

Announcement of appeal¹

Case	A-012-2017
Appellant	TÜV SÜD Iberia S.A.U., Spain
Appeal received on	5 November 2017
Subject matter	A decision adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 46(1) of the REACH Regulation
Keywords	<i>Substance evaluation – Error of assessment – Proportionality – Animal welfare – Good administration – Legal certainty – Use of languages</i>
Contested Decision	Decision of 10 August 2017 on the substance evaluation of benzene, mono-C ₁₁ -C ₁₃ -branched alkyl derivatives (BAB) (EC No 810-801-4)
Language of the case	English

Remedy sought by the Appellant

The Appellant requested the Board of Appeal to annul the Contested Decision, in full or in part, and take such other measures as justice may require.

The Appellant also requested the Board of Appeal to order the Agency to refund the appeal fee and/or to reimburse the costs incurred by the Appellant in the appeal proceedings.

Pleas in law and main arguments

The Contested Decision required the Appellant to provide the following information on benzene, mono-C₁₁-C₁₃-branched alkyl derivatives (BAB) (the 'Substance'):

1. Extended one-generation reproductive toxicity study ('EOGRTS'; test method: EU B.56 or OECD Test Guideline ('TG') 443), in rats, oral route.

The Appellant was also required to provide the following information 'on fraction(s) of the [Substance] or components that are representative for the(se) fraction(s)':

2. Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD TG 308).
3. Bioaccumulation in Fish, Aquatic Exposure (OECD TG 305-I).
4. Aquatic toxicity test with bivalves (test method OCSPP 850.1055).
5. Freshwater Algae and cyanobacteria, Growth Inhibition Test (OECD TG 201).
6. *Daphnia magna* Reproduction Test (OECD TG 211).
7. Fish, Early-life Stage Toxicity Test (OECD TG 210).
8. Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Sediment (OECD TG 233).

¹ Announcement published in accordance with Article 6(6) of Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency, as amended by Commission Implementing Regulation (EU) 2016/823.

The Appellant argued that, in relation to the first information requirement (the EOGRTS), the Agency breached:

- The principle of proportionality as the EOGRTS is not necessary or appropriate, and recourse was not had to the least onerous measure available.
- The requirement that testing on vertebrate animals is undertaken only as a last resort.
- The principle of legal certainty in view of the fact that there is a Commission decision requiring the Appellant to provide a testing proposal to conduct a similar EOGRTS.

Regarding the second to eighth information requirements (see above), the Appellant argued, amongst other things, that:

- The Agency committed an error of assessment as the information requested is not capable of clarifying whether the Substance has persistent, bioaccumulative and toxic ('PBT') properties.
- The information requests are disproportionate in particular as they are not necessary and/or appropriate and the Agency did not have recourse to the least onerous measure available.
- The Contested Decision breaches the principle of legal certainty with regards to the use of the terminology '*representative [component of a fraction]*'.
- The Contested Decision is arbitrary and breaches the Appellant's right to good administration, the principle of legitimate expectations, the requirement that testing on vertebrate animals is undertaken only as a last resort, the right to be heard, the duty to take into account all information, and the duty to state reasons.

In relation to the Contested Decision as a whole the Appellant claimed that, as the Appellant is registered in Spain, the Contested Decision, as well as the communications leading to the adoption of that decision should have been in Spanish. As a result, the Agency breached Article 104(1) of the REACH Regulation, Article 3 of Regulation No 1 determining the languages to be used by the European Economic Community, Article 20(2)(d) of the Treaty on the Functioning of the European Union, and the principle of good administration.

Other information

Pursuant to Article 93(1) of the REACH Regulation, the Executive Director of the Agency rectified the Contested Decision by withdrawing it in its entirety. The appeal was subsequently withdrawn by the Appellant and the case was closed by the Chairman of the Board of Appeal on 23 May 2018.

Further information

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

<https://echa.europa.eu/web/guest/regulations/appeals>

The CoRAP list of substances is available here:

<https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances>