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)*

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| **Case number** | A-013-2018 |
| **Language of the case** | English |
| **Appellant** | Tecnofluid S.r.l., Italy |
| **Intervener** | Umicore Specialty Materials Brugge NV, Belgium<br>Represented by:<br>Ruxandra Cana, Eléonore Mullier and Filippo Mattioli<br>Steptoe & Johnson LLP, Belgium |
| **Contested Decision** | DSH-30-3-D-0156-2017 of 25 May 2018, 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; 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. This appeal concerns the sharing of data and costs for the registration of the substance fatty acids, C18-unsatd., dimers, 2-ethylhexyl esters (EC No 500-204-4, CAS No 68334-05-4; the 'Substance').

2. The Appellant is a potential registrant of the Substance. The Intervener is the lead registrant for the Substance.

3. The information contained in the Intervener's registration dossier was gathered and/or generated by a '*consortium*' which '*managed*' the substance information exchange fora ('SIEFs') for a '*group*' of seven substances including the Substance (the 'PFAE M&B group').

4. Between 2014 and 2017, data and cost-sharing negotiations took place between the Appellant and the Intervener. During the course of these negotiations, the Appellant and the Intervener disagreed on the method for calculating the share of the costs to be borne by the Appellant (the 'cost-sharing model').

5. By the end of the negotiations, the respective positions of the Appellant and the Intervener on the cost-sharing model were as follows.

6. The Intervener proposed that the cost of the information required by the Appellant should be divided by the number of registrants of the seven substances in the PFAE M&B group who relied on that information in their registration dossiers. 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 23 June 2017 at 11:57 CET; of 29 June 2017 at 18:29 CET; 4 July 2017 at 18:16 CET; 8 September 2017 at 18:20; 26 September 2017 at 10:01 CET; 7 December 2017 at 19:43 CET).

7. The Appellant objected to this cost-sharing model on the grounds that it was unfair and discriminatory as the Appellant intended to register only one of the seven substances in the PFAE M&B group. The Appellant proposed that the cost of each piece of information it required should first be divided by the number of substances for which it was used, and this figure should then be divided by the number of registrants of each substance – including any affiliates – which rely on that information in their registration dossiers (notably, emails of 26 June 2017 at 17:51 CET; 30 June 2017 at 12:47 and 15:40 CET; 7 September 2017 at 11:52 CET; 6 December 2017 at 15:53 CET).

### Contested Decision

8. On 12 December 2017, the Appellant submitted to the Agency an application for permission to refer to the studies involving tests on vertebrate animals contained in the Intervener's registration dossier for the Substance, in accordance with Article 30(3) of the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise).

9. On 25 May 2018, the Agency adopted the Contested Decision.

10. The Contested Decision is 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').

11. In the Contested Decision, 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 application for permission to refer.

**Procedure before the Board of Appeal**

12. On 2 August 2018, the Appellant filed this appeal.
13. On 8 October 2018, the Agency filed its Defence.
14. On 23 January 2019, the Appellant submitted observations on the Defence.
15. On 15 April 2019, Umicore Specialty Materials Brugge NV (the 'Intervener') was granted leave to intervene in these proceedings in support of the Agency.
16. On 28 June 2019, the Intervener submitted a statement in intervention.
17. On 29 July 2019, the Agency submitted observations on the Appellant's observations on the Defence.
18. On 22 August and 5 September 2019 respectively, the Appellant and the Agency submitted observations on the statement in intervention.
19. 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 Intervener made oral submissions and answered questions from the Board of Appeal.
20. 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.
21. 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.

**Form of order sought**

22. The Appellant requests the Board of Appeal to:
    - annul the Contested Decision,
    - grant the Appellant permission to refer to the requested studies,
    - order the refund of the appeal fee, and
    - take such other or further measures as justice may require.
23. The Agency, supported by the Intervener, requests the Board of Appeal to dismiss the appeal as unfounded.

