

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

**30 January 2014**

**Application to intervene**

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

<b>Case number</b>	A-017-2013
<b>Language of the case</b>	English
<b>Applicant</b>	European Coalition to End Animal Experiments (ECEAE) United Kingdom  Represented by: Katy Taylor and David Thomas London United Kingdom
<b>Contested decision</b>	DSH-30-3-0018-2013 of 12 July 2013 adopted by the European Chemicals Agency (hereinafter the '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; hereinafter the 'REACH Regulation')
<b>Appellant</b>	Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein Austria
<b>Representative</b>	Darren Abrahams and Indiana de Seze Steptoe & Johnson LLP Brussels Belgium

**THE BOARD OF APPEAL**

composed of Mercedes ORTUÑO (Chairman), Andrew FASEY (Rapporteur) and Rafael Antonio LÓPEZ PARADA (Member)

Registrar: Sari HAUKKA

gives the following

## Decision

### SUMMARY OF THE FACTS

1. On 14 October 2013, the Appellant filed an appeal at the Registry of the Board of Appeal against the Contested Decision.
2. On 22 November 2013, an announcement of the Notice of Appeal was published on the website of the Agency in accordance with Article 6(6) of Commission Regulation (EC) No 771/2008 of 1 August 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; hereinafter the 'Rules of Procedure').
3. On 5 December 2013, the Applicant filed an application with the Registry of the Board of Appeal seeking leave to intervene in the proceedings. The Applicant opposes the remedy sought by the Appellant.
4. On 9 and 10 January 2014 respectively, the Appellant and the Agency submitted their observations on the application.

### ARGUMENTS OF THE PARTIES

#### Applicant's arguments

5. The Applicant claims an interest in the result of the case brought before the Board of Appeal for the following reasons:
  - (a) The Applicant is Europe's leading alliance of animal protection organisations, representing people who are concerned about the use of animals in laboratories. It has members in 22 European Union Member States and is an accredited stakeholder organisation with the Agency working for the avoidance of animal testing. The Applicant is also an observer at the Member State Committee and Risk Assessment Committee meetings;
  - (b) The Applicant was granted leave to intervene in previous cases before the Board of Appeal and the Board of Appeal's reasoning in those appeals concerning the Applicant's suitability to intervene in those appeals applies with equal force to the present proceedings;
  - (c) The data-sharing provisions of the REACH Regulation are crucial to the achievement of the key REACH principle that tests on vertebrate animals should be avoided wherever possible. It is in the interests of the Applicant, as well as its members, that the provisions of Article 30(3) of the REACH Regulation are construed in a way that encourages compliance;
  - (d) If the Contested Decision is overturned, animal studies are very likely to be duplicated and it is in the Applicant's interest to ensure that animal tests are a last resort, as required by Article 25(1) of the REACH Regulation; and
  - (e) As the outcome of the dispute will depend in part on the lawfulness of the approach taken by the Agency to the legal tests in Article 30 of the REACH Regulation, and to the lawfulness and application of its guidance on data-sharing, the appeal is likely to have implications beyond its particular facts.

#### Arguments of the Agency and the Appellant

6. The Agency does not oppose the application to intervene. In its observations on the application, however, the Agency stated that in the present case there is no direct link between the outcome of the Agency's decision on the data-sharing dispute and the performance of a vertebrate animals study. According to the Agency, if a claimant in a data-sharing dispute is not granted permission to refer to vertebrate animal studies, it

would be obliged to either keep negotiating the sharing of the studies, accept the conditions proposed by the data-owner, or decide not to manufacture or import the substance in question. According to the Agency the appeal does not therefore concern the need to repeat a vertebrate animal study but rather whether the parties have made every effort to reach an agreement in their data-sharing negotiations.

7. The Appellant objects to the application to intervene. The Appellant claims that the Applicant has not demonstrated that it has an interest in the result of the present case. In particular, the Appellant claims that in the event the Contested Decision is overturned the parties to the data-sharing dispute will resolve the issues which led to the dispute in question without the duplication of such tests. The Appellant claims moreover that it is not credible that the Agency could permit the repetition of tests in circumstances where the Board of Appeal had concluded that every effort to reach an agreement had not been made. The parties to the data-sharing dispute would either reach an agreement by making every effort, or the dossier of the company requesting permission to refer to the studies (hereinafter the 'data-claimant') would be deemed by the Agency to be incomplete and rejected.

