EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-011-2018
Appellant	Clariant Plastics & Coatings (Deutschland) GmbH, Germany
Appeal received on	6 July 2018
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	*Dossier evaluation – Compliance check – Testing on vertebrate animals – Error of assessment*
Contested Decision	CCH-D-2114394043-52-01/F
Language of the case	English

Remedy sought by the appellant

The Appellant requests the annulment of the Contested Decision insofar as it requires the submission of information on:

1. Sub-chronic toxicity study (90-day), inhalation route (Section 8.6.2 of Annex IX to the REACH Regulation) in rats modified to include bronchoalveolar lavage ('BAL') analysis;
2. Pre-natal developmental toxicity (PNDT) study in a first species (rat or rabbit), oral route (Section 8.7.2 of Annex IX);
3. PNDT study in a second species (rat or rabbit), oral route (Section 8.7.2 of Annex X);
4. Extended one-generation reproductive toxicity study (EOGRTS) in rats, oral route (Section 8.7.3 of Annex X);
5. Growth inhibition study, aquatic plants (Section 9.1.2 of Annex VII);
6. Long-term toxicity testing on aquatic invertebrates (Section 9.1.5. of Annex IX); and
7. Long-term toxicity testing on fish (Section 9.1.6.1 of Annex IX).

The Appellant also requests the Board of Appeal to order the refund of the appeal fee.

[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.

EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Pleas in law and main arguments

The Agency adopted the Contested Decision on 9 April 2018 following a dossier evaluation compliance check of the Appellant's registration dossier for the substance 3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide (EC No 229-440-3, CAS No 118-56-9, the 'Substance').

In relation to all seven information requirements, the Appellant submits that the Agency:

- committed an error of assessment because the information requested is not '*useful or necessary*' to meet the objectives of the REACH Regulation,
- breached Article 25 of the REACH Regulation which requires testing on vertebrate animals to be a last resort, and
- breached the principle of proportionality.

Concerning the first information requirement, the Appellant argues that the Agency erred in its assessment when it requested the Appellant to conduct a longer term study analysing BAL rather than shorter term studies which would have provided the same information. The Appellant further argues that the information request would, in breach of Article 25, result in the unnecessary animal testing. As the Agency rejected the Appellant's less onerous testing strategy, the Appellant argues that the Agency also breached the principle of proportionality.

Concerning the second to fourth information requirements, the Appellant argues that existing studies indicate that the Substance may not be bioavailable and, if this is the case, the requested studies would not provide information on whether the Substance is toxic or not. As there was a doubt about the bioavailability of the Substance, the Agency erred in its assessment and should have followed a tiered approach to determine the bioavailability of the Substance first and requested other studies thereafter if necessary. As the Contested Decision did not first address the bioavailability of the Substance, the Appellant argues that the Agency also breached Article 25 and the principle of proportionality.

Concerning the fifth to seventh information requriements, the Appellant followed the appropriate test guidelines (OECD TG 201 and OECD TG 211) modified in accordance with OECD Guidance Document 23 on Aquatic Toxicity Testing of Difficult Substances and Mixtures. The Appellant argues that the Agency erred in its assessment in requiring the Appellant to *'conduct the [existing] studies again*' following the OECD Guidance No. 36 on 'Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials' and OECD Expert Report No. 40 on the 'Ecotoxicology And Environmental Fate Of Manufactured Nanomaterials: Test Guidelines' instead. The Appellant argues that the Agency breached the principle of proportionality by disregarding the existing studies. As the existing studies were disregarded and new ones requested, it also considers these requests to be in breach of Article 25. The Appellant also considers that the Agency breached its legitimate expectations by stating in the Contested Decision that the substance is a nanomaterial when this statement had previously been withdrawn from 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