

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

**26 April 2012**

**Application to intervene**

*(Interest in the result of the case – Representative association – ECHA accredited stakeholder)*

<b>Case number</b>	A-001-2012
<b>Language of the case</b>	English
<b>Applicant</b>	European Coalition to End Animal Experiments (ECEAE)  <b>Represented by:</b> Dr. Katy Taylor 16a Crane Grove London N7 8NN United Kingdom
<b>Contested decision</b>	CCH-D-0000001716-72-04/F of 24 October 2011 adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 41 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>	Dow Benelux B.V. Netherlands  <b>Represented by:</b> Messrs Hartmut Scheidmann and Dr. Michael Winkelmüller Redeker Sellner Dahs - Rechtsanwälte Leipziger Platz 3 D-10117 Berlin Germany

### **THE BOARD OF APPEAL**

composed of Mercedes ORTUÑO (Chairman and Rapporteur), Mia PAKARINEN (Legally Qualified Member) and Andrew FASEY (Technically Qualified Member)

Registrar: Sari HAUKKA

gives the following

### **Decision**

#### **SUMMARY OF THE FACTS**

1. On 24 January 2012, the Appellant filed an appeal with the Registry of the Board of Appeal (hereinafter the 'Registry') against the contested decision.
2. On 20 February 2012, 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 March 2012, the Applicant filed an application with the Registry seeking to intervene in the proceedings in support of the Appellant.
4. On 7 March 2012, the application to intervene was served on the Appellant and the Agency.
5. On 15 March 2012, the Appellant submitted its observations on the application to intervene.
6. The Agency submitted its observations on the application to intervene on 26 March 2012.

#### **ARGUMENTS OF THE PARTIES**

##### **Applicant's arguments**

7. The Applicant claims an interest in the result of the present case. The reasons put forward by the Applicant to support its claim that it has an interest in the result of the case can be summarised as follows:
  - (a) The Applicant states that it is Europe's leading alliance of animal protection organisations, representing over one million supporters who are concerned about the use of animals in laboratories. It adds that it is an accredited stakeholder organisation with the Agency, and is the animal protection observer at the Agency's Member State Committee (hereinafter 'MSC') and Risk Assessment Committee (hereinafter 'RAC'). The Applicant also states that it has a team of toxicologists researching scientific information to help avoid animal tests proposed by registrants under the testing proposal system;
  - (b) The Applicant claims that it attended the open session of the 19<sup>th</sup> meeting of the MSC at which the substance, which is the subject of the contested decision, was discussed;

- (c) The Applicant states that its interest lies in the Agency's non-acceptance of the 'read-across' approach, which is a key way of avoiding animal testing, proposed by the registrant as part of their registration dossier. According to the Applicant, the present case is a test case on the application of 'read-across' for fulfilling information requirements for registration dossiers under the REACH Regulation. The Applicant adds that, in addition to the scientific issues specific to the substance, there will almost inevitably be questions of principle for the Board of Appeal to consider.

### **Appellant's arguments**

8. The Appellant supports the application to intervene and considers that the requirements for an intervention are fulfilled.

### **Agency's arguments**

9. The Agency objects to the application to intervene. The reasons the Agency has put forward in support of its objection can be summarised as follows:

- (a) The Agency considers that the Applicant has not established that it fulfils the four cumulative conditions for intervening as a representative association as developed in the case-law of the European Court of Justice.

More specifically, the Agency claims that, firstly, the Applicant has not demonstrated that it represents an appreciable number of operators active in the sector concerned.

Secondly, the Applicant has neither claimed that its objects include the protection of its members' interests nor has it put forward documentation that reflects that it protects such interests.

Thirdly, the Applicant has not shown in what way its members may be affected by the contested decision.

Fourthly, the outcome of the present appeal does not raise questions of principle affecting the functioning of the Applicant's members. As a stakeholder, the Applicant has no contributing role to play in the Agency's decision-making on compliance checks and therefore its status of stakeholder at MSC meetings is not sufficient to create an interest that affects its members to an appreciable extent;

- (b) The Agency states further that the Applicant cannot intervene on its own behalf as it has no direct interest in the case. The Agency adds that the Applicant's status as a stakeholder at the MSC and its representative's attendance at the open session of the relevant meeting of the MSC are not sufficient in themselves to grant the Applicant such an interest. As regards dossier evaluation, the involvement of stakeholders in decision-making processes is limited to a level that ensures appropriate transparency and, as observers they do not contribute to the decision-making process for dossier evaluation. Moreover, the legislator has not foreseen the possibility for any third party to bring forward concerns it might have regarding the outcomes of decision-making on compliance checks in accordance with Article 41 of the REACH Regulation. The Agency states that the meaning of 'interest' in the context of Article 8(1) of the Rules of Procedure needs to be interpreted in the context of the decision-making process established by the REACH Regulation and has a different meaning than the concept of 'interest' that underlies the wording 'interested parties' in the context of Recital 40 of the REACH Regulation.