**Reasons**

24. The Appellant raises seven pleas in support of its appeal, namely that the Agency:
    - breached an essential procedural requirement because the Contested Decision was 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 application 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),
- committed several errors in its assessment of the facts of the case (third, fourth, sixth and seventh plea), and
- failed to comply with its Guidance on data-sharing (version 3.1, January 2017) and Implementing Regulation 2016/9 (fifth plea).

25. The Board of Appeal will first examine the fifth plea.

**Arguments of the parties**

26. By its fifth plea, the Appellant argues, in essence, that the Agency failed to comply with its Guidance on data-sharing and breached Implementing Regulation 2016/9. According to the Appellant, the Agency should have granted the Appellant's application for permission to refer because the Intervener insisted on terms for data and cost-sharing which were unfair and discriminatory.

27. 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 Intervener responded to the Appellant's objections to the Intervener's cost-sharing model. On the other hand, the Appellant failed to '*engage in meaningful discussions and advance the parties' negotiations*' by, for example, refusing to meet with the Intervener, filing or threatening to file a complaint with the relevant competition authorities, and filing its application for permission to refer while the Agency's '*Ambassador for small and medium enterprises*' was still seeking to mediate between the Appellant and the Intervener. On balance, when assessing the efforts of the Appellant and the Intervener, the Agency therefore decided to refuse the Appellant's application for permission to refer.

28. The Intervener argues that it complied with the requirements for data and cost-sharing to be transparent, fair and non-discriminatory. In particular, the Intervener's cost-sharing model is non-discriminatory because the Appellant's affiliates – if any – would not be required to pay a share of costs of the information required for registration purposes either. 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 PFAE M&B group.

**Findings of the Board of Appeal**

29. 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).

30. 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).

31. In the present case, the Appellant and the Intervener could not agree on the cost-sharing model that should be applied for calculating the share of the costs to be borne by the Appellant.

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

### 1. Compliance with the requirements for data and cost-sharing to be fair, transparent and non-discriminatory

33. The assessment of whether a previous registrant complied with the requirements for data and cost-sharing to be transparent, fair and non-discriminatory 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, it is then possible to examine whether the terms proposed by the previous registrant are fair and non-discriminatory (see *REACH & Colours and REACH & Colours Italia*, cited in paragraph 29 above, paragraph 85).

34. First, 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 as to (i) which information is to be shared, (ii) how the cost of generating the information is determined, (iii) how the cost of gathering and submitting the information to the Agency is determined, and (iv) how costs are to be shared among registrants (see *REACH & Colours and REACH & Colours Italia*, cited in paragraph 29 above, paragraphs 77 and 78).

35. In the present case, the Intervener provided clear and comprehensible explanations of its proposed cost-sharing model. It therefore complied, to this extent, with the requirements for data and cost-sharing to be transparent.

36. Second, in order to comply with the requirements for data and cost-sharing to be fair, a previous registrant can only require a potential registrant to pay a share of the costs of generating, gathering and submitting to the Agency the information that the potential registrant requires for the purposes of its own registration. These costs must moreover be actual in the sense that they can be determined either by proof or by approximation (see *REACH & Colours and REACH & Colours Italia*, cited in paragraph 29 above, paragraphs 79 to 81).

37. In the present case, the Intervener proposed to divide the costs of the information at issue by the number of registrants who rely on that information in their registration dossiers. The Appellant proposed to divide those costs first by the number of substances for which the information is used, and then by the number of registrants of each substance who rely on that information in their registration dossiers.

38. Both of these cost-sharing models comply with the requirements for data and cost-sharing to be fair, as defined in paragraph 36 above. It falls to national courts, in accordance with the last sentence of Article 30(3), to decide which of these models constitutes an '*equal share of the cost*' and is therefore preferable.

39. Third, 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 29 above, paragraphs 82 and 83).

40. According to the cost-sharing model proposed by the Intervener, registrants' affiliates are not required to pay a share of the costs if they submit their own registration dossier to the Agency.

