EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	1 October 2020
Joined cases	A-006-2020 and A-007-2020
Appellants	BASF Colours & Effects GmbH, Germany (A-006-2020) BASF SE, Germany (A-007-2020)
Appeals received on	29 June 2020
Subject matter	Decisions 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 – Tonnage downgrade – Cut-off point for dossier updates – Proportionality – Animal welfare*
Contested Decisions	CCH-D-2114505954-46-01/F (A-006-2020) CCH-D-2114505954-44-01/F (A-007-2020)
Language of the cases	English

Background and remedy sought by the Appellants

The Appellants are both registrants of the substance Reaction product of [29H,31H-phthalocyaninato(2-)-N29, N30, N31, N32] zinc, sulphuric acid and caustic soda (List number: 939-524-8; the 'Substance').

The Appellants request the Board of Appeal to annul the Contested Decisions, insofar as those decisions required the Appellants to provide studies under Annex IX of the REACH Regulation (section C of the Contested Decisions), namely:

1. *In vivo* genotoxicity study to be selected according to the following scenarios:

a. If the test results of request B.1 [in vitro cytogenicity study in mammalian cells […] or in vitro micronucleus study […] with the Substance] are negative:
In vivo mammalian alkaline comet assay (Annex IX, Section 8.4., column 2; test method OECD TG 489) in rats, oral route, on the following tissues: liver, glandular stomach and duodenum, with the Substance; or

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Transgenic rodent somatic and germ cell gene mutation assays (Annex IX, Section 8.4., column 2; test method EU 8.58./OECD TG 488) in transgenic mice or rats, oral route on the following tissues: liver and glandular stomach and duodenum, with the Substance; duodenum must be harvested and stored for up to 5 years. The duodenum must be analysed if the results of the glandular stomach and of the liver are negative or inconclusive.

b. If the test results of request B.1 [in vitro cytogenicity study in mammalian cells […] or in vitro micronucleus study […] with the Substance] are positive:
In vivo mammalian alkaline comet assay (Annex IX, Section 8.4., column 2; test method OECD TG 489) in rats, oral route, on the following tissues: liver, glandular stomach and duodenum, with the Substance;

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211) with the Substance;

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance; and

4. Identification of degradation products (Annex IX, Section 9.2.3.) using an appropriate test method with the Substance.

The Appellants also request the Board of Appeal to order the refund of the appeal fees. If the Board of Appeal decides to uphold the Contested Decisions, the Appellants request "*a reasonable*" extension of the deadline of 7 July 2022 set in the Contested Decisions for the submission of the requested information.

The Board of Appeal decided to join the two appeal cases on 28 September 2020.

Pleas in law and main arguments

The Appellants argue that, after having received the drafts of the Contested Decisions and prior to the adoption of the Contested Decisions, they have downgraded the tonnage of the two registration dossiers. The Appellants argue that they mentioned these tonnage updates in their comments to the draft decisions. The Appellants argue that the information requirements for Annex IX endpoints are therefore disproportionate and no longer apply to their respective dossiers. The Appellants also argue that they have notified ECHA of their intention to officially cease manufacturing the Substance.

The Appellants also argue that the REACH Regulation does not contain provisions on a "cut-off point" after which the Agency would be entitled to ignore new facts in the dossier evaluation process.

Furthermore, the Appellants argue that the Contested Decisions violate Article 25 of the REACH Regulation according to which testing on vertebrate animals should be undertaken only as a last resort.

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