

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

18 January 2017

Application to intervene

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

Case number	A-005-2016
Language of the case	English
Appellant	Cheminova A/S
Representatives	Ruxandra Cana and Indiana de Seze Steptoe & Johnson LLP
Contested Decision	TPE-D-2114328778-35-01/F of 26 April 2016 adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 40 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')
Applicant to intervene	PETA International Science Consortium Ltd (PISC), United Kingdom

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. On 25 July 2016, the Appellant filed an appeal at the Registry of the Board of Appeal against the Contested Decision.
2. On 5 October 2016, an announcement of the Notice of Appeal was published on the website of the European Chemicals Agency (hereinafter 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; hereinafter the 'Rules of Procedure').
3. On 19 October 2016, the Applicant filed an application with the Registry of the Board of Appeal seeking leave to intervene in the proceedings. The Applicant supports the remedy sought by the Appellant, the annulment of the Contested Decision.
4. On 26 October 2016, the application to intervene was served on the Appellant and the Agency.
5. On 10 November 2016, the Agency and the Appellant each submitted their observations on the application to intervene.

Arguments

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) 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 members and their individual supporters are concerned about animal testing issues and seek to minimise the amount of animal testing conducted;
 - (b) The Applicant's objectives include representing and thereby protecting its members' interests and those of their individual supporters, including their core interest in the reduction and ultimate elimination of the use of animals in regulatory testing and other scientific procedures both within and outside the European Union. The Applicant promotes and funds non-animal research methods and relevant methods and strategies for reducing and eliminating animal testing. Collectively, its member organisations have a total of more than five million individual supporters, including individuals from every Member State of the European Union;
 - (c) The Applicant actively participates in the work of the Member States and certain committees, including attendance at the Member State Committee, and has considerable relevant scientific expertise;
 - (d) The appeal raises questions of principle which directly impact on issues regarding animal testing which may affect the interests of the Applicant and its members to an appreciable extent. These questions include:
 - the circumstances under which the Agency uses the testing proposal evaluation procedure to request additional tests on animals,
 - how the Agency evaluates adaptations to information requirements prior to requesting further tests on animals,
 - how the Agency considers the evaluation of testing proposals for analogue substances prior to requiring further tests on animals, and

- how the Agency considers updates to registration dossiers;
- (e) The outcome of the appeal will have an impact on the number of animals used for testing in relation to this case and future requirements under the REACH Regulation. As a result, the outcome of the appeal is of direct interest to and directly affects the Applicant, its members and their individual supporters in achieving the aim of the reduction and ultimate elimination of the use of animals in regulatory testing.

Arguments of the Agency and the Appellant

7. The Appellant states that it has no observations on the application to intervene.
8. The Agency requests the Board of Appeal to dismiss the application to intervene. The Agency states that it considers that the Applicant has failed to establish an interest in the result of the case within the meaning of Article 8(1) of the Rules of Procedure and does not state precisely the circumstances establishing the right to intervene. The Agency also states that it has doubts as to the relevance of granting the Applicant leave to intervene bearing in mind '*...the increased procedural time and phases incurred by interventions in an appeal*'.
9. The Agency claims that the subject matter of the appeal is not related to the necessity of testing on vertebrate animals but rather concerns the scope of an administrative practice and that in previous decisions on applications to intervene (Decision of the Board of Appeal of 5 September 2012 in case A-003-2012, *Thor GmbH*, and Decision of the Board of Appeal of 15 November 2013 in case A-005-2013, *Vanadium R.E.A.C.H. Forschungs-und Entwicklungsverein*) the Board of Appeal rejected applications to intervene on this basis. The Agency argues that the appeal does not concern the question whether other information would be sufficient to avoid the test imposed in the Contested Decision, but rather concerns aspects of the Agency's administrative practice, such as the use of the legal basis and the question whether the Agency is obliged to monitor other registration data in order to investigate adaptations to standard information requirements. The Agency claims that there is only a possibility that the decision requiring the proposed vertebrate animal tests would have been avoided with a different administrative practice. The Agency claims that the Applicant's interests will not be therefore affected to an appreciable extent by the Board of Appeal's decision on the appeal.
10. The Agency also argues that the Board of Appeal should apply to applications to intervene by animal welfare non-governmental organisations (hereinafter 'NGOs') the criteria developed by the European Court of Justice for examining applications to intervene by environmental NGOs as the two types of organisations operate in a similar manner. In this respect, the Agency refers to, for example, the Order of the President of the General Court of 7 July 2004 in Case T-37/04 R, *The Autonomous Region of the Azores v Council*, EU:T:2004:215. The Agency claims that there is no reason for the Board of Appeal to depart from the Court's case-law in this respect and invites it to reconsider its position adopted in previous intervention decisions.
11. The Agency claims that the Applicant undertakes to establish an interest in the case by referring to a question of principle but not to the precise subject matter of the appeal. The Agency states that the appeal process is not intended to discuss questions of policy and that accredited stakeholders may influence policy choices through other means. The Agency also argues that whilst the Agency's policy choice is relevant for the applicant on a larger scale, in the present case there is no direct interest established by the Applicant.
12. The Agency claims that the present appeal concerns whether the Agency rightfully examined the testing proposals submitted and whether the Agency should have conducted a compliance check instead. The Agency argues that in any case it may have come to the same conclusion under a compliance check as it did following the test proposal examination.

