

# Announcement of appeal<sup>1</sup>

Published on 4 April 2019

**Case** A-002-2019

**Appellant** BASF SE, Ludwigshafen am Rhein, Germany

**Appeal received on** 19 February 2019

**Subject matter** A decision taken by the European Chemicals Agency (the 'Agency')

pursuant to Article 41 of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH

Regulation

**Keywords** Dossier evaluation – Compliance check – Registration dossier update

during the decision-making procedure - Cut-off points for considering a dossier update - Article 25 - Legitimate expectations

- Good administration - Right to be heard

Contested Decision CCH-D-2114448631-50-01/F

Language of the case English

### Background and form of order sought

On 23 November 2018, pursuant to Article 41 of the REACH Regulation, the Agency adopted a decision following a compliance check of the Appellant's dossier for the substance 3,7-dimethyloct-6-enenitrile (EC No 257-288-8, CAS No 51566-62-2). In the Contested Decision, the Agency required the Appellant to submit information on a number of studies, including four ecotoxicity studies.

The Appellant requests the Board of Appeal to:

- partially annul the Contested Decision, in so far as it requires the Appellant to submit information on the four ecotoxicity studies,
- remit the case to the competent body of the Agency to decide on the adaptations submitted by the Appellant regarding the four ecotoxicity studies, and
- order the Agency to refund the appeal fee.

#### Pleas in law and main arguments

The Appellant states that, in its comments on the draft decision, it referred to a modified exposure and risk assessment and an update of its registration dossier. However, according to the

<sup>&</sup>lt;sup>1</sup> Announcement published in accordance with Article 6(6) of Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency, as amended by Commission Implementing Regulation (EU) 2016/823.



Contested Decision, the dossier update was not taken into account in the decision-making procedure leading to the adoption of the Contested Decision.

The Appellant argues that the Agency's practice of disregarding dossier updates received after the notification of a draft decision to a registrant, even when those updates are mentioned in the comments on the draft decision, is unlawful.

The Appellant argues that, in failing to take into account the Appellant's dossier update, the Agency breached Articles 25(1) and 50(1) of the REACH Regulation, the principle of the protection of legitimate expectations, and the right to be heard.

The Appellant argues that in failing to take into account all the relevant factors and circumstances of the case the Agency breached the principle of good administration.

The Appellant argues that the Contested Decision indicates that the Agency will only examine new information submitted by the Appellant in the follow-up procedure under Article 42. The Agency may consider that the information in the dossier update is not new information as it was already mentioned in the Appellant's comments on the draft decision. Therefore, the Agency may not examine the adaptation set out in its dossier update during the follow-up procedure under Article 42. The Appellant considers that this situation breaches Articles 25, 42, and 50 of the REACH Regulation, as well as the right to be heard and the principles of proportionality and legal certainty.

## Other information

Pursuant to Article 93(1) of the REACH Regulation, the Executive Director of the Agency rectified the Contested Decision by withdrawing the information requirements contested in this appeal. The Appellant subsequently withdrew the appeal and the Chairman of the Board of Appeal closed the case on 4 April 2019.

#### **Further information**

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

http://echa.europa.eu/web/guest/regulations/appeals