

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

3 May 2017

Application to intervene

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

Case number	A-013-2016
Language of the case	English
Appellant	BASF Personal Care and Nutrition GmbH, Germany
Representative	Kristian Fischer SZA Schilling, Zutt & Anschütz Rechtsanwalts-AG, Germany
Contested Decision	Decision on a testing proposal (TPE-D-2114344602-56-01/F) of 21 September 2016, adopted by the European Chemicals Agency pursuant to Article 40 of Regulation (EC) No 1907/2006 (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; hereinafter the 'REACH Regulation')
Applicant	The European Coalition to End Animal Experiments, United Kingdom

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. The Appellant filed its appeal on 16 December 2016. The appeal is directed against a decision rejecting a testing proposal put forward by the Appellant for the registration of the substance Reaction mass of sodium hydrogen N-(1-oxooctadecyl)-L-glutamate and stearic acid (EC No 939-201-1, hereinafter the 'Substance'). The Substance is registered only for use as an ingredient in cosmetic products.
2. The Appellant had proposed to perform a pre-natal developmental toxicity study in accordance with Section 8.7.2 of Annex IX to the REACH Regulation on another, allegedly analogue, substance. The Appellant did so on the basis of a proposed read-across of data from the other substance to the Substance.
3. The Agency found that the proposed read-across did not fulfil the requirements of Annex XI to the REACH Regulation. It consequently rejected the testing proposal and requested the Appellant to carry out a pre-natal developmental toxicity study on the Substance.
4. On 8 February 2017, an announcement was published on the Agency's website 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').
5. On 20 February 2017, the European Coalition to End Animal Experiments (hereinafter the 'ECEAE') applied for leave to intervene in these proceedings in support of the Appellant.
6. On 14 March 2017, the Agency submitted observations on the application for leave to intervene. The Appellant did not submit observations.

Arguments

Arguments of the Applicant

7. The ECEAE claims to have an interest in the result of the case because it is an accredited stakeholder of the Agency representing persons who are concerned about the use of animals in laboratories and seek to minimise animal testing.
8. The ECEAE further argues that this case concerns a test which causes significant suffering to a high number of animals. It claims that its members have an interest in ensuring that suffering of such nature and on such a scale does not take place if it is not legally warranted.
9. In the opinion of the ECEAE, this case raises the question of the relationship between REACH and Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59; hereinafter the 'Cosmetic Products Regulation').
10. The ECEAE argues that it has '*taken the lead*' over more than two decades in securing bans in the EU on the testing of cosmetic ingredients and products on animals. Preserving the integrity of bans on cosmetic products tested on animals and ensuring that these bans are properly taken into account in decisions adopted under the REACH Regulation is therefore of particular concern to the ECEAE and its members. The ECEAE also points out that it has taken legal action in the United Kingdom in this context, and that has intervened before the Court of Justice of the European Union.

Arguments of the Agency

11. The Agency objects to the application. It claims that the ECEAE has not established that it is directly affected by the Contested Decision nor that it has a sufficient interest in the result of this case.
12. The Agency argues that, instead of the criteria used in its previous decisions, the Board of Appeal should apply the test developed by the Court of Justice of the European Union for examining whether environmental non-governmental organisations (hereinafter 'NGOs') applying for leave to intervene have an interest in the result of a case.
13. The Agency relies, in this regard, on the criteria set out in paragraph 73 of the order of the General Court of 21 October 2014, *Bayer CropScience v Commission*, T-429/13, EU:T:2014:920. According to those criteria, the requirement for an interest in the result of the case '*means either that the scope of the activities of [environmental NGOs] should coincide with that of the region and sector concerned by the proceedings before the General Court or, where the scope of their activities is wider, that they should be actively involved in protection programmes or studies relating to the region and sector concerned, the viability of which may be jeopardised if the contested measure were adopted*'.
14. According to the Agency, the scope of the ECEAE's activities is wide and it has not demonstrated that it is actively involved in relevant programmes or studies.
15. In any event, the Agency argues that the case raises no question of principle capable of affecting the interests of the ECEAE's members.
16. In this regard, the Agency claims, first, that the Agency has no discretion as to whether or not to reject the proposed read-across because the proposed read-across was not supported by any evidence. Having rejected the proposed read-across, the Agency also had no discretion as to whether to request testing on vertebrate animals.
17. The Agency claims, second, that the Board of Appeal is not competent to '*interpret*' the consequences of testing under the REACH Regulation with regard to the Cosmetic Products Regulation.
18. The Agency consequently argues that the ECEAE has no interest in the result of the case and that the application for leave to intervene should be rejected.

Reasons

19. 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 the proceedings.
20. ECEAE is an accredited stakeholder organisation of the Agency. It is an NGO whose objects include minimising the amount of animal testing conducted.
21. When examining whether an NGO committed to the protection of animal welfare which is representative in its field and is also an accredited stakeholder of the Agency has an interest in the result of an appeal case, the Board of Appeal has developed certain criteria in light of the practice of the European Union courts concerning the intervention of representative associations (see Case A-004-2012, *Lanxess*, Decision of the Board of Appeal of 26 September 2012 on the application to intervene by the ECEAE, paragraphs 17 to 20).
22. The Board of Appeal has consistently held that a representative association may be granted leave to intervene in appeal proceedings 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 decision to be given (see, for instance, Case A-018-2014, *BASF Grenzach*, Decision of the Board of Appeal of 6 October 2015 on the application to intervene by the PETA International Science Consortium, paragraph 15). The interests in question may be non-economic as well as economic in nature (see the Decision of the Board of Appeal of 26 September 2012 in *Lanxess*, cited in the previous paragraph, paragraphs 18 and 19).

23. The Agency argues that a different test should be applied to appraise whether an applicant such as the ECEAE has an interest in the result of the case, namely the test applied by the Court of Justice of the European Union to applications for leave to intervene submitted by environmental NGOs.
24. This argument must be rejected for the following reasons.
25. The Board of Appeal observes that the criteria allowing entities such as the ECEAE to intervene in appeal proceedings must take account of the regulatory system within which the Board of Appeal operates and the role accredited stakeholders have under the REACH Regulation (see, to that effect, the Decision of the Board of Appeal of 26 September 2012 in *Lanxess*, cited in paragraph 21 above, paragraphs 19 and 20).
26. It should be emphasised, in this regard, that an implementing regulation such as the Rules of Procedure must be given, if possible, an interpretation consistent with the provisions of the basic regulation (see judgment of 14 November 2002, *SPKR*, C-112/01, EU:C:2002:663, paragraph 29 and the case-law cited, and judgment of 13 November 2014, *Spain v Commission*, T-481/11, EU:T:2014:945, paragraph 84).
27. Article 8(1) of the Rules of procedure, which requires applicants to establish an interest in the result of the case in order to be granted leave to intervene, should therefore be interpreted consistently with the REACH Regulation.
28. The REACH Regulation foresees the involvement of stakeholders in the Agency's work through consultations and in the work of the committees established within the Agency (see, for instance, the fifth subparagraph of Article 85(4) and the fourth subparagraph of Article 86(1) of the REACH Regulation; see also Article 108 of the REACH Regulation in conjunction with 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, MB/69/2011 final). Such stakeholder involvement aims to ensure that different interests, including non-economic interests, are considered as part of the Agency's decision-making (see the Decision of the Board of Appeal of 26 September 2012 in *Lanxess*, cited at paragraph 21 above, paragraph 19).
29. It is moreover evident from its Articles 1(1) and 13(1) that the REACH Regulation seeks to promote alternative methods for the assessment of the hazards of substances. Recital 40 to the REACH Regulation provides, in this regard, that '*[t]he Commission, Member States, industry and other stakeholders should continue to contribute to the promotion of alternative test methods on an international and national level including computer supported methodologies, in vitro methodologies, as appropriate, those based on toxicogenomics, and other relevant methodologies*'.
30. In light of the above, the Board of Appeal considers that the criteria suggested by the Agency (see paragraph 13 above) would be unduly restrictive in the specific context of appeal proceedings under the REACH Regulation.
31. The Board of Appeal will therefore proceed to examine the application for leave to intervene submitted by the ECEAE against the criteria set out in paragraph 22 above.
32. It is evident from its status as an ECHA stakeholder organisation that the ECEAE is a representative association. Its objects include minimising the amount of animal testing conducted. This is not disputed by the Agency.

33. It therefore remains to be examined whether the present case may raise questions of principle capable of affecting those interests.
34. The Board of Appeal observes, in this regard, that the present case may give rise to at least one question of principle, namely whether and how, for substances used in cosmetic products, the requirements of Section 1.5 of Annex XI to the REACH Regulation must be interpreted having regard to Article 18(1)(b) of the Cosmetic Products Regulation, which provides that cosmetic products containing ingredients which have been tested on animals in order to meet the requirements of this Regulation may not be placed on the market.
35. The Agency's argument that it had to reject the proposed read-across and had no discretion concerning the request for testing must be rejected as the question of principle that may be raised by this case is precisely the interpretation of the requirements for the rejection of a read-across.
36. The Agency's argument that the Board of Appeal is not competent to determine the consequences of testing under the REACH Regulation as regards the Cosmetic Products Regulation must moreover be rejected because it concerns the substance of the case and cannot be decided in the context of examining an application for leave to intervene.
37. The question of principle set out in paragraph 34 above is moreover capable of affecting the interests of the members of the ECEAE to an appreciable extent. This is borne out by the fact that, as is apparent from the application, the ECEAE is actively involved in furthering the protection of animal welfare under the REACH and Cosmetic Products Regulations, not only as an accredited stakeholder of the Agency but also by other measures, for example by intervening in a case concerning the interpretation of the animal welfare provisions in the Cosmetic Products Regulation (judgment of 21 September 2016, *European Federation for Cosmetic Ingredients*, C-592/14, EU:C:2016:703).
38. It follows from the above that the ECEAE has an interest in the result of this case within the meaning of the first subparagraph of Article 8(1) of the Rules of Procedure.
39. Since the application for leave to intervene also complies with the requirements of Article 8(2) to (4) of the Rules of Procedure it must be allowed.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Admits the application to intervene by the ECEAE in Case A-013-2016 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.**

Mercedes Ortuño
Chairman of the Board of Appeal

Alen Močilnikar
Registrar of the Board of Appeal