EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-018-2013
Appellant	BASF SE, Ludwigshafen, Germany
Appeal received on	23 October 2013
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 41(3) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	*Evaluation – Compliance check – Request to submit further information*
Contested Decision	CCH-D-0000002536-73-06/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

a. partially revoke or annul the Contested Decision requiring the Appellant to submit certain additional information; and
b. order the Agency to refund the appeal fee.

By a subsidiary plea, the Appellant requests that the Board of Appeal amends the Contested Decision so that it extends the time limit for submitting the information by at least two years after the date of the Board of Appeal's final decision.

Pleas in law and main arguments

The Contested Decision was adopted on 26 July 2013 following a compliance check under the dossier evaluation procedure of the Appellant's registration submitted for the registered substance (citronellol).

In the Contested Decision the Agency concluded that the registration did not comply with the requirements of Article 12, and with Annexes I and VII to XI of the REACH Regulation and requested the Appellant to submit additional information for the registered substance including:

a. mutagenicity, using an in vitro gene mutation study in bacteria with an additional, fifth strain of bacteria;
b. mutagenicity, using an in vitro cytogenicity study in mammalian cells or in vitro micronucleus study;

[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.

c. mutagenicity, using an in vitro gene mutation study in mammalian cell, provided that there is a negative result in the previous two requested mutagenicity studies;
d. sub-chronic toxicity study (90-days) in rats, inhalation route; and
e. prenatal developmental toxicity study in the rat or in the rabbit, by the oral route.

The Appellant claims firstly that the Contested Decision, as far as it is contested, is illegal as it violates Article 51(5) of the REACH Regulation. The Appellant argues that, although it sent its substantial comments on the amended draft of the Contested Decision within the prescribed time, neither the Contested Decision nor the minutes of the relevant Member State Committee (MSC) meeting indicate that the Appellant's arguments were considered. According to the Appellant, the obligation to take any comments received into account, as provided in Article 51(5), is not limited to the mere acknowledgment of receipt of the comments. Instead, the right to comment as provided in Articles 50(1) and 51(5) of the REACH Regulation ensures the Appellant's right to be heard as it gives it the possibility to influence the decision-making procedure. When submitting substantial comments, the Appellant has the legitimate expectation that the authorities will assess and address its arguments in a professional and scientific way. The Appellant claims that the text of the Contested Decision does not indicate whether its comments were assessed. The Appellant concludes that without substantial feedback on the comments it provided it cannot check whether the Agency observed the rights the Appellant has under Article 51(5) of the REACH Regulation.

Secondly, the Appellant claims that the Agency's violation of Article 51(5) of the REACH Regulation causes legal uncertainty for the Appellant. It argues that the commentary phase pursuant to Articles 50(1) and 51(5) of the REACH Regulation is vital for a registrant, since this is the only time it has the opportunity to enter into a scientific dialogue with the authorities at a European level. The Appellant considers that a token phrase stating that the Agency and the MSC '*took the comments […] into account*' without providing additional scientific arguments, showing fallacies in the registrant's argumentation, creates legal uncertainty for the Appellant and deprives it of the only chance it has to have the validity of its scientific arguments evaluated on a European, and thus harmonised, level.

With regard to the subsidiary claim, the Appellant claims that due to the suspensive effect of the appeal, as long as the appeal has not been decided, the Appellant's registration dossier subject to the Contested Decision may not be regarded as incompliant. In addition, the Appellant contends that it cannot have an obligation to begin testing to provide the required additional information before the appeal has been decided. The Appellant argues that the subsidiary plea is justified in order to ensure the legal certainty of its situation.

Other information

Pursuant to Article 93(1) of the REACH Regulation, the Executive Director of the European Chemicals Agency had rectified the Contested Decision and the appeal was subsequently withdrawn by the Appellant.

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