**REASONS**

10. 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.
11. 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.
12. In the present case, the application complies with Articles 8(2), (3) and (4) of the Rules of Procedure.
13. 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.

*Notion of 'interest in the result of the case' in proceedings before the Board of Appeal*

14. Article 8(1) of the Rules of Procedure provides that '[a]ny person establishing an interest in the result of the case submitted to the Board of Appeal may intervene in the proceedings before the Board of Appeal'. In addition, the Board of Appeal, when deciding on applications to intervene, must have regard to the interests of all parties involved, and the efficiency and proper course of proceedings before it.
15. The wording of Article 8(1) of the Rules of Procedure reflects Article 40 of the Statute of the Court of Justice of the European Union (hereinafter the 'Statute' and the 'European Court of Justice'), which provides that the right to intervene is open to '(...) any other person who can establish an interest in the result of a case submitted to the Court'.
16. Given the parallels between the Rules of Procedure and the Statute on this point, and notwithstanding the difference in the nature of proceedings before the Board of Appeal, on the one hand, and the European Court of Justice, on the other, the relevant case-law of the European Court of Justice related to the assessment of applications to intervene can provide assistance to the Board of Appeal when interpreting Article 8(1) of the Rules of Procedure.
17. By way of a preliminary observation, the European Court of Justice has consistently held that the required interest must be defined in relation to the subject-matter of the case, which is framed by the form of order sought by the parties. Further, for an application to intervene to be granted, an applicant must establish a direct and existing interest in the form of order sought by the party whom it intends to support (see, for instance, the Order of the President of the Second Chamber of the General Court of 5 October 2011 in Case T-454/10 *Associazione Nazionale degli Industriali delle Conserve Alimentari Vegetali v. Commission*, paragraphs 11 and 12).
18. The Board of Appeal also observes that the European Court of Justice has applied the concept of '*interest in the result of a case*' differently with respect to applications by natural and legal persons, on the one hand, and by representative associations, on the

other (see, for instance, the Order of the President of the Seventh Chamber of the General Court of 20 November 2008 in Case T-167/08 *Microsoft Corporation v. Commission*).

19. With regards to the possibility for representative associations to intervene, the European Court of Justice has consistently held that representative associations whose object is to protect their members in cases raising questions of principle liable to affect those members are allowed to intervene. More particularly, an association may be granted leave to intervene in a case if it represents an appreciable number of operators active in the sector concerned, its objects include that of protecting its members' interests, the case may raise questions of principle affecting the functioning of the sector concerned, and the interests of its members may therefore be affected to an appreciable extent by the judgment to be given (see, for instance, 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 Akcros Chemicals Ltd v. Commission*, paragraph 14 and the case-law cited therein).
20. In its previous assessment of an application to intervene by a representative association in a separate appeal, the Board of Appeal in principle applied the same four criteria used in the European Court of Justice's case-law. However, when applying those criteria, the Board of Appeal must also have regard to the specific context in which Article 8(1) of the Rules of Procedure is applied. That provision should not be interpreted without having necessary and due regard to the REACH Regulation and the regulatory framework that underpins it. In particular, the REACH Regulation seeks to promote and ensure various interests, including a high level of protection of human health and the environment, and the promotion of alternative methods for the assessment of the hazards of substances (see, to that effect, for instance Article 1(1) of the REACH Regulation). In that regard, it should be furthermore mentioned that another of the objectives of the REACH Regulation is the promotion of non-animal testing and the replacement, reduction or refinement of animal testing required under it (see, for instance, Article 138(9) of the REACH Regulation).
21. With regard to the considerations set out in the previous paragraph, the REACH Regulation foresees the involvement of stakeholders in the Agency's work through consultations and in the workings of the committees that are established within the Agency (see, for instance, Article 108 of the REACH Regulation). In addition, 'stakeholders should continue to contribute to the promotion of alternative test methods (...) including computer supported methodologies', and 'participation of stakeholders and initiatives involving all interested parties should be sought' (see Recital 40 to the REACH Regulation). This involvement is to help ensure that the various different interests are taken into account in the Agency's decision-making.
22. The case-law of the European Court of Justice related to the intervention of representative associations deals primarily with representative associations for particular interests that are composed of economic operators. It should be observed, however, that the Agency also engages with representative associations with the status of Accredited Stakeholder Organisations that do not only represent the economic interests of their members. When interpreting Article 8(1) of the Rules of Procedure, the Board of Appeal thus takes the view that representative associations or stakeholders representing interests other than economic ones can be considered to be 'operators active in the sector concerned' insofar as intervening in appeals is concerned.
23. In the wider context of the REACH regulatory framework, the document endorsed by the Management Board of the Agency on ECHA's approach towards involving Accredited Stakeholder Organisations in the Agency's work (Doc.: MB/65/2011 final)

states that the Agency's values of transparency, trustworthiness, efficiency, independence and commitment to well-being encourage it to extend its engagement beyond what is specifically stated in the REACH Regulation. According to that document, the engagement is based on cooperation 'models providing maximum mutual benefit', and is 'proactive'. Moreover, Accredited Stakeholders Organisations represent a variety of different areas of interest and allow the Agency to engage in a dialogue with key actors having an interest in REACH at the European Union level. The document endorsed by the Management Board states furthermore that one of the main objectives for the Agency's stakeholder engagement policy is working together with them through 'meaningful' activities.

