EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	27 September 2022
Case	A-008-2022
Appellant	Dragon Chemical Europe GmbH, Germany
Appeal received on	23 August 2022
Subject matter	A decision taken by the European Chemicals Agency pursuant to Article 46(1) of the REACH Regulation[2]
Keywords	*Substance evaluation – Principle of proportionality – Error of assessment – Article 25 of the REACH Regulation*
Contested Decision	Decision of 24 May 2022 on the substance evaluation of 5-amino-o-cresol (EC number 220-618-6; CAS number 2835-95-2)
Language of the case	English

Background and remedy sought by the Appellant

On 24 May 2022, the Agency adopted the Contested Decision requesting the Appellant to submit, by 29 August 2023, information on an *in vivo* mammalian alkaline comet assay test (OECD test guideline 489) in liver, gastro-intestinal tract (glandular stomach and duodenum) and urinary bladder performed in rats via the oral route. The study was requested to clarify a potential risk related to mutagenicity.

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

Pleas in law and main arguments

The Appellant raises the following pleas in law in support of its appeal:

1. The Agency breached the principle of proportionality, made errors of assessment, and failed to take all relevant information into account in concluding that:
   (a) there is a potential risk related to mutagenicity,
   (b) there is need to clarify the alleged potential risk, and
   (c) the information requested has a realistic possibility of leading to improved risk management measures.

[1] Announcement published in accordance with Article 6(6) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5).
[2] All references to Articles concern the REACH Regulation unless stated otherwise.

2. The Agency breached the Appellant's legitimate expectations.

3. The Agency breached Article 25 of the REACH Regulation.

4. The Agency breached its duty to state reasons in the Contested Decision.

In support of its pleas in law, the Appellant argues that the Contested Decision requires the Appellant to repeat a vertebrate animal study that is already available in the registration dossier for the Substance, even though there is extensive *in vivo* data available which allows a firm conclusion on the mutagenic potential of the Substance to be reached.

The Appellant argues that the Contested Decision therefore imposes testing which is unnecessary, will not provide additional information on the mutagenic potential of the Substance, and will lead to the unnecessary suffering and sacrifice of vertebrate animals.

The Appellant argues that the Agency's request for information is inconsistent with the conclusion of the European Commission's Scientific Committee on Consumer Products ('SCCP')[3] which concluded that the Substance – a cosmetic product ingredient – is safe and has no relevant mutagenic potential *in vivo*.

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

[3] Now known as the Scientific Committee on Consumer Safety ('SCCS').