## REASONS

8. In accordance with Article 8(1) of the Rules of Procedure, any person establishing an interest in the result of a case submitted to the Board of Appeal may intervene in that case.
9. Article 8(2) of the Rules of Procedure provides further that an application to intervene must state the circumstances establishing the right to intervene and must be submitted within two weeks of publication of the announcement of the notice of appeal on the website of the Agency. Furthermore, pursuant to Article 8(3) the application must be limited to supporting or opposing the remedy sought by one of the parties. In addition, Article 8(4) lists the information the application shall contain.
10. Since the application complies with Articles 8(2), 8(3) and 8(4) of the Rules of Procedure, the Board of Appeal shall therefore examine whether the application also 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.
11. An interest in the result of the case must be defined in the light of the precise subject-matter of the dispute and be understood as meaning a direct, existing interest in the decision on the form of order sought and not as an interest in relation to the pleas in law and arguments put forward. The expression 'result' is to be understood as meaning the operative part of the final decision of the Board of Appeal. It is necessary, in particular, to ascertain whether the Applicant is directly affected by the contested decision and whether its interest in the result of the case is established (see, by analogy, for example, the Order of the Fourth Chamber of the General Court of 25 February 2003 in Case T-15/02 *BASF v Commission*, [2003] ECR II-213, paragraph 26).
12. 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, an 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, by analogy, for example, the Order of the President of the First Chamber of the General Court of 26 February 2007 in Case T-125/03 *Akzo Nobel Chemicals Ltd and Akros Chemicals Ltd v Commission*, paragraph 14 and the case-law cited therein).

*Applicant's interest in the result of the present case*

13. In the present case, the Applicant is an Accredited Stakeholder Organisation with the Agency. As such, the Applicant must, by implication, 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 Doc: MB/34/2011). During the validation process for Accredited Stakeholder Organisations, the Agency, inter alia, verifies that a stakeholder has a legitimate interest in the areas of work of the Agency and that the stakeholder is representative in its field of competence.
14. In particular having regard to its status as an Accredited Stakeholder Organisation, and in line with its previous decisions on applications to intervene, the Board of Appeal considers that the Applicant satisfies the criteria of being a representative association which aims to protect its members' interests, namely the avoidance of animal testing.
15. The Board of Appeal is therefore required to consider whether the present case raises questions of principle capable of affecting the interests of the Applicant and its members and whether those interests may be affected to an appreciable extent by the Board of Appeal's decision on the appeal.
16. The present appeal was brought following a dispute between the Appellant and the data-claimant concerning the sharing of data involving tests on vertebrate animals. According to the Contested Decision, the Agency decided that the data-claimant had made every effort, whereas the Appellant had not, 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-claimant permission to refer to the requested information.
17. In the present appeal, the Appellant requests the Board of Appeal to annul the Contested Decision in so far as it granted the data-claimant permission to refer to studies involving testing on vertebrate animals which the Appellant had included in its registration dossier. The Appellant also requests the Board of Appeal to adopt a decision refusing the data-claimant's claim to refer to the requested information in its registration dossier.
18. The Board of Appeal observes that the subject-matter of the appeal is therefore related to the Agency's decision to grant the data-claimant permission to refer to information involving testing on vertebrate animals and 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. As stated in paragraph 11 above, it is in relation to that subject-matter that the required interest must be defined.
19. The Board of Appeal observes that it is clear that the interest of the Applicant and its member organisations, in this case, is to ensure that animal tests are undertaken only as a last resort, as required by Article 25(1) of the REACH Regulation, and that duplication of animal testing is avoided. With this interest in mind, and with a view to establishing an interest in the result of the present appeal, the Applicant claims that if the Contested Decision is overturned by the Board of Appeal it is very likely that animal testing will be duplicated.
20. The Board of Appeal notes however that both the Appellant and the Agency have stated in their observations on the application to intervene that if the data-claimant is not granted permission to refer to the requested information it does not mean that the data-claimant is permitted to repeat the studies in question. In such circumstances, both parties are still obliged to make every effort to reach an agreement on the sharing of the requested information and even if these efforts fail the data-claimant is not permitted to repeat the studies in question. The Board of Appeal considers that this position is supported by Article 30(1) and (3) of the REACH Regulation and the Agency's Guidance on Data Sharing (Version 2.0 of April 2012).

21. In the present case, the Board of Appeal notes that the Appellant was an existing registrant of vanadium at the time the data-sharing dispute was initiated by the data-claimant. Furthermore, as confirmed by the Agency, even if the Board of Appeal decides that the data-claimant has not made every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way, the data-claimant would have to either continue negotiating the sharing of the studies with the Appellant, accept the conditions proposed by the data-owner, or decide not to manufacture or import the substance in question. In addition, if an agreement could not be reached between the parties another data-sharing dispute could be submitted to the Agency.
22. The Board of Appeal also 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 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. As indicated above, those circumstances are not present in this case.
23. In view of the above, the Board of Appeal considers that even if the form of order sought by the Appellant is granted in the present case this will not lead to the duplication of animal testing. As a result, the interests of the Applicant and its members will not be affected to an appreciable extent by the Board of Appeal's decision. 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.
24. For the above reasons, the application to intervene submitted by the Applicant must be dismissed.

## **ORDER**

On those grounds,

THE BOARD OF APPEAL

hereby:

**Dismisses the application to intervene.**

Mercedes ORTUÑO  
Chairman of the Board of Appeal

Sari HAUKKA  
Registrar of the Board of Appeal