

Announcement of appeal¹

Published on	25 June 2019
Case	A-007-2019
Appellant	Chemours Netherlands B.V., the Netherlands
Appeal received on	17 May 2019
Subject matter	A decision adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 46(1) of the REACH Regulation
Keywords	<i>Substance evaluation – Error of assessment – Grounds for concern – Animal welfare – Proportionality</i>
Contested Decision	Decision of 20 February 2019 on the substance evaluation of ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate (the 'Substance'; EC No 700-242-3, CAS No 62037-80-3)
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision insofar as it requires the Appellant to conduct a carcinogenicity study in mice in accordance with OECD test guideline ('TG') 451.

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

Pleas in law and main arguments

The Appellant argues that the Agency committed a manifest error of assessment in concluding that there is a mutagenicity concern for the Substance.

In particular, the Appellant argues that:

- The liver tumours and effects on the pancreatic and Leydig cells observed in the available studies on rats are caused by a peroxisome proliferator-activated receptor alpha (PPAR α)-related '*mechanism*' and are therefore not relevant to humans;

¹ 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 Agency committed a manifest error of assessment in concluding that there are similarities between the Substance and another substance capable of justifying the concern. In this respect, the Appellant argues that the Agency failed to consider the structural and kinetic differences between the two substances;
- The Agency committed a manifest error of assessment in concluding that the information requested has a realistic possibility of leading to improved risk management measures. More specifically, a study conducted according to OECD TG 451 will not provide the information that the Agency considers necessary.

The Appellant argues that the Contested Decision breaches Article 25 of the REACH Regulation as it requires a study using a large number of animals when the results from the study will not lead to improved risk management measures. In addition, the Agency did not adequately consider less onerous alternatives to generate the required information.

The Appellant argues that the Contested Decision breaches the principle of proportionality as the Agency has not demonstrated that the requested study would be necessary or appropriate as the results from the study will not lead to improved risk management measures.

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>