

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

3 December 2015

Application to intervene

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

Case number A-014-2015

Language of the case

English

Applicant PETA International Science Consortium Ltd (PISC), United Kingdom

Contested Decision

Decision of 11 March 2015 on the substance evaluation of silicon dioxide 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 Grace GmbH & Co. KG, Germany

Advanced Refining Technologies GmbH, Germany

Representatives David Scannell and Andrew McIntyre, Brick Court Chambers

Lydia Duff, W.R. Grace & Co.

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 10 June 2015, the Appellants filed an appeal at the Registry of the Board of Appeal against the Contested Decision.
- 2. On 19 August 2015, 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 2 September 2015, 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 Appellants to annul the Contested Decision in its entirety, specifically the requirement to conduct a sub-chronic toxicity study (90-day; OECD Test Guideline 413) in rats via the inhalation route.
- 4. On 28 September 2015, the application to intervene was served on the Appellants and the Agency. On 9 and 17 October 2015 respectively, the Agency and the Appellants 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 how the Agency: evaluates and interprets data, in particular its use of full study reports and the application of a weight of evidence approach to considering all information available to it; decides that substances are nanomaterials; considers different products, types, or grades of the same substance registered in a single dossier and whether it may request information on surface treated forms of a substance; considers read-across and grouping with regard to nanomaterials; and decides which substances should be included on the Community Rolling Action Plan and subject to substance evaluation;

- (e) The Applicant has considerable scientific expertise in the field, including on the inhalation toxicity of nanomaterials; and
- (f) The outcome of the appeal will have an impact on the number of animals used for testing.

Arguments of the Agency and the Appellants

- 6. The Agency states that it leaves the Board of Appeal to decide whether the conditions set out in Article 8(1) of the Rules of Procedure have been met in the present case. The Agency adds however that the Applicant did not take part in the discussions leading to the adoption of the Contested Decision. The Agency also states that, according to the minutes of the MSC meeting at which the Contested Decision was agreed upon, the Applicant did not observe the deliberations of the Committee.
- 7. The Agency also makes reference to the observations it has made in other cases regarding its interpretation of the case-law of the European Courts on the notion of interest in the result of a case.
- 8. The Appellants do not oppose the application to intervene.

Reasons

- 9. 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.
- 10. 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.
- 11. 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.
- 12. The Board of Appeal observes firstly that in its observations on the application to intervene the Agency refers to the fact that it considers the Board of Appeal has previously made a broad interpretation of the case-law of the European Courts and that in observations on applications to intervene made in other cases the Agency has presented a different and narrower interpretation of that case-law. The Board of Appeal observes, however, that only arguments specifically made in a submission for the case at issue can be considered by the Board of Appeal for the purposes of that case. References to arguments made in other cases, unless reiterated in full, cannot be accepted. Consequently, the Agency's references to observations it has made in previous cases cannot be taken into account by the Board of Appeal for the purposes of the present application.
- 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*, 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).
- 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 Stakeholder Organisations, 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, 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).
- 17. In the present appeal the Appellants request the Board of Appeal to annul the Contested Decision which includes, inter alia, a requirement to conduct a sub-chronic toxicity study (90-day; OECD Test Guideline 413) in rats via the inhalation route.
- 18. The Board of Appeal observes that in its appeal the Appellants claim that neither the Contested Decision nor the minutes of the MSC meeting at which it was agreed show that the Agency paid any, or alternatively adequate, attention to its obligation to assess whether there were suitable alternatives to vertebrate animal testing. The Appellants also argue that additional testing was not necessary and that there were viable alternatives to animal testing such as reliance on the extensive toxicological information already available. According to the Appellants, the Agency therefore acted in breach of, inter alia, Article 25(1) of the REACH Regulation.
- 19. 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.
- 20. 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.
- 21. The Agency stated that the Applicant was not present when the MSC discussed and reached an agreement leading to the adoption of the Contested Decision. In this respect the Board of Appeal observes that an applicant's involvement in the decision-making process leading to the adoption of the decision contested in proceedings before it may contribute to that applicant being able to demonstrate an interest in the result of the case within the meaning of Article 8(1) of the Rules of Procedure. However, an applicant's non-participation in the decision-making process or its non-presence at relevant meetings cannot in itself lead to the contrary conclusion that an applicant does not have an interest in the result of a case. The lack of participation of the Applicant in the decision-making process and the relevant MSC meeting leading to the adoption of the Contested Decision does not therefore mean that the Applicant does not have an interest in the result of the present case.

22. 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 Appellants. 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 by PETA International Science Consortium Ltd in Case A-014-2015 in support of the Appellants.
- 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.

Andrew FASEY
On behalf of the Chairman of the Board of Appeal

Alen MOČILNIKAR Registrar of the Board of Appeal