

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

17 May 2016

Application to intervene

(Interest in the result of the case – Representative association – Animal welfare non-governmental organisation – Accredited stakeholder organisation)

Case number	A-023-2015
Language of the case	English
Applicant	PETA International Science Consortium Ltd (PISC), United Kingdom
Contested Decision	Decision of 14 August 2015 on the substance evaluation of tert-butyl perbenzoate adopted by the European Chemicals Agency pursuant to Article 46(1), and in accordance with the procedure laid down in Articles 50 and 52, 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')
Appellants	S.A. Akzo Nobel Chemicals NV, Belgium Arkema GmbH, Germany Pergan GmbH, Germany REACH Compliance Services Limited (trading under the name REACH24H Consulting Group), Ireland United Initiators GmbH & CoKG, Germany
Representatives	Ruxandra Cana and Indiana de Seze Steptoe and Johnson LLP

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 13 November 2015, the Appellants filed an appeal at the Registry of the Board of Appeal against the Contested Decision.
2. On 3 February 2016, 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 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 12 February 2016, the Applicant filed an application with the Registry of the Board of Appeal seeking leave to intervene in the proceedings in support of the remedy sought by the Appellants.
4. On 29 February 2016, the application to intervene was served on the Appellants and the Agency. On 4 and 23 March 2016 respectively, the Appellants and the Agency submitted their observations on the application to intervene.

Arguments

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) 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 three million individual supporters, including individuals from every Member State of the European Union;
 - (c) The Applicant also actively participates in the work of the Member States and certain committees, including attendance at the Member State Committee (hereinafter the 'MSC');
 - (d) The appeal raises questions of principle which directly impact on issues regarding animal testing. These questions include the circumstances under which the Agency uses the substance evaluation or compliance check procedure to request additional tests on animals and how the Agency evaluates submitted and available studies prior to requesting further tests on animals. The Applicant claims that the case also raises questions regarding how the Agency amends draft decisions and how the Agency considers a registrant's comments on draft decisions; and
 - (e) The outcome of the appeal will have an impact on the number of animals used for testing.
6. The Applicant presents several arguments of fact and law in its application. The Applicant states *inter alia* that the Agency's decision requesting the Appellants to perform an *in vivo* alkaline single-cell gel electrophoresis assay for DNA strand breaks

in rats by the oral route is unlawful in particular because there is sufficient scientific data demonstrating that the substance subject to the Contested Decision is not a mutagen. In addition the Applicant states that, as the tests requested in the Contested Decision are not scientifically justified, the Agency has breached the principle of proportionality and Article 25 of the REACH Regulation.

Arguments of the Parties

7. 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. The Agency claims further that the Applicant has failed to fulfil the requirements of Article 8(2) of the Rules of Procedure according to which applications to intervene must state 'the circumstances establishing the right to intervene'.
8. The Agency argues in particular 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, paragraphs 57 to 71. 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 the Board of Appeal to reconsider its position adopted in previous intervention decisions.
9. The Agency states that the Applicant represents a significant number of organisations and that the scope of interests embraces many aspects of the field of animal rights protection. According to the Agency, the Applicant's missions are therefore likely to always interact with the REACH Regulation. The Agency argues further that the Applicant merely sets out the general description of its activities in the broad field of animal rights protection and its involvement in issues related to the avoidance of animal testing.
10. The Agency states that without a strict assessment of the requirement to establish an interest in the result of the case defined in light of the precise subject-matter of the appeal, the Applicant is likely to be concerned by all appeals involving questions on animal testing. According to the Agency, granting the Applicant leave to intervene in all appeals involving questions on animal testing has an impact on the efficiency and proper course of the appeal proceedings, and in particular its length.
11. The Agency claims that by describing its interest at such a general level, the Applicant has failed to establish its direct interest in the precise subject-matter of the present appeal. The Agency claims that the application contains only general statements which could apply to any appeal challenging any Agency request to perform animal tests. According to the Agency, this is not sufficient to establish an actual direct interest in the result of the appeal.
12. The Agency also claims that the Applicant has failed to demonstrate how the issues raised by the Appellants are questions of principle for the Applicant's interests. In particular, the Agency argues that the main question of principle raised by the Appellants is related to the Agency's competence to propose amendments in the substance evaluation process. According to the Agency, the application to intervene fails to demonstrate how this issue is a question of principle for the interests of the Applicant and its members. The Agency claims that the Applicant only makes general statements which could be applicable to any appeal against a decision requiring animal testing.
13. The Agency argues that, taking into account the criteria set by the European Court of Justice for examining applications to intervene by environmental NGOs, since the sphere of activity of the Applicant is broad, it would have to demonstrate that it is

actively engaged in programmes or studies on the testing required by the Contested Decision (i.e. second species pre-natal developmental toxicity study in rabbits and *in vivo* comet assay in rats) and that the Contested Decision would jeopardise the viability of those programmes or studies. The Agency is of the opinion that the Applicant has failed to do so in the present case.