Reasons

13. 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.
14. 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 three weeks of publication of the announcement of the notice of appeal on the Agency's website. Furthermore, pursuant to Article 8(3), the application must be limited to supporting or opposing the form of remedy sought by one of the parties. In addition, Article 8(4) lists the information the application shall contain.
15. Since the application complies with Article 8(2), (3) and (4) of the Rules of Procedure, the Board of Appeal will 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.
16. When examining previous applications to intervene from the Applicant and a similar animal welfare NGO the Board of Appeal has applied, by analogy, the criteria developed by the European Court of Justice for examining applications to intervene by representative associations (see, for example, Case A-005-2014, *Akzo Nobel Industrial Chemicals GmbH and Others*, Decision of the Board of Appeal of 13 October 2014 on the application to intervene by the European Coalition to End Animal Experiments, paragraphs 17 to 19). According to those criteria, a representative association whose object is to protect its 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, 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 Akcros Chemicals Ltd v Commission*, EU:T:2007:57, paragraph 14 and Case A-001-2014, *Cinic Chemicals Europe Sàrl*, Decision of the Board of Appeal of 2 June 2014 on the application to intervene by the European Coalition to End Animal Experiments, paragraph 13).
17. In its objections to the application to intervene the Agency argues in particular that, rather than the criteria set out in the previous paragraph, the Board of Appeal should apply the criteria developed by the European Court of Justice for examining applications to intervene by environmental NGOs (see for example the Order of the Eighth Chamber of the General Court of 6 November 2012 in Case T-520/10, *Comunidad Autónoma de Galicia v Commission*, EU:T:2012:581).
18. The Board of Appeal considers however that the Agency has not demonstrated that the European Court of Justice applies the criteria developed for examining application to intervene by environmental NGOs to applications to intervene by animal welfare NGOs such as the Applicant. Furthermore, the Board of Appeal emphasises that Article 8(1) of the Rules of Procedure should be interpreted with due regard to the REACH Regulation and the administrative nature of these proceedings. In particular, the Board of Appeal observes that 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). This involvement aims to help ensure that various interests are taken into account in the Agency's decision-making (Case A-004-2012, *Lanxess Deutschland GmbH*, Decision of the Board of Appeal of 26 September 2012 on the application to intervene by the European Coalition to End Animal Experiments, paragraph 19).

19. The document endorsed by the Management Board of the Agency on 16 December 2011 on the Agency's approach to engagement with its Accredited Stakeholder Organisations (Doc.: MB/69/2011 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 Stakeholder 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 the REACH Regulation. In addition, the document endorsed by the Management Board states that one of the main objectives for the Agency's stakeholder engagement policy is working together with them through '*meaningful activities*'.
20. The Board of Appeal has also highlighted in previous cases (see for example Case A-001-2014, *Cinic Chemicals Europe Sàrl*, Decision of the Board of Appeal of 2 June 2014 on the application to intervene by the European Coalition to End Animal Experiments, paragraphs 20 to 22) that 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, for example, 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 example, Article 138(9) 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).
21. Consequently, when assessing the present application to intervene, the Board of Appeal must have regard to the role given to stakeholders in the REACH Regulation and in the documents endorsed by the Agency's governing body. The Board of Appeal must also have regard to the need for the Agency to promote alternative testing methods and the need to ensure that, pursuant to Article 25(1) of the REACH Regulation, testing on vertebrate animals is undertaken only as a last resort.
22. The Agency argues that, according to the criteria developed by the European Court of Justice with respect to environmental NGOs, the requirement to establish a direct and existing interest in the result of the case implies that the applicant's sphere of interest must relate to the geographical area and field of the proceedings or, if the applicant's sphere of activity is broad that they are actively engaged in protection programmes or studies on the geographical areas and field concerned which may be jeopardised by the adoption of the Contested Decision.
23. In response to these arguments the Board of Appeal observes that whilst many of its members' activities are concerned generally with animal welfare, the objects of the Applicant, as set out in point 4 of its Articles of Association, focus primarily on the avoidance of animal testing. The Applicant, as an Accredited Stakeholder Organisation, has also demonstrated that its activities are closely linked with the REACH Regulation.
24. Furthermore, having regard to the Agency's commitment to involve stakeholders in its work (see paragraphs 18 to 21 above), it would be an unnecessarily restrictive interpretation of Article 8(1) of the Rules of Procedure in relation to Accredited Stakeholder Organisations to require that an applicant's activities would have to be specifically focused on the actual substance or test concerned within the context of the REACH Regulation. The Board of Appeal observes that it is rarely in the remit of an animal welfare NGOs to work solely on a specific substance or a specific test method. The application of such a criterion would therefore effectively prevent all such organisations from intervening in appeal proceedings. Such an approach would be overly restrictive and would not be consistent with the Agency's commitment to involve stakeholders in its work.

