

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

2 June 2014

Application to intervene

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

Case number A-001-2014

Language of the case

English

Applicant PETA International Science Consortium Ltd (PISC)

London

United Kingdom

Represented by: Dr. Gilly Stoddart

London

United Kingdom

Contested Decision

TPE-D-0000003219-74-05/F of 15 October 2013 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')

Appellant CINIC Chemicals Europe Sàrl

Saint Louis France

Representative Ruxandra Cana and Indiana de Seze

Steptoe & Johnson LLP

Brussels Belgium

THE BOARD OF APPEAL

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

Registrar: Sari HAUKKA

gives the following

Decision

SUMMARY OF THE FACTS

- 1. On 15 January 2014, the Appellant filed an appeal at the Registry of the Board of Appeal against the Contested Decision.
- 2. On 26 March 2014, 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 8 April 2014, 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.
- 4. On 10 April 2014, the application to intervene was served on the Appellant and the Agency.
- 5. On 28 April 2014, the Agency and the Appellant submitted their 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) As an accredited stakeholder, the Applicant is representative in its field of competence and has a legitimate interest in the Agency's work. It has considerable scientific expertise in the field and actively participates in the work of the member states and other Committees including attendance at the Member State Committee;
 - (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;
 - (c) The appeal raises questions of principle which directly impact on issues regarding animal testing. These questions include whether the Agency may consult third parties on a testing proposal other than the one included in a registrant's registration dossier; whether the Agency is required under the REACH Regulation to take into account information on the relevant end-point included in other registration dossiers submitted for the substance concerned; and what is the

- correct test for the substance concerned to meet the requirements of Section 8.7.1 of Annex VIII of the REACH Regulation and consequently the number of animals required for reproductive toxicity testing; and
- (d) The issues which are the subject 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.

Arguments of the Agency and the Appellant

- 7. The Agency opposes the application to intervene submitted by the Applicant on the grounds that the interests of the Applicant and its members will not be affected to an appreciable extent by the Board of Appeal's decision.
- 8. The Agency argues in particular 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. According to the Agency, the appeal concerns the issue of whether the Agency should have taken into account information submitted in another registration dossier for the same substance before reaching a decision on whether to impose the study in question. The appeal does not however concern the question of whether this information would be sufficient to avoid the test imposed in the Contested Decision. As a result, there is only a possibility that testing on vertebrate animals would be avoided if the Agency had followed a different administrative practice.
- 9. The Appellant does not oppose the application to intervene.

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. Since the application complies with Articles 8(2), 8(3) and 8(4) of the Rules of Procedure, 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.
- 13. 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, ECLI:EU:T:2007:57, paragraph 14).
- 14. 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, 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.

- 15. 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.
- 16. 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, ECLI:EU:C:1997:307, paragraph 66).
- 17. In the present appeal the Appellant requests the Board of Appeal to annul the Contested Decision, in so far as it requests the Appellant to carry out an extended one-generation reproductive toxicity study in rats, oral route (OECD 443), and to order the opening of a new testing proposal examination procedure for the same endpoint, or reopen the testing evaluation procedure for the same end-point.
- 18. The Board of Appeal observes that in its appeal the Appellant claims that by failing to take into consideration the information available in other registration dossiers submitted for the same substance the Agency had breached inter alia the REACH Regulation, including Article 25 thereof which requires that testing on vertebrate animals shall only be undertaken as a last resort. In this respect, the Appellant claims that the information available in other registration dossiers may have rendered the performance of the test in question unnecessary.
- 19. In its appeal, the Appellant also claims that by opening a third party consultation on a test other than the testing proposal included in the Appellant's registration dossier, the Agency had breached an essential procedural requirement and acted in violation of Article 40(2) of the REACH Regulation.
- 20. The Board of Appeal also notes that in the present case, according to the documents provided in the Notice of Appeal, the Applicant provided observations in response to the third party consultation which was held between 25 September 2012 and 12 November 2012 in relation to the testing proposal which is subject of the present appeal.
- 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 how the Agency reaches its decisions on whether companies should be required to perform testing on vertebrate animals.
- 22. The Board of Appeal considers therefore that the Applicant and its members may be affected to an appreciable extent by the decision of the Board of Appeal in this case.
- 23. For the above reasons, the Board of Appeal finds that the Applicant 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.

ORDER

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Admits the application to intervene in Case A-001-2014 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 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

Sari HAUKKA Registrar of the Board of Appeal