

Announcement of appeal¹

Case A-002-2015

Appellant Lubrizol France SAS, France

Appeal received on 17 February 2015

Subject matter A decision taken by the European Chemicals Agency (the 'Agency')

pursuant to Article 41 of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation

Keywords Evaluation – Compliance check – Request for further information

Contested Decision CCH-D-0000004032-89-05/F

Language of the case English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision in its entirety and refund the appeal fee to the Appellant.

Pleas in law and main arguments

The Contested Decision was adopted on 17 November 2014 following a compliance check under the dossier evaluation procedure of the registration submitted by the Appellant for zinc bis[O,O-bis(2-ethylhexyl)] bis(dithiophosphate) (hereinafter the 'Substance').

The Contested Decision requested the Appellant to conduct, using the Substance, a sub-chronic toxicity study (90-day), inhalation route (Section 8.6.2 of Annex IX²; test method: OECD 413) in rats, and a pre-natal developmental toxicity study (Section 8.7.2 of Annex IX; test method: EU B.31/OECD 414) in rats or rabbits, oral route.

The Appellant claims that the Substance is part of a larger group of highly similar zinc dialkyldithiophosphate (ZDDP) substances which comprise a validated category of substances.

By its first plea, the Appellant claims that, by failing to consider that the Substance was part of a group of substances that would benefit from the use of a category approach, as well as failing to respond to a formal request by the Appellant to discuss the proposed category in order to select the substance in that category that would be appropriate to test, the Agency adopted the Contested Decision in breach of Article 13 and the principle of proportionality.

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.

² All references are to the REACH Regulation unless stated otherwise.



By its second plea, the Appellant claims that, by failing to consider that the Substance was part of a group of substances that would benefit from the use of a category approach and by requiring the Appellant to carry out the same vertebrate animal tests on the Substance and on a similar substance subject to a separate Agency decision, the Contested Decision breaches Article 25(1), and Article 13 of the Treaty on the Functioning of the European Union (TFEU), in that it would cause unnecessary testing on vertebrate animals.

By its third plea, the Appellant claims that, by requesting it to conduct a study on sub-chronic toxicity (90-day) by the inhalation route, the Contested Decision breaches the principle of proportionality, Article 25(1), and Article 13 TFEU, in that the inhalation route is not relevant for the Substance, will induce intense suffering for the tested animals and/or will not produce meaningful results.

By its fourth plea, the Appellant claims that, by splitting the initial draft decision notified to the Appellant into two separate decisions, and by not justifying such a split in due time and in a detailed manner, the Agency adopted the Contested Decision in breach of Article 51, as well as the principles of good administration, duty to provide reasons, legal certainty, coherence, and legitimate expectations.

By its fifth plea, the Appellant claims that the Contested Decision breaches the fundamental right to be heard, the principle of legal certainty, the principle of equality before the law, and Article 51(5) in that:

- (i) the Contested Decision was communicated to the Member State Committee (hereinafter 'MSC') before the deadline for the Appellant to comment on the revised draft decision and the Member States' comments, and before the Appellant actually filed its comments;
- (ii) the MSC did not take some of the Appellant's comments into account; and
- (iii) the Appellant was not given the possibility to attend the MSC Meeting at which the Contested Decision was adopted.

By its sixth plea, the Appellant claims that the Contested Decision infringes the principles of legal certainty and non-retroactivity as the statement that the Contested Decision will not take into account any updates of the registration dossier of the Substance made after 12 June 2014 was notified to the Appellant only on 18 July 2014.

Other information

Pursuant to Article 93(1), the Executive Director of the European Chemicals Agency rectified the Contested Decision on 1 April 2015 by withdrawing it in its entirety. The appeal was subsequently withdrawn by the Appellant and the case was closed by the Board of Appeal on 24 April 2015.

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