25. Additionally, the criteria used in the case-law for environmental NGOs clearly refer to geographical areas and is consequently not directly applicable to animal welfare NGOs.
26. In view of the above, the Board of Appeal will therefore continue to examine the present application to intervene against the criteria set out in paragraph 16 above.
27. In this respect, 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, 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 the field of its competence.
28. In particular having regard to its status as an Accredited Stakeholder Organisation, the Board of Appeal considers that the Applicant satisfies the criteria of being a representative association which aims to protect its members' interests, in particular the reduction, and ultimate elimination, of animal testing.
29. The Board of Appeal will next examine whether the case may raise questions of principle capable of affecting the interests of the Applicant's members and whether those interests may be affected to an appreciable extent by the Board of Appeal's decision in this case.
30. In the present appeal the Appellant requests the Board of Appeal to annul the Contested Decision which requires it to perform a sub-chronic toxicity study (90-day), oral route in rats, and a pre-natal developmental toxicity study in rats or rabbits, oral route.
31. According to the Contested Decision, the Appellant's proposals for the abovementioned tests to be carried out using an analogue substance and then applied to the Substance using a read-across approach were rejected by the Agency pursuant to Article 40(3)(d) of the REACH Regulation.
32. In its appeal the Appellant claims inter alia that the Contested Decision was adopted on the wrong legal basis and that the Agency exceeded its powers, as the read-across justifications were rejected under Article 40 rather than Article 41 of the REACH Regulation.
33. The Appellant also argues that the adaptations it included in its registration dossier comply with the requirements of Sections 1.2, 1.3 and 1.5 of Annex XI to the REACH Regulation and that, in rejecting those adaptations, the Contested Decision infringes Annex XI. The Appellant adds that the testing on the analogue substance could not have been available because the Agency was required to first carry out a testing proposal examination for the analogue substance pursuant to Article 40 of the REACH Regulation. The Appellant argues that Annex XI, read in accordance with the principles of the REACH Regulation and the overriding principles of European Union law, allows the Agency to accept a legitimate delay in the availability of the studies on the analogue substance before deciding to request testing on the Substance.
34. The Appellant also claims inter alia that the Agency breached Article 25 of the REACH Regulation by failing to consider alternatives to animal testing.
35. The Board of Appeal observes that the Contested Decision rejects the Appellant's read-across proposal and thus requires the Appellant to conduct animal testing. Furthermore, it is possible, based on the submissions in the case to date, that the Agency has simultaneously requested animal testing for the same end-points for two potentially analogous substances which may be in breach of the Article 25 requirement for testing on vertebrate animals to be a 'last resort'.

36. In view of paragraphs 30 to 35 above, the Board of Appeal considers that the appeal raises questions of principle which relate directly to the avoidance of animal testing. As the Applicant has an established interest in the avoidance of animal testing, the Board of Appeal considers that its decision in this case may affect the interests of the Applicant and its members to an appreciable extent.
37. For the above reasons, the Board of Appeal finds that the Applicant, in its capacity of representative association which aims to protect its members' interests, in particular the reduction, and ultimate elimination, of animal testing, has established an interest in intervening in the present proceedings in support of the form of order sought by the Appellant. The application to intervene must therefore be granted.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Admits the application to intervene by PETA International Science Consortium Ltd in Case A-005-2016 in support of the Appellant.**
- 2. Instructs the Registrar to arrange for copies of the non-confidential versions of the Notice of Appeal and the Defence to be served on the Intervener.**
- 3. Allows the Intervener a period of one month, following the serving of the Notice of Appeal and the Defence, to lodge a statement in intervention.**
- 4. Other procedural documents lodged in the present case will be served on the Intervener in due course.**

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Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal