

**SUMMARY OF DECISION OF 29 APRIL 2013
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

Case number: A-005-2011

(Compliance check of a registration – Testing involving vertebrate animals – Principle of last resort - Section 8.6.4 of Annex X– Discretion of the Agency – Principle of proportionality)

Factual background

Following a compliance check, under the dossier evaluation procedure, of the registration submitted by Honeywell Belgium N.V. (hereinafter the 'Appellant'), the European Chemicals Agency (hereinafter the 'Agency') adopted a decision in which, pursuant to Section 8.6.4 of Annex X to the REACH Regulation¹, it requested the Appellant to submit further information following the performance of a 90-day repeated dose toxicity study in the rabbit by inhalation (hereinafter the 'Study').

The Appellant lodged an appeal before the Board of Appeal seeking the annulment of the Agency's decision to the extent that the Agency required the Appellant to conduct the Study (hereinafter the 'Contested Decision').

Main findings of the Board of Appeal

In its Decision of 29 April 2013, the Board of Appeal recalled that Section 8.6.4 of Annex X confers a wide margin of discretion on the Agency in the context of a dossier compliance check. The Agency's margin of discretion under Section 8.6.4 of Annex X applies first to the assessment of the need for further information and second to the determination of what further studies are appropriate to address the concerns identified. However, the Board of Appeal underlined that the Agency's discretion does not prevent the Board of Appeal from assessing whether that discretion was correctly used and, in particular, whether the evidence upon which the Agency relied to reach its decision is factually accurate, reliable and consistent, whether that evidence contains all the information which must be taken into account in order to assess a complex situation, and whether the evidence is capable of substantiating the conclusions drawn from it.

The Board of Appeal then examined the Appellant's plea that the Contested Decision breached the requirement of Article 25 of the REACH Regulation that testing on vertebrate animals must be undertaken only as a last resort. The Board of Appeal highlighted that the case concerned Section 8.6.4 of Annex X to the REACH Regulation where no specific information requirement is set out. The Board of Appeal considered that when the Agency has identified an information gap pursuant to Section 8.6.4 of Annex X and when considering how that gap should be addressed, the Agency must ensure that all reasonable and relevant options have been examined before requiring tests on vertebrate animals. In

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).

addition, when considering whether to require a test under Section 8.6.4 of Annex X, the obligation to ensure that vertebrate animal testing is only undertaken as a last resort applies also to the Agency.

Furthermore, after examining the specific facts of the case, the Board of Appeal considered that, in this particular case, there was no evidence that alternative methods, not requiring the use of vertebrate animals, were considered by the Agency to generate the required information and that the Agency attempted to ensure that testing on vertebrate animals was undertaken only as a last resort. Therefore, the Board of Appeal concluded that the Agency had failed to assess all the information which must be taken into account in order to assess a complex situation and consequently had exceeded its margin of discretion. As a result, the Board of Appeal considered that there were grounds to annul the Contested Decision and to remit the case to the Agency as it was taken in breach of the requirements of Article 25(1) of the REACH Regulation.

With a view to assisting the Agency in its preparation of a new decision, the Board of Appeal also considered certain of the Appellant's other claims regarding the legality of the Contested Decision.

In particular, the Board of Appeal explained that, when requiring tests under Section 8.6.4 of Annex X, the Agency should examine how the fewest number of animals possible could be used to satisfy the objective pursued. The Board of Appeal considered that in the present case, even in the event that the Agency could demonstrate that testing on vertebrate animals was unavoidable, it nonetheless failed to ensure that the minimum number of animals were used. As a result, the Board of Appeal considered that the Agency had again failed to assess all the information which must be taken into account in order to assess a complex situation and consequently had exceeded its margin of discretion.

In addition, the Board of Appeal also examined the proportionality of the Contested Decision. In particular, the Board of Appeal found that the precise objective(s) pursued by the Agency in requiring the Study were not made clear in the Contested Decision. According to the Board of Appeal, this lack of clarity may pose certain problems for the Appellant, including in designing an appropriate study and in providing the information required. The Board of Appeal further concluded that the Study is unprecedented, that there are credible grounds to doubt whether it would yield useful results, and that there may be problems in commissioning the Study. Furthermore, the Board of Appeal recalled that when the Agency has a choice between several appropriate measures that will meet the objectives pursued, recourse should be had to the least onerous. In the present case, the Board of Appeal considered that the Agency had not established that the Study was the least onerous way to achieve the objectives pursued.

Taking into account all the circumstances of the case, and having regard in particular to the unprecedented nature of the Study, the Board of Appeal concluded that the Contested Decision also breached the principle of proportionality. However, the Board of Appeal added that these findings do not mean that a requirement for a registrant to perform a 90-day sub-chronic test by inhalation in rabbits is a breach of the proportionality principle *per se*. Nevertheless, in order for such a requirement to comply with the proportionality principle, the concerns over its appropriateness and whether it is the least onerous option to achieve the objective(s) pursued must be addressed.

In consideration of all the above, the Board of Appeal upheld the appeal and remitted the case to the Agency for re-examination.

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