

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

<b>Published on</b>	17 May 2021
<b>Case</b>	A-005-2021
<b>Appellant</b>	Albemarle Europe SPRL, Belgium
<b>Appeal received on</b>	12 April 2021
<b>Subject matter</b>	A decision of the European Chemicals Agency based on Article 41 of the REACH Regulation (Regulation (EC) No 1907/2006)
<b>Keywords</b>	<i>Dossier evaluation – Compliance check – Comments to the draft decision – Section 9.2. of Annex IX to the REACH Regulation – Test method and timeline</i>
<b>Contested Decision</b>	CCH-D-2114539007-53-01/F
<b>Language of the case</b>	English

## Remedy sought by the Appellant

On 13 January 2021, the Agency adopted the Contested Decision following the compliance check of the Appellant's dossier for N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide) ('the Substance'). The Appellant requests the Board of Appeal to annul the Contested Decision insofar as it requires the Appellant to submit information related to the identification of degradation products, according to Section 9.2.3. of Annex IX to the REACH Regulation, "using an appropriate test method".

The Appellant also requests the Board of Appeal to order the refund of the appeal fee and take such other or further measures as justice may require.

## Pleas in law and main arguments

The Appellant submits that section B of the Contested Decision is legally flawed.

With its first plea, the Appellant argues that the chemical safety assessment of the Substance did not show any need to investigate further the degradation of the Substance and its degradation products. The Appellant considers that the conditions set out in Annex IX, Section 9.2., column 2, were not met in this case. By requiring the Appellant to submit information on the degradation products the Agency therefore erred in its assessment, acted ultra vires and infringed the principle of proportionality. The Appellant argues that it fulfilled Section 9.2.3. of Annex IX, column 1, by relying on an adaptation related to:

---

<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.

- the persistence of the Substance where results of the evaluation conducted by the EU PBT Expert Working Group indicated that the Substance is not expected to form degradation products,
- the Substance's insolubility,
- the limited ability of bacteria to biotransform the Substance.

The Appellant argues that it had also relied on Section 2 of Annex XI to the REACH Regulation, the adaptation in cases where testing is not technically possible, due to its past experience showing that it was not possible to synthesize the radiolabelled material.

If the Board of Appeal dismisses the first plea, the Appellant submits the following additional pleas:

The Appellant argues, with its second plea, that the Agency misinterpreted Section 9.2.3. of Annex IX of the REACH Regulation by requesting the identification of degradation products separately from a simulation test in Section 9.2.1. of Annex IX, whereas the identification of potential degradation products is a consequence of either one of the simulation tests under Section 9.2.1. of Annex IX, during which degradation products may be formed.

The Appellant argues, with its third plea, that the Agency infringed the principle of legal certainty by not specifying the applicable test method for the required information. The Agency did not specify which simulation test in Section 9.2.1. of Annex IX or other simulation test should be carried out to bring the Appellant's dossier into compliance. The Appellant cannot be therefore certain that, if it carries out one of the biotic degradation tests for one compartment (soil or sediment), the Agency will accept it and not require that the Appellant submits the test for another compartment.

The Appellant argues, with its fourth plea, that the Agency infringed the principle of proportionality and failed to take all relevant information into account by requiring the Appellant to provide the requested information by April 2023. The Agency should consider that, due to the Substance being unstable, it does not behave as a standard material and the radiolabelled material is difficult to obtain. The Appellant further argues that the timeline it proposed in its comments to the draft decision (39 months) is more appropriate for the extraction methodology, development and validation of the analytical methods for the Substance.

### **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>