EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

26 September 2012

Application to intervene

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

Case number	A-004-2012
Language of the case	English
Applicant	European Coalition to End Animal Experiments (ECEAE) Represented by: Dr. Katy Taylor and Mr David Thomas 16a Crane Grove London N7 8NN United Kingdom
Contested decision	CCH-D-0000002044-86-04/F of 5 April 2012 adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 41(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')
Appellant	Lanxess Deutschland GmbH Germany
Representative	Ms. Ursula Schliessner and Mr. Nicolas A.J. Croquet McKenna Long & Aldridge LLP 2 , Avenue de Tervueren 1040 Brussels Belgium

THE BOARD OF APPEAL

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

Registrar: Sari HAUKKA

gives the following

Decision

SUMMARY OF THE FACTS

1. On 5 July 2012, the Appellant filed an appeal at the Registry of the Board of Appeal (hereinafter the 'Registry') against the Contested Decision, which was adopted on 5 April 2012.
2. On 7 August 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 13 August 2012, the Applicant filed with the Registry an application to intervene in the appeal proceedings in support of the Appellant.
4. On 14 August 2012, the application to intervene was served on the Appellant and the Agency.
5. On 5 and 6 September 2012, respectively, the Appellant and the Agency submitted observations on the application to intervene.

ARGUMENTS OF THE PARTIES

Applicant's arguments

6. The Applicant claims an interest in the result of the case brought before the Board of Appeal for the following reasons:
   (a) ECEAE is Europe's leading alliance of animal protection organisations, representing people who are concerned about the use of animals in laboratories. It has organisation 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 the '*animal protection observer*' at the Member State Committee (hereinafter 'MSC') and Risk Assessment Committee, the meetings of which it attends regularly. The Applicant also states that its representative, senior scientific advisor Dr. Katy Taylor, attended the meeting of the MSC at which the Contested Decision was discussed.
   (b) ECEAE supports the Appellant's contention that the Agency should allow the Appellant to rely on the results of a future 90-day sub-chronic toxicity study on mice, to be conducted under the auspices of the United States National Toxicology Program (hereinafter 'NTP'). More specifically, the Applicant argues that it agrees with the Appellant that the NTP study will comply with the

information requirements of Section 8.6.2 of Annex IX to the REACH Regulation. According to the Appellant, in some cases the Agency argues that a registrant is legally bound to carry out the studies required by the decision whilst in others the Agency appears to accept that a Registrant can make a case for adaptation, under column 2 of Annexes VII to X or Annex XI, even with regard to studies required by a final decision and can provide new information after the decision. The Agency's position in this respect is a '[…] *crucial issue, with obvious implications for animal welfare, a key objective of REACH*'. The Applicant also maintains, as regards the Appellant's arguments on the weight-of-evidence approach, that '[w]*eight of evidence is a key way of avoiding animal tests under REACH.*' According to ECEAE, '[…] *the Agency (including the MSC) often adopts an unnecessarily conservative approach, with the result that unnecessary animal tests are ordered*'.

(c) ECEAE also supports the Appellant's claim that the Agency's decision to request information from a pre-natal developmental toxicity (PNDT) study in the rabbit via the oral route should be annulled. ECEAE agrees with the Appellant that a study in a second species is not a mandatory information requirement pursuant to Section 8.7.2 of Annex X to the REACH Regulation but is dependent on the results of the PNDT study on the first species as required by Section 8.7.2 of Annex IX to the REACH Regulation. According to the Applicant, PNDT studies '[…] *impose a high welfare burden on the animals involved and consume a large number of animals, so it is particularly important that decisions about them properly reflect REACH principles about avoiding animal tests wherever possible and good science.*'

Appellant's arguments

7. The Appellant supports ECEAE's application to intervene. In its observations on the application to intervene the Appellant has provided comments on ECEAE's arguments:

(a) As regards ECEAE's argument with regard to the adaptation of a registration dossier, the Appellant maintains that the Agency should always have the possibility to revise its compliance check decisions, including before the expiry of the time limit provided to the registrant for providing the updated information, the corollary of which is that a registrant has a constant duty to update its registration dossier on its own initiative. Otherwise, the dossier evaluation procedure would be made ineffective for potentially long periods of time.

