

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

20 December 2017

Application to intervene

(Interest in the result of the case – Representative association – ECHA accredited stakeholder – Data-sharing dispute)

Case number	A-010-2017
Language of the case	English
Appellants	REACH & Colours Italia Srl, Italy REACH & Colours Kft, Hungary
Representatives	Ruxandra Cana, Eléonore Mullier and Hannah Widemann Steptoe & Johnson 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')
Applicant	PETA International Science Consortium Ltd, United Kingdom

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. On 4 August 2017, the Appellants filed an appeal against the Contested Decision.
2. On 17 October 2017, an announcement of the appeal was published on the website of the European Chemicals Agency (the 'Agency') in accordance with Article 6(6) 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; as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.5.2016, p. 4; the 'Rules of Procedure').
3. On 31 October 2017, PETA International Science Consortium Ltd applied to intervene in these appeal proceedings in support of the Agency.
4. On 15 and 17 November 2017 respectively, the Appellants and the Agency submitted observations on the application to intervene.

Arguments

Arguments of the Applicant

5. The Applicant claims to have an interest in the result of the case for the following reasons.
6. First, as an accredited stakeholder of the Agency, the Applicant is representative in its field of competence and has a legitimate interest in the Agency's work. The Applicant's member organisations and their individual supporters are concerned about animal testing issues and seek to minimise the amount of animal testing conducted.
7. Second, the Applicant's objectives include representing, and thereby protecting, the interests of its member organisations as well as those of the member organisations' individual supporters. The core interest of the member organisations and their supporters is reducing, and ultimately eliminating, the use of animals in regulatory testing and other scientific procedures both within and outside the European Union.
8. Third, the Applicant is an ECHA-accredited stakeholder and actively '*participates in the work of the Member States and certain committees, including attendance at the Member State Committee.*'
9. Fourth, the appeal raises questions of principle which directly impact animal testing and may affect the interests of the Applicant and its members to an appreciable extent. These questions of principle include:
 - the extent of the Agency's powers and competences with regards to the requirements for sharing data from tests on vertebrate animals under the REACH Regulation and the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing (OJ L 3, 6.1.2016, p. 41, the 'Implementing Regulation');
 - the relationship between Article 25 and the other Articles under Title III of the REACH Regulation; and
 - the '*standard of effort*' required from registrants to demonstrate that every effort has been made to reach an agreement on data sharing under the REACH Regulation.

10. Fifth, the outcome of the appeal will have an impact on how the data sharing provisions of the REACH Regulation, which are central to ensuring compliance with Article 25, are applied. As a result, the outcome of the appeal is of direct interest to, and directly affects, the Applicant, its member organisations and the member organisations' individual supporters in achieving the aim of the reduction and ultimately elimination of the use of animals in regulatory testing.

Arguments of the Appellants

11. The Appellants argue that the Applicant has failed to demonstrate that it would be directly affected by the outcome of the present appeal. The Contested Decision grants a number of data claimants permission to refer to vertebrate animal studies submitted by the Appellants. If the Contested Decision is annulled the data claimants would not be allowed to conduct or duplicate tests on vertebrate animals and would have to continue negotiating access to the results of the vertebrate animal studies.
12. Therefore the outcome of the present appeal will have no impact on animal testing because, whatever its outcome, it will not lead to a repetition or duplication of existing animal tests or *'to a possibility for the potential registrants to conduct new animal tests'*.

Arguments of the Agency

13. The Agency argues that there is no direct link between the outcome of an Agency decision on a data sharing dispute and the performance of a vertebrate animal study. The REACH Regulation does not allow data claimants to repeat vertebrate animal studies even if the Agency has not granted permission to refer to them. On the contrary, data claimants in this situation would have to keep negotiating the sharing of such studies with existing registrants or to accept the conditions imposed by the other party to the dispute or to decide not to manufacture or import the substance in question. The present appeal does not concern the need to repeat a vertebrate animal study. Rather it concerns whether the parties to the data sharing dispute made every effort to reach an agreement on the sharing of data from vertebrate animal studies.

Reasons

14. Article 8(1) of the Rules of Procedure provides that any person establishing an interest in the result of a case submitted to the Board of Appeal may be granted leave to intervene in that case.
15. Article 8(2) of the Rules of Procedure further provides that an application to intervene must state the circumstances establishing the right to intervene and must be submitted within three weeks of publication of the announcement of the notice of appeal on the Agency's website. Article 8(3) provides that the application must be limited to supporting or opposing the remedy sought by one of the parties. Article 8(4) lists the information the application must contain.
16. Since the application complies with Article 8(2), 8(3) and 8(4) of the Rules of Procedure, the Board of Appeal will examine whether the application complies with Article 8(1) of the Rules of Procedure, in other words whether the Applicant has established an interest in the result of the present case.
17. Representative associations whose object is to protect their members' interests in cases raising questions of principle liable to affect those members may be granted leave to intervene. More particularly, a representative association may be granted leave to intervene in a case if it represents an appreciable number of those active in the field concerned, its objects include that of protecting its members' interests, the case may raise questions of principle capable of affecting those interests, and the interests of its

members may therefore be affected to an appreciable extent by the judgment to be given (see Case A-018-2014, *BASF Grenzach*, Decision of the Board of Appeal of 6 October 2015 on the application to intervene by PISC, paragraph 15).

18. In the present case, the Applicant is an accredited stakeholder organisation with the Agency. As such, the Applicant must fulfil the five eligibility criteria set by the Agency for accredited stakeholders (see the Revised Eligibility Criteria for ECHA's Accredited Stakeholders, adopted by the Management Board on 21 June 2011, MB/34/2011). One of these criteria, in the validation process for accredited stakeholder organisations, is that a stakeholder must have a legitimate interest in the areas of work of the Agency. A second criteria is that the stakeholder must be representative in its field of competence.
19. As the Applicant has been approved as an accredited stakeholder organisation it follows that the Applicant satisfies the criteria of being a representative association which aims to protect its members' interests, namely the avoidance of animal testing.
20. It remains to be examined whether the present case raises questions of principle capable of affecting the Applicant's and its members' interests and whether those interests may be affected to an appreciable extent by the Board of Appeal's decision on the appeal.
21. The present appeal was brought following a dispute between the Appellants and the data claimants concerning the sharing of data from tests on vertebrate animals. According to the Contested Decision, the Agency found that the data claimants had, whereas the Appellants had not, made every effort to reach a fair, transparent and non-discriminatory agreement on the sharing of information requested under Article 30(1) of the REACH Regulation. As a result, the Agency granted the data claimants permission to refer to the requested information.
22. The subject-matter of the appeal is therefore, firstly, related to the Agency's decision to grant the data claimants permission to refer to information derived from testing on vertebrate animals. And, secondly, whether the parties to the data sharing dispute had made every effort to ensure that the costs of sharing the information were determined in a fair, transparent and non-discriminatory way. It is in relation to this subject-matter that the required interest must be determined.
23. The Applicant's interest must therefore be determined in the context of the Agency's decision to grant the data claimants permission to refer and the Agency's assessment of every effort the Parties made during the data sharing dispute under Article 30(1) of the REACH Regulation.
24. It is clear that the Applicant's and its member organisations' and individual supporters' interest, in this case, is in relation to animal welfare, reducing the suffering of animals in testing and avoiding animal testing where possible. This relates to Articles 13 and 25 of the REACH Regulation.
25. The Board of appeal considers that pursuant to Article 30(3) of the REACH Regulation, following the initiation of a data-sharing dispute, animal testing may only be repeated in those circumstances where that dispute occurs before the submission of the registration dossier of the study owner, the Agency has prevented a registration being made by the owner of the study, and the Agency has decided that the test in question should be repeated (see Case A-017-2013, *Vanadium R.E.A.C.H. Forschungs- and Entwicklungsverein*, Decision of the Board of Appeal of 30 January 2014 on the application to intervene by ECEAE, paragraph 22). Those circumstances are not present in this case.

26. Therefore, even if as a result of the Board of Appeal's decision the data claimants were not granted permission to refer to the requested information, the data claimants would not be permitted to repeat the studies in question. In this situation, Article 30(1) and (3) of the REACH Regulation and the Agency's Guidance on Data Sharing (version 3.1, January 2017) state that the Appellants and the data claimants still have to make every effort to reach an agreement on the sharing of the requested information. Even if these efforts fail the data claimant is not permitted to repeat the studies in question.
27. It follows that if the Board of Appeal decides that the data claimants have not made every effort during the data sharing negotiation, they would have to continue negotiating to share the studies with the Appellants, accept the conditions proposed by the data-owner, or decide not to manufacture or import the substance in question. If an agreement cannot be reached between the parties another data sharing dispute can be submitted to the Agency (see the Decision of the Board of Appeal of 30 January 2014 in *Vanadium R.E.A.C.H. Forschungs- and Entwicklungsverein*, cited in paragraph 25, paragraph 21)).
28. In view of the above, even if the form of order sought by the Appellants is granted in the present case this will not lead to the duplication of animal testing. It follows that the outcome of the present appeal will not affect the interests of the Applicant, its member organisations and its individual supporters to an appreciable extent. The Applicant's interest in the result of the present case is therefore not established as required by Article 8(1) of the Rules of Procedure.
29. The present application to intervene must therefore be dismissed.

On those grounds,

THE BOARD OF APPEAL

hereby:

Dismisses the application to intervene.

Mercedes Ortuño
Chairman of the Board of Appeal

Alen Močilnikar
Registrar of the Board of Appeal