

Announcement of appeal¹

Case	A-002-2012
Appellant	BASF SE, Ludwigshafen, Germany
Appeal received on	30 April 2012
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 40(3) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	<i>Testing proposal – Updated dossier - Waiving</i>
Contested decision	TPE-D-0000002006-86-03/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests that, if the Executive Director of the Agency does not rectify the contested decision, the Board of Appeal should:

- revoke or annul the contested decision or, in the alternative, order the Agency to act to that effect, and
- order the Agency to refund the appeal fee.

Pleas in law and main arguments

In its initial registration dossier for the substance Aziridine, CAS No 151-56-4 (EC No 205-793-9), the Appellant had submitted a testing proposal for a fish short-term toxicity test in order to fulfil the information requirements set out in Annex IX to the REACH Regulation.

The Appellant claims, however, that, following the receipt of the written comments of one of the Member State competent authorities during the evaluation process, it realised that the test was in fact not necessary. The Appellant states that Annex IX, 9.1.6 to the REACH Regulation provides that the long-term toxicity fish test is only necessary if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. According to the Appellant, as there was no such indication in the chemical safety assessment, the initially proposed test is not needed.

¹ Announcement published 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 a result, on 21 December 2011, the Appellant submitted an updated dossier including arguments to justify the waiving of the additional testing requirements. On 22 December 2011, the Appellant received confirmation from the Agency that the update of its registration was considered complete and that the new information had been included in the registration dossier.

On 7 February 2012, however, the Agency adopted the contested decision on the testing proposal. According to that decision, the Appellant is obliged to carry out a long-term toxicity test on fish with the originally proposed test being rejected.

The Appellant claims, however, that at the time of the adoption of the contested decision the registration dossier had been updated to include a waiving statement instead of the original testing proposal. The Appellant therefore considers that a decision on the testing proposal was no longer relevant since the testing proposal was not contained in the dossier at the time of the adoption of the contested decision.

In addition, the Appellant states that the contested decision did not contain a reminder of the possibility of waiving the test for long-term toxicity on fish based on an updated registration dossier and the chemical safety assessment, despite the fact that this had been agreed at the relevant Member State Committee meeting.

According to the Appellant, the Agency subsequently informed it that any updates of a registration dossier after the time a draft decision has been sent to the Member State Competent Authorities for their comments cannot be taken into account for the purposes of that decision. The Appellant argues, however, that there is no reason for the Agency not to have taken into consideration the updated dossier and in failing to do so the Agency had acted illegally.

The Appellant claims further that if the Agency considered that it was not in a position to deviate from the findings of the Member State Committee, the Member State Committee members should have been consulted again.

The Appellant claims alternatively that, even if the Agency had acted legitimately in not taking into account the updated dossier, the Agency should have revoked the contested decision once it had received the updated dossier.

Although the Appellant claims that its updated dossier is complete even without the information on the test requested in the contested decision, it considers that the present appeal is necessary as the contested decision remains in force and enforcement actions may therefore theoretically follow.

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>