EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-023-2015
Appellants	S.A. AKZO NOBEL CHEMICALS NV, Belgium ARKEMA GmbH, Germany PERGAN GmbH, Germany REACH COMPLIANCE SERVICES Limited (trading under the name REACH24H Consulting Group), Ireland UNITED INITIATORS GmbH & CoKG, Germany
Appeal received on	13 November 2015
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 46(1) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 52 of the REACH Regulation
Keywords	*Substance evaluation – Article 42 – Grounds for concern*
Contested Decision	Agency Decision of 14 August 2015 on the substance evaluation of tert-butyl perbenzoate (CAS No 614-45-9, EC No 210-382-2)
Language of the case	English

Remedy sought by the Appellants

The Appellants request the Board of Appeal to:

(i) Annul the Contested Decision insofar as it requests the Appellants to conduct:
- a pre-natal developmental toxicity (hereinafter 'PNDT') study (test method: EU B.31./OECD 414) in rabbits, oral route, and
- an in vivo alkaline single-cell gel electrophoresis assay for DNA strand breaks (Comet assay, OECD 489) in rats, oral route, with examination of liver and either glandular stomach or duodenum/jejunum;

(ii) If the Board of Appeal upholds the animal testing requests, amend the Contested Decision to allow 24 months, instead of 15 months, for the requested information to be submitted;

(iii) Order the refund of the appeal fee;

(iv) Take such other or further measures as justice may require.

If the appeal is found inadmissible or is dismissed the Appellants request the Board of Appeal to amend the deadline set in the Contested Decision to take account of the suspensive effect of the appeal.

[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.

Pleas in law and main arguments

With regards to the requirement for a PNDT study the Appellants argue that the Agency:

(i) breached Articles 42 and 46 of the REACH Regulation and misused its powers. In particular, the Appellants argue that the Agency unlawfully used the substance evaluation procedure instead of the compliance check procedure;
(ii) committed a manifest error of assessment in concluding, on the basis of the registration dossier, that there is a concern that needs to be addressed. In particular, the Appellants claim that the results of an earlier PNDT study do not suggest that the Substance has an adverse effect on the reproductive functions in the absence of maternal toxicity. There is therefore no real concern that would justify the need to carry out additional testing in a second species;
(iii) breached the duty to state reasons by not considering the Appellants' comments;
(iv) acted ultra vires by submitting proposals for amendment to the draft decision to itself.

With regards to the requirement for a Comet assay (OECD 489), the Appellants submit that:

(i) there is not a real mutagenicity concern that needs to be addressed. The Agency committed a manifest error of assessment in concluding, on the basis of information in the registration dossier, that there is a concern that needs to be addressed;
(ii) there is sufficient scientific information demonstrating that the Substance is not a mutagen. The Agency therefore committed a manifest error of assessment in interpreting the available data to the opposite effect;
(iii) there is no realistic possibility that the requested study would provide results that would address the Agency's concerns;
(iv) the Contested Decision does not state any reasons as to why the conclusions previously reached by the evaluating Member State Competent Authority, removing concerns for carcinogenicity, were disregarded by the Agency.

In addition, the Appellants claim that:

(i) the Agency breached Article 25 of the REACH Regulation by failing to consider alternatives to the animal testing required by the Contested Decision;
(ii) the 15-month deadline imposed for the Appellants to provide the requested information is inadequate;
(iii) the Agency infringed the principle of proportionality as the information requirements are not necessary to clarify a real concern and the Comet assay is not appropriate to address the alleged concern; and
(iv) the Agency infringed the Appellants' right to be heard in particular as they were not given the opportunity to comment on the version of the decision discussed at the Member State Committee and to participate at the meeting of that Committee.

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