(b) ECEAE has wrongly interpreted the Contested Decision as requiring the Appellant to conduct the requested studies, that is a 90-day sub-chronic toxicity study in the rat via oral route, and a PNDT study in the rabbit via the oral route. The Appellant argues that the Contested Decision should be read as imposing on the Appellant an obligation to produce information on the specific endpoints regardless of who the '[…] *author or sponsor of these two studies is*'.

Agency's arguments

8. The Agency objects to ECEAE's application insofar as it relates to the Appellant's request to be allowed to use the results of the NTP study to satisfy the information requirements for sub-chronic toxicity. The Agency considers that the Applicant has failed to establish the required interest and therefore requests the Board of Appeal to dismiss the application in this regard.

9. The Agency has raised the following arguments in support of its objection:

   (a) The Agency states that ECEAE's argument is that the Appellant's request raises the question of whether a registrant is required to conduct studies imposed by the Agency's decision, or whether new information can be provided even after the adoption of such a decision, where the information would render the conduct of the specific study unnecessary. According to the Agency this is not the issue in this case. The Agency states that the issue in the present case is of a procedural nature, and more specifically, whether the Agency is required to revise the Contested Decision in light of information raised by the Appellant after that decision was adopted. In this regard, the Agency does not see how the remedy sought by the Appellant will result in a question of principle that can affect the interests of ECEAE's members to an appreciable extent.

   (b) Second, as regards ECEAE's attempt to establish an interest on the basis of prospective arguments on the sufficiency of the NTP to meet the information requirement of the REACH Regulation, the Agency considers that the Applicant is arguing for a remedy not sought by the Appellant. The present appeal does not concern the question of whether the planned NTP study will meet the information requirements imposed by Section 8.6.2 of Annex IX to the REACH Regulation. According to the Agency, ECEAE's justification must be dismissed as it fails to support or oppose the remedy sought by the Appellant, which is the revision of the Agency's decision as regards the 90-day sub-chronic toxicity study.

   (c) Finally, ECEAE has raised, as a question of principle, the Agency's approach to weight-of-evidence adaptations. According to the Agency, the Appellant has sought the revision of the Contested Decision while the arguments based on weight-of-evidence could only lead to the annulment of the Contested Decision. Therefore, the Agency maintains that the Applicant has failed to establish an interest in the remedy sought by the Appellant.

10. Further, the Agency has requested, in the event that the application to intervene were to be admitted, that the Board of Appeal invite the Applicant to submit observations on the admissibility of the first form of order sought by the Appellant, that is the revision of the Contested Decision with respect to the 90-day sub-chronic toxicity study.

11. As regards the Appellant's plea for annulment of the Contested Decision insofar as it requests information from a PNDT study in a second species, the Agency requests that the application to intervene be dismissed, if it fails to meet the criteria laid down by the Board of Appeal, or in the alternative, to admit the application if the Applicant has met these criteria.

REASONS

12. 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.

13. 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 it must be submitted within two weeks of publication of the announcement of a notice of appeal on the website of the Agency. Furthermore, pursuant to Article 8(3), an application to intervene 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.

14. The application complies with Articles 8(2), 8(3) and 8(4) of the Rules of Procedure. Therefore, the Board of Appeal shall 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' with respect to representative associations in proceedings before the Board of Appeal

15. 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*'.

16. The wording of Article 8(1) of the Rules of Procedure reflects Article 40 of the Statute of the European Court of Justice (hereinafter the 'Statute'), 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*'.

17. The Board of Appeal has held, given the parallels between the Rules of Procedure and the Statute on this point, that the relevant case-law of the European Court of Justice concerning the assessment of applications to intervene provides guidance when applying Article 8(1) of the Rules of Procedure.

18. The European Court of Justice has consistently held that representative associations whose object is to protect their members' interests 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 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, 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). Further, although the interests recognised in the case-law of the European Court of Justice have been primarily of economic and legal nature, it should be noted that these have included also non-economic interests (see, for example, Case T-37/04 R *Região autónoma dos Açores* v. *Council of the European Union*).

19. While the Board of Appeal has, in principle, drawn guidance from the criteria applied in the case-law of the European Court of Justice, it has also observed that Article 8(1) of the Rules of Procedure is applied in a specific legal context. More specifically, Article 8(1) of the Rules of Procedure must be interpreted and applied having due regard to the objectives of the REACH Regulation and the regulatory framework that underpins it. This includes, in particular as regards an application to intervene by a representative organisation, 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). Such stakeholder involvement is foreseen to ensure that various different interests, including non-economic interests, are considered as part of the Agency's decision-making.

20. Therefore, when called upon to apply the criteria for intervention, the Board of Appeal shall have due regard to the specific legal context in which Article 8(1) of the Rules of Procedure is applied and the circumstances of each individual case.

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

21. The Applicant maintains that it is an accredited stakeholder organisation with the Agency. As such, the Applicant must, by implication, fulfil the eligibility criteria laid down by the Agency for accredited stakeholders (see the Revised eligibility criteria for ECHA's Accredited Stakeholders, MB/34/2011). As part of the validation process for accredited stakeholder organisations, the Agency must, inter alia, satisfy itself that an applicant stakeholder has a legitimate interest in the areas of work of the Agency and that the applicant is representative in its field of competence.

22. Considering that the Agency has accepted the Applicant as an accredited stakeholder organisation, the Board of Appeal is satisfied as to the Applicant's representativity and its object, which is seeking to minimise animal testing under the REACH Regulation.

23. It follows, and the Agency has not directly contested this, that the Applicant satisfies the first two criteria for admitting a representative association as an intervener in a case. Therefore, it falls on the Board of Appeal to assess whether the present case raises questions of principle that are liable to affect the interests of the Applicant and its members to an appreciable extent.

24. By its appeal, the Appellant has contested the Agency's decision to request information following the conduct of a 90-day sub-chronic toxicity study in the rat and a PNDT study in the rabbit, both via the oral route.

25. The Applicant argues, inter alia, that pre-natal developmental toxicity studies '[…] *impose a high welfare burden on the animals involved and consume a large number of animals*'.

26. The Board of Appeal considers that there is a clear nexus between the Agency's view that Section 8.7.2 of Annex X to the REACH Regulation requires, as a standard information obligation, the submission of information on a second species, and the Applicant's object to minimise animal testing under the REACH Regulation. As such, the Board of Appeal considers that the Agency's interpretation of Section 8.7.2 of Annex X to the REACH Regulation raises a question of principle, which is liable - in view of the potential animal welfare implications – to affect the interests of the Applicant and its members to an appreciable extent.

27. While the Board of Appeal finds that the Applicant has advanced limited arguments on the issues of principle that are liable to affect its interests and those of its members to an appreciable extent, and some arguments that are not relevant for appraising such interests, the Board of Appeal considers nevertheless that the information provided in the application to intervene is sufficient to establish the Applicant's interest in the PNDT study.

28. By way of a related observation, the Board of Appeal remarks, however, that as an application for intervention is appraised on its specific facts, it is for an applicant to establish, in each individual case where intervention is sought, its interests in the result of that specific case.

29. It follows that as the Applicant has established an interest with respect to the pre-natal developmental toxicity study, the Applicant must be considered as having established an interest in the result of the case, as required by Article 8(1) of the Rules of Procedure.

30. For this and the above reasons, the application to intervene submitted by the Applicant must be granted.

ORDER

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Admits the application to intervene in Case A-004-2012 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, following the serving of the procedural documents, to lodge further observations on the pleas in law and arguments upon which it relies.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal