

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

<b>Published on</b>	25 February 2021
<b>Case</b>	A-002-2021
<b>Appellants</b>	LANXESS Deutschland GmbH, Germany Schirm GmbH, Germany
<b>Appeal received on</b>	22 January 2021
<b>Subject matter</b>	A decision taken by the European Chemicals Agency pursuant to Article 46(1) of the REACH Regulation
<b>Keywords</b>	<i>Substance evaluation – Error of assessment – Good administration – Proportionality – Equal treatment and non-discrimination – Right to be heard</i>
<b>Contested Decision</b>	Decision of 26 October 2020 on the substance evaluation of diuron (EC No 206-354-4; CAS No 330-54-1)
<b>Language of the case</b>	English

### Remedy sought by the Appellants

On 26 October 2020, the Agency adopted the Contested Decision requesting the Appellants to submit information on a larval amphibian growth and development assay (the 'LAGDA') according to OECD test guideline 241 using African clawed frog (*Xenopus laevis*), including measurements of plasma vitellogenin. The study was requested to clarify concerns about the potential endocrine disrupting properties of diuron in the environment.

The Appellants request the Board of Appeal to annul the Contested Decision.

The Appellants also request the Board of Appeal to order the Agency to refund the appeal fee.

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<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.

### **Pleas in law and main arguments**

The Appellants argue that the Agency committed a manifest error of assessment of the scientific facts of the case and infringed the duty of good administration under Article 41 of the Charter of Fundamental Rights of the European Union by:

- (a) Failing to reassess the scientific situation based on new information regarding the suitability of the LAGDA which became available during the more than one-year period between the Appellants' comments on the draft decision and the adoption of the Contested Decision;
- (b) Disregarding the fact that the LAGDA is not a sufficiently validated test method and is not suitable for testing the thyroidal mode of action. The Agency did not demonstrate therefore that the requested information has a realistic possibility of clarifying the potential concern identified; and
- (c) Failing to assess the suitability of alternative test methods proposed by the Appellants in their comments on the draft decision.

The Appellants argue that the Agency breached the principle of proportionality enshrined in Article 5(4) of the Treaty on European Union by requesting an unnecessary test. The LAGDA cannot achieve the objectives pursued by the Agency in the substance evaluation of diuron, in particular because that test is not sufficiently validated to examine the thyroid mode of action. In addition, less onerous and more appropriate alternative test methods are available to address the concern identified by the Agency.

The Appellants argue that the Agency infringed the principle of equal treatment and non-discrimination enshrined in Article 18 of the Treaty on the Functioning of the European Union and Articles 20 and 21 of the Charter of Fundamental Rights of the European Union by:

- (a) Accepting in similar substance evaluation decisions the amphibian metamorphosis assay (OECD Test Guideline 231) as a first step in the testing approach of the thyroidal mode of action instead of the LAGDA; and
- (b) Accepting in a similar case non-validated fish studies to test the thyroidal mode of action, an approach which was rejected in the present case.

The Appellants argue that the Agency breached their right to be heard by raising a new argument in the Contested Decision that was not mentioned in the draft decision.

### **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>