SUMMARY OF THE DECISION OF 23 February 2021 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Joined Cases A-016-2019 to A-029-2019

(Dossier evaluation – Article 40 – Read-across testing proposals – Conduct of the decision-making procedure – Duties of the Agency – Article 25 – Addressees of a testing proposal decision)

Factual background

The Appellants are the lead registrants for fourteen substances. These substances are substances of unknown or variable composition, complex reaction products or biological materials ('UVCB') consisting of several constituents.

Between 2016 and 2018, the Agency and the Appellants had several informal exchanges concerning the possibility of relying on a category approach for the registration of the substances in accordance with Section 1.5. of Annex XI to the REACH Regulation.

In 2017, the Appellants submitted a testing strategy to the Agency. Following that testing strategy, the Appellants proposed to carry out a repeated-dose oral toxicity study and a pre-natal developmental toxicity study on four of the fourteen substances, and then satisfy the relevant information requirements for the registration of the remaining substances by means of a category approach under Section 1.5. of Annex XI to the REACH Regulation.

By the Contested Decisions, the Agency rejected the category approach and required each of the Appellants to carry out the studies at issue on those substances for which it is the lead registrant. The Appellants subsequently requested the Board of Appeal to annul the Contested Decisions.

Main findings of the Board of Appeal

1. Choice of legal basis

The Agency rejected the testing strategy because it held that there was insufficient information on the composition or '*identity*' of the substances, so that structural similarity could not be established. According to the Appellants, this assessment should have been carried out by means of a compliance check under Article 41 of the REACH Regulation, and not following the procedure for the assessment of testing proposals under Article 40 of that regulation.

The Board of Appeal held that a testing proposal based on an adaptation under Section 1.5. of Annex XI to the REACH Regulation (a 'read-across testing proposal') constitutes a testing proposal within the meaning of Article 40 of that regulation. As a consequence, the Agency was entitled to assess the Appellants' category approach, which was set out in fourteen read-across testing proposals, under that provision.

Furthermore, Section 1.5. of Annex XI to the REACH Regulation requires registrants to show, amongst other conditions, that the substances in a proposed category are structurally similar. The Agency was consequently also entitled to assess, under Article 40 of the RECH Regulation, whether the information on the structure and composition of the substance provided by the Appellants was sufficient.

The Appellants' argument was therefore rejected.

2. Conduct of the decision-making procedure

Before deciding on the Appellants' testing proposals, the Agency conducted informal exchanges with the Appellants, aimed at clarifying the composition of the substances. The Appellants argued that the Agency should have continued these exchanges, or in any event should not have used any information provided by the Appellants during the exchanges against the Appellants in the assessment of their category approach.

The Board of Appeal held that the Agency does not have a legal obligation, under either Article 40 or Article 41 of the REACH Regulation, to wait for registrants to improve their justification for an adaptation. However, there is also no rule of law preventing the Agency from discussing with, or seeking information from, registrants outside the procedure set out in Article 40, 50 and 51, if it so chooses. If the Agency requests registrants to provide information outside the formal decision-making procedure, and information is provided as a result, the principle of good administration requires the Agency to take any information provided into account in its decision.

The Appellants' argument was therefore rejected.

3. Errors in the assessment of the Appellants' 'testing strategy'

The Appellants argued that the Agency made several errors in its scientific assessment of their category approach. In particular, according to the Appellants, the Agency failed to take into account numerous elements concerning the toxicological properties of the substances.

The Board of Appeal held that Section 1.5. of Annex XI to the REACH Regulation allows for an adaptation if it is established that (i) the substances in a group or category are structurally similar, (ii) the properties of the substances are likely to be similar or follow a regular pattern, and (iii) the similarity of properties or their regular pattern is the result of structural similarity. As these conditions are cumulative, and as the Appellants failed to establish that the substances are structurally similar, the Agency was entitled to reject their category approach without examining the toxicological properties of the substances.

The Appellants' argument was therefore rejected.

4. Requesting further information to substantiate an adaptation

The Appellants argued that their category approach would comply with Section 1.5. of Annex XI to the REACH Regulation if further information on the composition of the substances were generated, gathered, and submitted. The Agency should therefore have requested that information from the Appellants.

The Board of Appeal examined the respective responsibilities of registrants and of the Agency in ensuring that vertebrate animal testing is carried out only as a last resort.

On the one hand, registrants are obliged to submit to the Agency registration dossiers which comply with all the information requirements set out in, amongst other provisions, Annexes VII to X. Where those Annexes require information from testing on vertebrate animals, registrants are also obliged to ensure that such testing is only carried out if the conditions for an adaptation cannot be fulfilled.

On the other hand, the Agency's dossier evaluation procedures ensure that registrants have the possibility to comply with their duties, including providing adaptations instead of vertebrate animal studies whenever possible. Furthermore, during the conduct of its procedures the Agency is required to examine carefully and impartially all the relevant aspects of the individual case. The Agency's assessment is carried out as thoroughly as possible on the basis of the principles of scientific excellence, transparency and independence. All of these procedures and safeguards ensure that studies – and especially studies on vertebrate animals – are carried out only if no adaptation is possible. However, the REACH Regulation does not empower the Agency to require registrants to generate, gather and submit information to substantiate an adaptation. It is not the role of the Agency to develop or improve adaptations on a registrant's behalf.

As a consequence, the Board of Appeal held that the Agency was neither required nor empowered to request the Appellants to generate, gather and submit information to substantiate their category approach.

The Appellants' argument was therefore rejected.

5. Choice of addressees

The Agency addressed each Contested Decision only to the lead registrant of the relevant substance, and not to all the registrants of each substance. The Appellants argued that this was incorrect, as each Contested Decision should have been addressed to all registrants of the relevant substance.

The Board of Appeal found that a decision on a testing proposal must be addressed to all those registrants of the same substance to whom an information requirement applies and who have not decided to opt out from the testing proposal in accordance with Article 11(3) of the REACH Regulation.

It was not contested that in twelve of the present fourteen cases there were such registrants. However, they were not involved in the decision-making procedure and the relevant Contested Decisions were not addressed to them. In those twelve cases, the Agency consequently made an error.

The Board of Appeal also found that the Agency's error affected the legal position of the Appellants. By addressing the relevant Contested Decisions only to the lead registrants of the relevant substances, each lead registrant – that is, each Appellant – was deprived of the benefit of the data-sharing rules in Article 53 of the REACH Regulation in relation to the other registrants of the relevant substance.

Furthermore, it could not be excluded that the registrants in question, if involved in the procedure, will be able to contribute to the assessment of the testing proposals with relevant information. That information would then have to be examined by the competent authorities of the Member States during the decision-making process. As a consequence, the Board of Appeal could not replace the twelve Contested Decisions at issue with its own decision.

In twelve of the fourteen cases at issue, the Contested Decisions were therefore annulled, and those cases were remitted to the Agency for further action. In the remaining two cases, the appeals were rejected.

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 and Article 77(1) of the Biocidal Products 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 is available on the Board of Appeal's section of ECHA's website:
http://echa.europa.eu/about-us/who-we-are/board-of-appeal