

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

**6 October 2015**

**Application to intervene**

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

<b>Case number</b>	A-018-2014
<b>Language of the case</b>	English
<b>Applicant</b>	PETA International Science Consortium Ltd. (PISC) United Kingdom
<b>Contested Decision</b>	SEV-D-2114285478-33-01/F of 19 September 2014 adopted by the European Chemicals Agency pursuant to Article 46(1) 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>	BASF Grenzach GmbH, Germany

**THE BOARD OF APPEAL**

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Rafael López Parada (Legally Qualified Member)

Registrar: Sari Haukka

gives the following

## Decision

### Summary of the facts

1. On 17 December 2014, the Appellant filed an appeal at the Registry of the Board of Appeal against the Contested Decision.
2. On 3 March 2015, an announcement of the 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 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. The Appellant claims that the Board of Appeal should modify the Contested Decision insofar as it obliges the Appellant to conduct testing on the persistence of triclosan (hereinafter the 'Substance') and permit the Appellant to conduct OECD TG 309, as further specified by the Appellant, instead; and annul the Contested Decision insofar as it requires the Appellant to conduct, first, an Enhanced Developmental Neurotoxicity Study (OECD TG 426 with relevant elements of a Extended One-Generation Reproductive Toxicity Study, OECD TG 443), second, a Fish Sexual Development Test (OECD TG 234) and, third, a cardiotoxicity literature review.
4. By application received at the Registry of the Board of Appeal on 17 March 2015, the Applicant applied to intervene in the appeal proceedings in support of the Appellant, insofar as the Contested Decision requires the Appellant to conduct an Enhanced Developmental Neurotoxicity Study with relevant elements of an Extended One-Generation Reproductive Toxicity Study and a Fish Sexual Development Test.
5. After being invited to submit their respective observations on the application to intervene, the Agency submitted its observations on 7 April 2015. The Appellant did not submit observations on the application.

### 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, the Applicant is a representative organisation in its field of competence and has a legitimate interest in the Agency's work. The Applicant's members and their supporters are concerned with animal testing issues and seek to minimise the amount of animal testing conducted;
  - (b) Each of its member organisations works to end the use of animal experiments at the national level. Collectively, its member organisations have a total of more than three million individual supporters, including individuals from every EU Member State. The Applicant's objectives include representing and thereby protecting its members' interests, including their core interest of the reduction, and ultimate elimination of the use of animals in regulatory testing and other scientific procedures both within and outside the EU. The Applicant's goals are consistent with goals established for REACH as laid out in, among others Articles 1, 13, 25 and 138 of the REACH Regulation and Recitals 40 and 47 and Annex XI to the REACH Regulation;

- (c) The appeal raises questions of principle which directly impact on issues regarding animal testing. These questions include how the Agency evaluates submitted and available studies prior to requiring further animal testing; whether the Agency can adopt a decision without considering all available data; and how the Agency adheres to Articles 25, 47 and 130 of the REACH Regulation (all references to Articles hereinafter concern the REACH Regulation unless stated otherwise);
- (d) The outcome of the appeal will impact on the number of animals used for testing. As a result, the issues and outcome are of direct interest to, and directly affect, the Applicant, its members and their supporters in achieving the Applicant's core interest; and
- (e) The Substance is one of twelve substances that are subject of the United States' competent authority proposed rule to establish conditions under which consumer antiseptic products are generally recognized as safe and effective. It is therefore possible that data addressing developmental neurotoxicity have already been generated. Considering that, it is important that the regulatory efforts related to the Substance are coordinated in order to avoid duplicative testing.

### **Arguments of the Agency**

7. Whilst acknowledging the practice of the Board of Appeal related to applications to intervene submitted by animal welfare representative associations that are also accredited stakeholders, the Agency states that the Applicant has not shown its pre-existing interest and active engagement in the subject-matter of the case, as it did not take part in the discussion leading to the adoption of the Contested Decision.
8. The Agency also contends that the decision of the General Court in case T-673/13, may be of significance to how the Board of Appeal assesses applications to intervene submitted by animal welfare representative associations.
9. The Agency concludes in its observations on the present application to intervene that it leaves it to the Board of Appeal to decide whether the Applicant meets the conditions of Article 8(1) of the Rules of Procedure.

