29 of the REACH Regulation. This information is also not available to the Board of Appeal.
58. The present case must therefore be remitted to the competent body of the Agency for further action.

Application for the reimbursement of costs

59. The Appellants request the reimbursement of the costs incurred for these proceedings. In accordance with Article 17a of the Rules of Procedure, the parties to an appeal shall bear their own costs. The application for the reimbursement of costs must therefore be rejected.

Refund of the appeal fee

60. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to the REACH Regulation (OJ L 107, 17.4.2008, p. 6), the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the Contested Decision has been annulled, the appeal fee must be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Annuls the Contested Decision.**
- 2. Remits the case to the competent body of the Agency for further action.**
- 3. Rejects the application for the reimbursement of the costs of these proceedings.**
- 4. Decides that the appeal fee is refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal