

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

30 November 2017

Application to intervene

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

Case number	A-006-2017
Language of the case	English
Appellant	Climax Molybdenum B.V., the Netherlands
Representatives	Scott Megregian and Zanda Romata K&L Gates LLP, United Kingdom
Contested Decision	CCH-D-2114356486-40-01/F of 13 March 2017 adopted by the European Chemicals Agency pursuant to Article 41(3) of Regulation (EC) No 1907/2006 (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation')
Applicant	PETA International Science Consortium Ltd, United Kingdom

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman and Rapporteur), Sari Haukka (Legally Qualified Member) and Jonna Sunell-Huet (Technically Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. On 9 June 2017, the Appellant filed an appeal against the Contested Decision. The Agency adopted the Contested Decision on 13 March 2017 which concerned a compliance check of the Appellant's registration dossier for the substance disodium molybdate (EC No 231-551-7, CAS No 7631-95-0 (anhydrous) and 10102-40-6 (dehydrate), the 'Substance').
2. The Contested Decision requires the Appellant to perform a pre-natal developmental toxicity study in accordance with Section 8.7.2 of Annex IX to the REACH Regulation.
3. On 28 July 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; the 'Rules of Procedure').
4. On 9 August 2017, PETA International Science Consortium Ltd ('PISC') applied for leave to intervene in the proceedings in support of the Appellant.
5. On 8 September 2017, the Appellant informed the Registry of the Board of Appeal that it did not object to PISC's application for leave to intervene.
6. On 11 September 2017, the Agency submitted observations on the application for leave to intervene requesting the Board of Appeal to dismiss the application to intervene.

Arguments

Arguments of the Applicant

7. PISC claims to have an interest in the result of the case for the following reasons.
8. First, as an accredited stakeholder of the Agency, PISC is representative in its field of competence and has a legitimate interest in the Agency's work. PISC's members and their individual supporters are concerned about animal testing issues and seek to minimise the amount of animal testing conducted.
9. Second, PISC's objectives include representing and thereby protecting its members' and their individual supporter's interests. Their core interest is the reduction and ultimate elimination of the use of animals in regulatory testing and other scientific procedures both within and outside the European Union. PISC promotes and funds non-animal research methods and methods and strategies for reducing and eliminating animal testing.
10. Third, PISC actively participates in the work of the Member States and certain committees, including attendance at the Member State Committee. It has scientific expertise concerning the replacement, reduction and refinement of testing on vertebrate animals and the use of alternative test methods to meet the information requirements of the REACH Regulation.
11. Fourth, the appeal raises questions of principle which directly impact on issues regarding animal testing which may affect the interests of the Applicant and its members to an appreciable extent. These questions include:
 - the circumstances under which the Agency can request tests on animals to fulfil REACH Regulation data requirements in a compliance check procedure if a study performed in any OECD member country and covered by Mutual Acceptance of Data addressing the information requirement has already been submitted;
 - what degree of deviation from an OECD test guideline justifies rejection of a study by the Agency; and

- under which circumstances the Agency must consider new information when performing a compliance check.
12. Fifth, the outcome of the appeal will have an impact on the number of animals used for testing in relation to this case and future requirements under the REACH Regulation. As a result, the outcome of the appeal is of direct interest to and directly affects PISC, its members and their individual supporters in achieving the aim of the reduction and ultimate elimination of the use of animals in regulatory testing.

Arguments of the Agency

13. The Agency objects to the application because PISC has not established an interest in the result of this case for the following reasons.
14. 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 assessing whether environmental non-governmental organisations ('NGOs') have an interest in the result of a case.
15. The representative associations' interest is too wide and general to be significantly affected by the outcome of the present proceedings.
16. The requirement to establish a direct and existing interest in the result of the case implies that the representative associations' sphere of activities relates to the geographical area and field concerned by the proceedings or, when their sphere of activities is broad, that they are actively engaged in protection programmes or studies on the geographical areas and the field concerned which may be jeopardised by the contested act. The participation of environmental representative associations in the decision-making process is not in itself sufficient to establish such interest.
17. Therefore PISC has not demonstrated a specific interest because :
- the interest described by PISC is very broad;
 - PISC was not involved in the decision-making leading to the adoption of the Contested Decision; and
 - PISC has no specific interest in the Substance.
18. The questions raised by PISC in its application are not questions of principle because:
- the compliance of the Appellant's registration dossier with the requirements of the REACH Regulation is only a matter of assessment of the circumstances of the particular case at hand;
 - conformity with the OECD Mutual Acceptance of Data is a question of compliance with international law that should not be considered for the purposes of intervening before the Board of Appeal; and
 - the question as to when the Agency must take new information into account has already been addressed by the European Court of Justice and the Board of Appeal.
19. The Contested Decision does not have an impact on the activities of PISC.

Reasons

20. Under 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.
21. PISC is an accredited stakeholder organisation of the Agency. It is an NGO whose objects, as is apparent from its articles of association, include the reduction, and ultimate elimination, of animal testing.
22. 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-013-2016, *BASF Personal Care and Nutrition*, Decision of the Board of Appeal of 3 May 2017 on the application to intervene by the European Coalition to End Animal Experiments, paragraph 21).

23. 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 PISC, 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 3 May 2017 in *BASF Personal Care and Nutrition*, cited in the previous paragraph, paragraph 22).
24. The Agency argues that a different test should be applied to appraise whether an applicant such as PISC has an interest in the result of the case.
25. This argument must be rejected for the following reasons.
26. The criteria allowing entities such as PISC 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 3 May 2017 in *BASF Personal Care and Nutrition*, cited in paragraph 22 above, paragraph 25).
27. In addition, 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 Case A-013-2016, *BASF Personal Care and Nutrition*, Decision of the Board of Appeal of 3 May 2017 cited in paragraph 23 above, paragraph 26).
28. 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.
29. 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 Case A-013-2016, *BASF Personal Care and Nutrition*, Decision of the Board of Appeal of 3 May 2017 cited in paragraph 22 above, paragraph 28).
30. 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'.
31. It follows that the criteria suggested by the Agency (see paragraphs 15 and 17 above) would be unduly restrictive in the specific context of appeal proceedings under the REACH Regulation.
32. The Board of Appeal will therefore proceed to examine the application for leave to intervene submitted by PISC against the criteria set out in paragraph 23 above.

33. It is evident from its status as an ECHA stakeholder organisation and from its articles of association that PISC is a representative organisation aiming to protect its members' interests, namely the reduction, and ultimate elimination, of animal testing. This is not disputed by the Agency.
34. It therefore remains to be examined whether the present case may raise questions of principle capable of affecting those interests.
35. The present case may give rise to three questions of principle concerning the way the Agency reaches its decisions on whether registrants should be requested to perform testing on vertebrate animals. These questions concern the circumstances under which the Agency can request tests on animals to fulfil REACH Regulation data requirements in a compliance check procedure if a study performed in any OECD member country and covered by Mutual Acceptance of Data addressing the information requirement has already been submitted; what degree of deviation from an OECD test guideline justifies rejection of a study by the Agency and under which circumstances the Agency must consider new information when performing a compliance check. These three questions are questions of principle which have consequences beyond the circumstances of the present case in relation to dossier evaluation and animal testing.
36. These questions of principle are moreover capable of affecting the interests of the members of PISC to an appreciable extent. This is borne out by the fact that, as is apparent from the application, PISC is actively involved in furthering the protection of animal welfare under the REACH Regulation as an accredited stakeholder of the Agency.
37. In the present case the Appellant claim inter alia that the Agency breached Article 25 of the REACH Regulation by requiring a pre-natal developmental toxicity study. The appeal therefore raises questions which relate directly to the avoidance of animal testing and the Appellant's interest therein.
38. It follows from the above that PISC 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 PISC in Case A-006-2017 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