### **REASONS**

10. As the Agency has made it clear that it leaves the Board of Appeal to decide whether the application to intervene fulfills the conditions of Article 8(1) of the Rules of Procedure it is not necessary for the Board of Appeal to specifically address the Agency's observations.
11. 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.
12. 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.
13. In the present case, the application complies with Articles 8(2), (3) and (4) of the Rules of Procedure.

14. 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.
15. 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 Akros Chemicals Ltd v Commission*, EU:T:2007:57, paragraph 14).
16. 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, MB/34/2011). During the validation process for Accredited Stakeholder Organisations, the Agency, among others, 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.
17. 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.
18. 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).
19. In the present appeal the Appellant seeks, among others, the annulment of the Contested Decision insofar as it requests it to submit an Enhanced Developmental Neurotoxicity Study (OECD TG 426 with relevant elements of an Extended One-Generation Reproductive Toxicity Study, OECD TG 443) and a Fish Sexual Development Test (OECD TG 234).
20. The Board of Appeal observes that the Applicant supports the Appellant's claim that the Agency did not base its decision on all relevant submitted or available information. In relation to neurotoxicity testing, the Appellant also claims that the Agency ignored a study funded by the Danish Competent Authority, which revealed that the neurological effects that the Contested Decision seeks to investigate do not exist. As a result, the Contested Decision breached Article 47. The Applicant also supports the Appellant's claim that, in the circumstances of the case, the requested studies breach Article 25(1) as the requirements would effectively lead to the unnecessary sacrifice of animals.
21. The Board of Appeal considers that some of the questions raised in the present appeal may be considered to be questions of principle concerning the way the Agency reaches its decisions on whether registrants should be requested to perform testing on vertebrate animals.

22. 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. The fact that the Applicant has not been present when the Agency's Member State Committee (hereinafter the 'MSC') discussed and reached an agreement leading to the adoption of the Contested Decision does not change this. The Board of Appeal observes that the Applicant's non-participation in the discussions or its non-presence at the relevant MSC meeting cannot lead to the conclusion that the Applicant does not have an interest in the result of the present case.
23. For the above reasons, the Board of Appeal finds that the Applicant, in its capacity of representative association, 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 submitted by the Applicant must therefore be granted.
24. Whilst the application has been granted, the Board of Appeal considers it necessary to briefly address the Agency's contention that that the General Court's order of 13 March 2015 in case T-673/13 *European Coalition to End Animal Experiments v European Chemicals Agency*, EU:T:2015:167 may be of significance to how the Board of Appeal assess applications to intervene from animal welfare representative associations, including the present application to intervene.
25. The Board of Appeal observes that the decision in case T-673/13 was adopted in relation to proceedings before the General Court following an action for annulment brought by an animal welfare association and the Agency's arguments related to that case may be applicable in circumstances related to the proceedings before the General Court. In the present case, the Board of Appeal is however called upon to decide whether or not to allow a leave for intervention in proceedings before it. These are different legal proceedings with different legal requirements, where the roles in the proceedings in both cases are different. The Board of Appeal considers that the Agency's arguments are therefore irrelevant in relation to the present application.
26. The Board of Appeal adds that when considering applications to intervene in proceedings before it, it is necessary to have regard to the specific context in which Article 8(1) of the Rules of Procedure is applied, that is the REACH Regulation and the regulatory framework that underpins it. In particular, the REACH Regulation seeks to promote various interests. Those interests include the protection of human health and the environment and also the promotion of alternative methods for assessment of hazards of substances in order to replace, reduce or refine animal testing (see Case A-005-2011, *Honeywell Belgium N.V.*, Decision of the Board of Appeal of 8 November 2011, paragraph 22). To his effect the REACH Regulation foresees the involvement of stakeholders in the Agency's work aiming to ensure that the different interests are considered in the Agency's decision-making.
27. Considering all of the above, the Board of Appeal therefore considers that the Applicant's application to intervene in the present case should be granted.

**ORDER**

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Grants the application of PISC to intervene in Case A-018-2014 in support of the Appellant.**
- 2. Instructs the Registrar to arrange for copies of the non-confidential version of the procedural documents to be served on PISC.**
- 3. Allows PISC 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

Sari HAUKKA  
Registrar of the Board of Appeal