24. Consequently, when assessing the present application to intervene, the Board of Appeal cannot disregard the role given to stakeholders in the regulatory framework of the REACH Regulation and in the documents endorsed by the Agency's governing body. Moreover, consideration should be also given to the fact that while the four criteria mentioned above in paragraph 19 and those applied by the Agency to an Accredited Stakeholder Organisation are placed within different contexts, certain of the criteria nevertheless overlap. Accordingly, this consideration should also be taken into account when assessing the Applicant's interest in the result of the case.

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

25. The Applicant claims to be a regular participant at the MSC and RAC meetings as the animal protection observer. The Applicant stated, without being contradicted on this point by the Agency, that its representative was present at the open session of the MSC meeting at which the draft of the contested decision was discussed.
26. The Applicant also claims, and the Agency does not dispute it, that it 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, Doc: MB/34/2011). During the selection 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 the field of its competence. Noting that its status as an Accredited Stakeholder Organisation was accepted by the Agency, the Board of Appeal is satisfied as to the Applicant's representativity and its object, which is seeking to minimise the amount of animal testing under the REACH Regulation. Moreover, the supporters of the Applicant's member organisations are concerned about the use of animals in the testing of chemicals. The Applicant is an organisation that is opposed to all experiments on live animals and is actively working for the reduction of animal testing and campaigns on behalf of animals used in laboratories. As a part of this work, the Applicant tries to influence decision-making in relation to animal tests in the context of the REACH Regulation, including by participating in the work of the MSC as an observer.
27. Having regard to the above considerations, the Agency's claim that the Applicant does not protect the interests of its members but that it rather seeks to protect animals cannot be accepted. The Board of Appeal considers that by campaigning for the reduction of animal testing and in promoting the use of alternative test methods as an alternative to tests on vertebrate animals the Applicant protects its members' interests.

28. Having established that the Applicant satisfies the first two criteria for admitting a representative association as an intervener in a case, the Board of Appeal needs to consider whether the present case raises questions of principle that are liable to affect the interests of the Applicant and its members.
29. The Appellant contests the Agency's decision to request further information following the conduct of a specific animal study. More specifically, the Appellant contests, *inter alia*, the Agency's rejection of the Appellant's proposal to use 'read-across' from another substance to satisfy the information requirements in question. In that regard the Appellant also alleges that the Agency 'exhibited an insufficient handling of the read-across approach in general'.
30. The Board of Appeal considers that these issues raise questions of principle regarding the Agency's approach towards the use of 'read-across' to generate information to meet the information requirements specified for registration purposes and more specifically the use of 'read-across' to avoid unnecessary testing on vertebrate animals.
31. Furthermore, the Board of Appeal takes the view that the position taken by it in the present appeal proceedings is liable to affect the Applicant's and its members' interests as described in paragraphs 26 and 27 above. More specifically, the contested decision requires the Appellant to submit to the Agency information for the registered substance obtained from a test involving vertebrate animals. The Applicant's interest in having the contested decision annulled in so far as the Appellant is required to submit further information following the conduct of a specific animal study is consequently established.
32. In view of the above, the Applicant fulfils the criteria to intervene as a representative association. It is therefore not necessary for the Board of Appeal to assess the Agency's claim that the Applicant cannot intervene on its own behalf.
33. For the sake of completeness and as regards the Agency's claim regarding the Applicant's limited involvement in the decision-making on compliance checks in accordance with Article 41 of the REACH Regulation, it should be added that the extent of the Applicant's involvement in the Agency's decision-making is not decisive for the purposes of assessing whether the Applicant fulfils the criteria enabling it to intervene in the present appeal proceedings.
34. In light of the above considerations, the Board of Appeal rejects the Agency's arguments raised in support of its objection to the application to intervene. In this specific case, the Board of Appeal finds that the Applicant's status as an Accredited Stakeholder Organisation and its interest in minimising animal testing in the sphere of the REACH Regulation establish the required interest in the result of the present case.
35. For the above reasons, the application to intervene submitted by the Applicant must be granted.

**ORDER**

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Grants the application to intervene in Case A-001-2012 in support of the Appellant.**
- 2. Instructs the Registrar to arrange for a copy of the procedural documents to be served on the intervener.**
- 3. Allows the intervener a period of one month to lodge further observations on the pleas in law and arguments upon which it relies after copies of the procedural documents have been served on it.**

Mercedes ORTUÑO  
Chairman of the Board of Appeal

Sari HAUKKA  
Registrar of the Board of Appeal