41. 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.

42. 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.

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

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

45. 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.

46. 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.

47. First, contrary to the Intervener's 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.

48. 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.

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

**2. Result**

50. 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 29 above).

51. The Intervener failed to comply with the requirements for data and cost-sharing to be non-discriminatory as regards the status of registrants' affiliates (see Section 1 above).

52. The Contested Decision states in this regard:

'*[The Agency] notes that in the context of their efforts to reach an agreement with the [Appellant], the [Intervener] could have nevertheless taken steps to concretely demonstrate how the participation of affiliates in the data and cost sharing for the substance complies with the requirements of fairness, transparency and non-discrimination. […] [Finding that the Appellant's application for permission to refer must be denied] is without prejudice to whether the [Intervener] made every effort or not […].*'

53. This wording shows that the Agency was aware of the fact that the Intervener failed to comply with the requirements for data and cost-sharing to be non-discriminatory as regards the status of registrants' affiliates. However, the Agency did not draw any consequence from that finding with regard to the permission to refer.

54. It must consequently be held that the Agency breached Article 5 of Implementing Regulation 2016/9 because it failed to take into account the fact that the Intervener did not comply with the requirements for data and cost-sharing to be non-discriminatory as regards the status of registrants' affiliates.

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

56. 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.

57. The Appellant's application for permission to refer must be granted because, despite the Appellant's objections, the Intervener failed to comply with the requirements for data and cost-sharing to be non-discriminatory as regards the status of registrants' affiliates.

58. Furthermore, the documentation in this case is sufficiently complete to allow the Board of Appeal to adopt its own decision. The Notice of Appeal in this case contains a list of the studies to which the Appellant seeks permission to refer and the Intervener confirmed the accuracy of this list during the hearing.

59. The Board of Appeal therefore considers it appropriate to grant the Appellant permission to refer to the relevant studies, listed in the Annex to this decision.

**Refund of the appeal fee**

60. The appeal fee is 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. **Annuls the Contested Decision.**
2. **Grants Tecnofluid S.r.l. permission to refer to the studies listed in the Annex to this decision.**
3. **Decides that the appeal fee is 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

**Annex**

**Studies to which the Appellant is granted permission to refer**

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| 6.1.1. Short-term toxicity to fish | Swarbrick, 2005, OECD TG 203<br>(CAS No 68334-05-4) |
| 6.1.2. Long-term toxicity to fish | Marshall, 2004, ISO/DIS 10229-1<br>(CAS No 68783-41-5) |
| 7.2.1. Acute toxicity: oral | Thouin, 1986, OECD TG 401<br>(CAS No 61788-89-4)<br>Rowe and McCollister, 1982, no guideline<br>(CAS No 104-76-7) |
| 7.2.2. Acute toxicity: inhalation | Huygevoort, 2010, OECD TG 436<br>(CAS No 68334-05-4) |
| 7.3.1. Skin irritation/corrosion | Stitzinger, 2010, OECD TG 404<br>(CAS No 68334-05-4) |
| 7.3.2. Eye irritation | Stitzinger, 2010, OECD TG 405<br>(CAS No 68334-05-4) |
| 7.4.1. Skin sensitisation | Stitzinger, 2010, OECD TG 429<br>(CAS No 68334-05-4) |
| 7.5.1. Repeated dose toxicity: oral | Spurgeon and Hepburn, 1993, OECD TG 408<br>(CAS No 61788-89-4)<br>Astill, 1996, OECD TG 408<br>(CAS No 104-76-7) |
| 7.6.2. Genetic toxicity *in vivo* | Putman, 1983, OECD TG 475<br>(CAS No 104-76-7) |
| 7.8.2. Developmental toxicity/ teratogenicity | Tyl, NTP, 1991, OECD TG 414<br>(CAS No 104-76-7) |