EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 10 JUNE 2015
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-001-2014

(Testing proposal – Third party consultation procedure – Administrative efficiency – Information in other registration dossiers – Article 25(1) of the REACH Regulation)

Factual background

In its registration dossier for 3,6-bis(4-tert-butylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione (hereinafter the 'Substance'), CINIC Chemicals Europe Sárl (hereinafter the 'Appellant') included a testing proposal for an OECD 443 extended one-generation reproductive toxicity study (hereinafter 'EOGRTS'). The Appellant proposed an EOGRTS as a means to investigate the concerns identified in the OECD 421 screening study it had previously performed pursuant to Section 8.7.1 of Annex VIII to the REACH Regulation[1].

Following the Appellant's testing proposal, the Agency held a third party consultation pursuant to Article 40(2) on 'reproductive toxicity (two-generation reproductive toxicity)', the information requirement that the testing proposal was intended to address (Section 8.7.3 of Annex IX).

On 13 June 2013, the Agency's Member State Committee (hereinafter 'MSC') unanimously agreed on the draft decision on the Appellant's testing proposal.

On 24 June 2013, another registrant of the Substance (hereinafter 'the other registrant') updated its registration dossier and added the results of an OECD 421 screening study. Information contained in the other registrant's updated registration dossier was disseminated on the Agency's website on 15 August 2013. According to this information, the OECD 421 screening study performed by the other registrant showed that the Substance revealed no parental, reproductive or developmental toxicity.

On 15 October 2013, the Agency adopted the Contested Decision on the Appellant's testing proposal requesting the Appellant to conduct an EOGRTS.

The Appellant lodged an appeal before the Board of Appeal seeking the annulment of the Agency's Decision in so far as it requests the Appellant to carry out an EOGRTS. The Appellant claimed that the Contested Decision was adopted in breach of Article 25(1) which requires that testing on vertebrate animals shall be undertaken only as a last resort and in breach of the Agency's obligation to take into account all information available to it. According to the Appellant, the Agency should have taken into account the results of the OECD 421 screening study contained in the other registrant's dossier for the Substance, which was submitted prior to the adoption of the Contested Decision. In relation to the third party consultation on the testing proposal, the Appellant claimed further that the Contested Decision was adopted in breach of an essential procedural requirement, as well as of Article 40(2).

[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). All references to Articles and Annexes hereinafter concern the REACH Regulation.

Main findings of the Board of Appeal

In its Decision of 10 June 2015, the Board of Appeal found that the Agency had complied with Article 40(2) by publishing on its website the substance name, the hazard endpoint for which vertebrate testing was proposed and the deadline for responding to the consultation. The Board of Appeal added that the Agency is not required by the REACH Regulation to publish details of the actual test proposed by a registrant to meet a specific endpoint. The Board of Appeal thus rejected the Appellant's claim that the Contested Decision was adopted in breach of an essential procedural requirement and of Article 40(2).

The Board of Appeal then examined the Appellant's claim that, before adopting the Contested Decision, the Agency should have taken into account the OECD 421 screening study contained in the other registrant's dossier for the Substance. The Board of Appeal acknowledged that the Agency has a wide discretion when examining the merits of a testing proposal. However, in exercising its discretion the Agency is required to take into account and balance a number of, sometimes competing, considerations. The Board of Appeal noted that, for the purposes of the present case, those considerations included the need for administrative efficiency and the need to ensure that testing on vertebrate animals is undertaken only as a last resort.

The Board of Appeal observed that, with the aim of ensuring efficiency in its dossier evaluation processes, the Agency had introduced a cut-off point in the decision-making process after which it will not take into account, for the purposes of its decision, any new information that comes to light. In this particular case, the cut-off point was the moment the draft decision was sent to the MSCAs for their proposals for amendment pursuant to Article 51(1). The Board of Appeal noted that the other registrant's OECD 421 screening study was submitted to the Agency after the cut-off point but before the Contested Decision was adopted by the Agency. According to the Agency, any information coming to light after the cut-off point will only be assessed by the Agency if the registrant includes it in a dossier update and even then not before the deadline defined in the decision requiring the information.

The Board of Appeal found that the duty to avoid animal testing pursuant to Article 25(1) applies to the Agency, as well as to registrants, when it examines a testing proposal under Article 40.

The Board of Appeal also found that, in the present case, the other registrant's OECD 421 screening study was clearly a relevant factor in the consideration of whether the EOGRTS proposed by the Appellant should be performed. In particular, if the results of both OECD 421 screening studies had been known this information might have changed the Appellant's conclusion that an EOGRTS was necessary. Equally, this information might have changed the Agency's conclusion regarding the proposed test, the comments of the MSCAs, and the MSC's agreement that the proposed test was required. The Board of Appeal considered that the results of the other registrant's OECD 421 screening study therefore constituted substantial new information that could potentially have influenced the Contested Decision. The Board of Appeal therefore concluded that, in the present case, the Agency should have taken into account in the decision-making process leading to the adoption of the Contested Decision the other registrant's OECD 421 screening study.

The Board of Appeal found that the Agency did not have in place a suitable mechanism for dealing with substantial new information that was unknown to the Appellant prior to the cut-off point and was submitted to the Agency after its cut-off point but before the Contested

Decision was adopted. According to the Board of Appeal, the Agency's procedures in this respect were too rigid and led to the situation where the Contested Decision was adopted without taking into account substantial new information available prior to its adoption. This failure could have resulted in the unnecessary use of a substantial number of animals and associated costs.

The Board of Appeal acknowledged that if the Agency is required to examine all information coming to light after the draft decision has been sent to the MSCAs it would inevitably entail additional work for the Agency and all those involved in the decision-making process and would delay the adoption of decisions. The Board of Appeal noted, however, that administrative burden alone cannot justify the Agency's departure from the obligations incumbent upon it. The Board of Appeal also found that the Agency had failed to establish that the requirement to check other registration dossiers for the same substance and subsequently take into account any new information found as a result is an excessive administrative burden.

The Board of Appeal concluded that the Agency's decision was in breach of Article 25(1) insofar as it did not take account of all the relevant circumstances in applying that Article. The Board of Appeal thus annulled the Contested Decision and remitted the case to the Agency for re-evaluation of the Appellant's testing proposal. The Board of Appeal also observed that, based on the Board of Appeal's findings in the case, in a re-examination of the Appellant's testing proposal and the preparation of any draft decision the Agency should take into consideration the OECD 421 screening study available in the other registrant's dossier. As a result, the Agency should recommence the decision-making process provided for in Articles 50 and 51.

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.
