

**SUMMARY OF DECISION OF 1 AUGUST 2013
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

Case number: A-003-2012

(Compliance check of a registration – Dossier updates submitted during the decision-making process – Legal certainty)

Factual background

Following a compliance check, under the dossier evaluation procedure, of the registration submitted by THOR GmbH (hereinafter the 'Appellant'), the European Chemicals Agency (hereinafter the 'Agency') adopted a draft decision requesting the Appellant to conduct tests to satisfy certain information requirements and to submit information regarding a test already conducted. The Agency notified the draft decision to the Appellant and invited it to provide comments. Having received the Appellant's comments, the Agency notified the draft decision to the Member State Competent Authorities (hereinafter 'MSCAs' or 'MSCA' if singular) for them to submit proposals for amendments.

Following the receipt of a proposal for amendment by one MSCA, the Agency amended the draft decision to include an additional information requirement. The Appellant provided comments on the proposal for amendment, and also updated its registration dossier to include information on the test already conducted and an exposure-based waiving strategy intended to cover the requested studies.

After the final amendments to the draft decision were agreed by the Member State Committee, the Agency adopted the final decision on the information requests (hereinafter the 'Contested Decision'). According to the cover letter accompanying the Contested Decision, the information contained in the Appellant's updated registration dossier was not taken into account by the Agency for the purposes of the Contested Decision on the grounds that the decision-making process was at its final stages at the time the update was submitted.

The Appellant lodged an appeal against the Contested Decision in which it requested the Board of Appeal to order the Agency to use the Appellant's updated registration dossier as the basis for its final decision.

Main findings of the Board of Appeal

In its Decision of 1 August 2013, the Board of Appeal observed that, in the compliance check decision-making process, the rule that updates to the registration dossier will not be taken into account after the draft decision has been notified to the MSCAs is not specifically foreseen in the REACH Regulation¹. In fact, this rule had been established by the Agency.

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p.1; corrected by OJ L 136, 29.5.2007, p. 3).

Consequently, in the present case, to have known precisely the scope of its obligations with regard to the decision-making process, the Appellant not only had to know the relevant provisions of the REACH Regulation but also the Agency's practice in implementing those provisions.

The Board of Appeal observed further that whilst it is the responsibility of all registrants to know the obligations applicable to them, the principle of legal certainty requires that every measure creating such obligations must be clear and precise and must be clearly brought to the attention of those concerned. In the present case, particularly since the rule at issue was not contained in the REACH Regulation, the Agency was obliged to clearly and precisely inform the Appellant in due time that updates received after the draft decision had been sent to the MSCAs would not be taken into account in the decision-making process.

The Board of Appeal noted that the documents submitted during the appeal proceedings showed that the Agency had specifically and individually informed the Appellant of this rule only after the draft decision had been sent to the MSCAs and after the update had been made. Therefore, the Agency's actions cannot be considered as being sufficient to inform the Appellant of the rule at issue in due time. In addition, the Board of Appeal found that, having regard also to the circumstances of the case, the general guidance available on that rule was unclear.

The Board of Appeal also considered that it was pertinent in the present case that, before the draft decision was sent to the MSCAs, the Appellant had informed the Agency that it intended to update its registration dossier in response to the concerns set out in the draft decision. The Board of Appeal noted that, since the Appellant had informed the Agency of its intention to update its dossier, the latter was under an even greater responsibility to inform the Appellant that updates would not be taken into consideration after the dossier had been sent to the MSCAs.

The Board of Appeal confirmed that the decision-making process should not be unreasonably delayed by unrealistic or vague assurances that a registration dossier will be updated. In addition, the Board of Appeal considered that, in the present case and in line with the Member State Committee's Working Procedure, as the Appellant had indicated its intention to update its dossier to take into account the Agency's concerns as set out in the draft decision, the Agency should have seriously considered whether it was appropriate to delay sending the draft decision to the MSCAs to give the Appellant the opportunity to update its dossier.

In conclusion, the Board of Appeal found that, in the present case, even a diligent and prudent registrant exercising a reasonable level of due care could have been mistaken in thinking that updates made at any time before the adoption of the Contested Decision would be taken into consideration in the decision-making process. The Board of Appeal therefore considered that in the present case the Agency had infringed the principle of legal certainty.

In consideration of the above, the Board of Appeal annulled the Contested Decision and remitted the case to the Agency for re-evaluation of the registration dossier as updated by the Appellant.

NOTE: The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 91(1) of the REACH Regulation. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.

Unofficial document, not binding on the Board of Appeal

The [full text](#) of the decision of the Board of Appeal is published on the ECHA website on the day of delivery