

**SUMMARY OF DECISION OF 7 DECEMBER 2016 OF THE BOARD OF APPEAL OF THE
EUROPEAN CHEMICALS AGENCY**

Case number: A-013-2014

(Substance evaluation – Addressees of a decision – Concerned registrants – Relevant conditions for testing)

Factual background

Following the substance evaluation of octocrilene (CAS No 6197-30-4, EC No 228-250-8; hereinafter the 'Substance'), the European Chemicals Agency (hereinafter the 'Agency') adopted a decision requesting certain registrants to provide additional information.

On 10 December 2014, the Appellant lodged the present appeal at the Registry of the Board of Appeal requesting the Board of Appeal to annul the Contested Decision in its entirety.

The Contested Decision had been addressed to three registrants of the Substance. The Appellant claimed however that the Contested Decision should also have been addressed to a fourth registrant. The fourth registrant had submitted its registration dossier before the draft of the Contested Decision had been sent to the addressees thereof for comments but had not yet passed the technical completeness test pursuant to Article 20 of the REACH Regulation at that time and therefore not yet received a registration number. The Appellant also claimed that the draft decision should have been addressed to a fifth registrant who had submitted a registration dossier after the draft decision had been sent to addressees thereof for comments but before the Contested Decision had been adopted.

In the alternative, if the Board of Appeal did not annul the Contested Decision in its entirety, the Appellant requested the Board of Appeal to annul or amend the Contested Decision insofar as it required the Appellant to submit information related to bioaccumulation test(s) and to conduct an Androgenised Female Stickleback Screen study (hereinafter the 'AFSS study').

Main findings of the Board of Appeal

In its Decision of 12 October 2016, the Board of Appeal examined the Appellant's claim that the Agency had breached Articles 50(1) and 51(5) of the REACH Regulation, as well as the principle of equal treatment by failing to address the Contested Decision to the fourth and the fifth registrants.

The Board of Appeal firstly dismissed the Appellant's claim in relation to the fifth registrant. In particular, the Board of Appeal found that the Agency was justified in applying a cut-off point for identifying addressees of a contested decision, in this case the date the draft decision was sent to registrants for comments. In particular, the Board of Appeal considered that this was necessary to avoid the possibility of the decision-making procedure being extended unreasonably or even indefinitely.

The Board of Appeal found however that the fourth registrant should have been included in the list of addressees of the Contested Decision. In particular, the Board of Appeal found that the fourth registrant was known to the Agency at the time the draft decision was sent to certain registrants. The draft decision could therefore have been sent to the fourth registrant without the need for the decision-making procedure to be interrupted, and potentially re-started. However, the Board of Appeal considered that this procedural irregularity was not sufficient to lead to the annulment of the Contested Decision. In particular, from the facts of the case the Board of Appeal considered that the Contested Decision would not have been different had the fourth registrant been included as an addressee of the Contested Decision.

The Board of Appeal also dismissed the Appellant's claim that the Contested Decision generates legal uncertainty regarding the sharing of costs of the information required by the Contested Decision. In particular the Board of Appeal found that after a substance evaluation decision has been adopted all the members of the joint submission for that substance are potentially concerned by its outcomes. In particular, when new tests on vertebrate animals are required, this may be relevant information for the registration dossiers of present and future registrants. As a result, costs should be shared by all co-registrants (present and future) in a fair, non-discriminatory and transparent way.

The Board of Appeal also dismissed the Appellant's claim that the requirement to provide information on bioaccumulation should be annulled on the grounds that it had already submitted a correct calculation of the bioconcentration factor value, based on results from non-filtered water, and that therefore there is no need for a recalculation based on filtered water, or for it to submit any new data. In particular, the Board of Appeal found that '*relevant conditions*' within the meaning of Annex XIII of the REACH Regulation means those conditions that allow for an objective assessment of the persistent, bioaccumulative and toxic (PBT)/very persistent and very bioaccumulative (vPvB) properties of a substance and not the PBT/vPvB properties of a substance in particular environmental conditions.

The Board of Appeal also dismissed as unfounded the Appellant's arguments related to the proportionality of the request to perform the AFSS study.

The Appellant's appeal was therefore dismissed in its entirety.

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>