14. The Agency states that as an accredited stakeholder organisation there are other, more appropriate fora than the one of the Board of Appeal where the Applicant could voice concerns on animal testing and work with the Commission, the Agency and the Member States on alternative testing methods.
15. The Appellants state that they have no observations on the application to intervene.

Reasons

16. 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.
17. 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.
18. The Board of Appeal considers that an application to intervene must be considered to comply with Article 8(2) if that application was received within two weeks of the publication of the announcement and contains a description of the circumstances the applicant considers establishes its right to intervene. If, following an evaluation of the application, the Board of Appeal considers that the applicant has not established a right to intervene because it has failed to establish its interest in the result of the case, the application will be dismissed on the basis of Article 8(1), and not Article 8(2), of the Rules of Procedure. The Agency's claim that the applicant has failed to satisfy the requirements of Article 8(2) of the Rules of Procedure must therefore be dismissed.
19. The Board of Appeal also finds that the application complies with Article 8(3) regarding the requirement that the application must be limited to supporting or opposing the remedy sought by one of the parties as well as Article 8(4) regarding the information that the application shall contain.
20. 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 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.
21. 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).

22. The Board of Appeal has adopted a broad interpretation of the right of representative associations to intervene in order to facilitate the assessment of the context of certain cases whilst avoiding multiple individual interventions which would compromise the effectiveness and proper course of the procedure (see, by analogy, for example, the Order of the President of the Court of 17 June 1997 in Joined cases C-151/97 P(I) and C-157/97 P(I), *National Power plc and PowerGen plc v British Coal Corporation and Commission*, EU:C:1997:307, paragraph 66 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 16).
23. In its objections to the application to intervene the Agency argues in particular that, rather than the criteria set out in paragraph 21 above, the Board of Appeal should apply in the present case 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).
24. In response to the Agency's arguments the Board of Appeal considers firstly 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. 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).
25. 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'.
26. The Board of Appeal has also highlighted in previous cases (see for example Case A-001-2012, *Dow Benelux B.V.*, Decision of the Board of Appeal of 26 April 2012 on the application to intervene by the European Coalition to End Animal Experiments, paragraphs 20 and 21) 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, 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). 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).

27. 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.
28. 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 21 above.
29. In this respect the Board of Appeal observes that 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.
30. 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.
31. In the present appeal the Appellants request the Board of Appeal in particular to annul the Contested Decision insofar as it requests the Appellants to conduct a pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rabbits, oral route, and an *in vivo* alkaline single-cell gel electrophoresis assay for DNA strand breaks (Comet assay, OECD 489) in rats, oral route, with examination of liver and either glandular stomach or duodenum/jejunum.
32. The Board of Appeal observes that in the present case the Appellants claim inter alia that the Agency breached Article 25 of the REACH Regulation by failing to consider alternatives to the animal testing required by the Contested Decision. The appeal therefore raises questions which relate directly to the avoidance of animal testing and the Applicant's interest therein.
33. As the Applicant has an 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.
34. The Agency argues that to be granted leave to intervene the Applicant should demonstrate a more specific interest in the result of the case than the protection of animal rights. In response to this argument 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.
35. The Agency argues further that, taking into account the criteria set by the European Court of Justice for applications to intervene by environmental NGOs, since the sphere of activity of the Applicant is broad, it would have to demonstrate that it is actively engaged in programmes or studies on the testing required by the Contested Decision. The Board of Appeal considers however that, having regard to the Agency's commitment to involve certain stakeholders in its work (see paragraphs 24 to 27 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 certain stakeholders in its work.

36. 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.
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 Appellants. The application to intervene submitted by the Applicant 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-023-2015 in support of the Appellants.**
- 2. Instructs the Registrar to arrange for copies of the non-confidential version 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 procedural documents, to lodge observations on the Notice of Appeal and the Defence.**

Mercedes Ortuño
Chairman of the Board of Appeal

Alen Močilnikar
Registrar of the Board of Appeal