

Announcement of appeal¹

Case	A-013-2014
Appellant	BASF SE, Germany
Appeal received on	10 December 2014
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 46(1) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 52 of the REACH Regulation
Keywords	<i>Evaluation – Substance evaluation – Request for further information</i>
Contested Decision	Decision on substance evaluation for octocrilene of 11 September 2014. The Decision was notified to the Appellant through the annotation number SEV-D-2114287467-34-01/F.
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

- a. annul the Contested Decision; and
- b. order the Agency to refund the appeal fee.

With a subsidiary plea, should the Board of Appeal dismiss the request to annul the Contested Decision in its entirety, the Appellant requests the Board of Appeal to annul or amend the Contested Decision insofar as it requires the Appellant to submit the information related to the bioaccumulation test(s) and information using the Androgenised Female Stickleback Screen test method.

Pleas in law and main arguments

The Contested Decision was adopted by the Agency on 11 September 2014 following a substance evaluation of octocrilene (the 'Substance') by the French Competent Authority.

In the Contested Decision the Agency requested the registrant(s) of the Substance, among them the Appellant, to submit, amongst other information: data regarding the recalculation of relevant values related to bioaccumulation or to conduct a specified

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.

bioaccumulation test in fish; and information using the Androgenised Female Stickleback Screen (AFSS) test method.

The Appellant states that the Contested Decision included the statement that the Agency has 'notified the Registrant(s) of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments [...]'. However, the Appellant further claims that the Agency notified a draft version of the Contested Decision to the Appellant as well as two other registrants of the Substance but not to all other existing registrants of the Substance, who were consequently not informed of their right to comment on the draft decision. As a consequence, the Contested Decision violates Articles 50(1) and 51(5) of the REACH Regulation.

The Appellant also argues that the Agency's conduct described above 'constitutes an interpretation of the term "concerned registrant" not covered by the REACH Regulation'. This conduct breached the principles of legal certainty and equal treatment and jeopardised the legal right of the registrant conducting the required study to request a financial contribution for its activities from other registrants of the Substance.

The Appellant also claims that, in particular by requiring the Appellant to submit the information related to bioaccumulation test(s) and information using the AFSS test method, the Agency violated the principle of proportionality. The Appellant contends that this AFSS test method has not been endorsed by OECD as a testing guideline for several good scientific reasons and that any data generated would therefore be of questionable scientific value. According to the Appellant, there is insufficient likelihood that the information requested will provide scientifically meaningful results to justify its use.

Finally, the Appellant also argues that the request to conduct an unsuitable animal test, namely using the AFSS test method, violates the principle of 'animal welfare' and is contrary to Article 25(1) of the REACH Regulation which requires vertebrate animal testing to be conducted as a last resort.

Further information

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

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