

SUMMARY OF THE DECISION OF 25 SEPTEMBER 2015 OF THE CHAIRMAN OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-019-2015

(Biocidal Products — Active substance — Article 95 list — Admissibility)

Factual background

The Appellants were members of a task force (hereinafter the 'task force') created to share the costs of submitting a dossier for the review of several existing substances under the BPD¹ and its implementing legislation².

The Appellants made a notification to the Commission for an existing substance (hereinafter the 'active substance') and submitted a dossier to the Rapporteur Member State (hereinafter 'the RMS'). During the process of the review of the active substance, the RMS requested the Appellants to perform a Comet Assay on rat liver, stomach and blood cells (hereinafter the 'Comet Assay'). The task force subsequently generated and submitted the results of the Comet Assay to the RMS.

After the repeal of the BPD on 1 September 2013, and in accordance with Article 95(1) of the BPR, the Appellants were eligible to be automatically included as a supplier of the active substance on the list of suppliers that the Agency publishes on its website pursuant to Article 95(2) of the BPR (hereinafter the 'Article 95 list'). The Appellants were subsequently included on the list.

A company outside the task force (hereinafter the 'other company') requested the Appellants for access to an inhalation toxicity study. The other company subsequently submitted a dossier to the Agency for the active substance to be included on the Article 95 list. The Agency granted the application to include the other company on the Article 95 list.

The Appellants later informed the Agency that the other company, although it applied for inclusion on the Article 95 list, had not submitted, nor had access to, the Comet Assay. The Agency replied to the Appellants that data requirements may differ between dossiers for the same substance and that the Comet Assay was not required in order for the other company to be included on the Article 95 list.

The Appellants lodged an appeal seeking the annulment of the Decision of the Agency to include the other company on the Article 95 list (hereinafter the 'Contested Decision').

Main findings of the Chairman of the Board of Appeal

The Appellants claimed that while the Contested Decision was not expressly adopted on the basis of Article 63(3) of the BPR, the appeal could be brought under Article 77(1) as if it had been. The Appellants argued that mandatory data sharing under the BPR applied to the

¹ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ((OJ L 123, 24.4.1998, p. 1)

² Commission Regulation (EC) No 1896/2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products (OJ L 228, 8.9.2000) and Commission Regulation (EC) No 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007)

Comet Assay and that the other company should have requested access to it in order to complete its dossier. The Appellants further claimed that, had the proper rules been in place, the Agency would have adopted a decision under Article 63(3) of the BPR which would have been appealable under the BPR.

The Chairman of the Board of Appeal observed that Article 63(3) is only triggered when no agreement had been reached between a data owner and a prospective applicant under the BPR and after a request from a prospective applicant had been made to the Agency to be given the contact details of the data owners under Article 62(2) of the BPR. In the absence of such a request, the Chairman noted that the Agency could not have taken a decision of its own motion under Article 63(3) of the BPR.

The Chairman further observed that the Appellants' arguments amounted in essence to request for the Board of Appeal to consider whether the Agency could take data sharing decisions of its own motion in the absence of a legal basis in the BPR. The Chairman considered that by this question, the Appellants implicitly contested the legality of the BPR. The Chairman noted that only the Court of Justice of the European Union was competent to rule on this issue.

The Appellants also submitted that the Contested Decision was of direct concern to them in that it granted an unfair competitive advantage to the other company as it did not have to pay a proportion of the costs borne by the Appellants to generate the Comet Assay.

The Appellants considered that they were individually concerned by the Contested Decision as they were participants in the review programme and owners of the Comet Assay which the Appellants claimed the Agency had used for the review of the active substance. The Appellants also considered that they were individually concerned by the fact that their competitive relationship with the other company was altered as the latter was allowed to remain on the market as a result of the Contested Decision.

The Chairman noted that even if Article 92(1) of the REACH Regulation does open the possibility for potential appellants to appeal decisions not addressed to them it does not open the possibility to appeal against decisions that are not under the competence of the Board of Appeal. The Chairman concluded that the Contested Decision, which was not listed as an appealable decision on the BPR, that the Contested Decision could not be contested by persons claiming to be individually and directly concerned.

In light of the above, the Chairman dismissed the appeal as inadmissible and decided that, in accordance with Article 93(2) of the REACH Regulation, it was not necessary to examine the grounds raised by the Appellants in support of their request to annul the Contested Decision.

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 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>*