EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	12 October 2020
Case	A-008-2020
Appellant	Sustainability Support Services (Europe) AB
Appeal received on	3 September 2020
Subject matter	A decision of the European Chemicals Agency based on Article 51 of the REACH Regulation (Regulation (EC) No 1907/2006)
Keywords	*Dossier evaluation - Compliance check – Read-across – Comments to the draft decision – Animal welfare*
Contested Decision	CCH-D-2114512168-54-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision insofar as it requires that the Appellant submits the following tests according to Annex VIII and IX of the REACH Regulation:

- an in vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487);
- an in vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method OECD TG 476 or TG 490), only if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. is obtained;
- a screening test for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method OECD 422) in rats, oral route;
- a sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats;
- a pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route;
- a long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211);
- a long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210).

The Appellant also requests the Board of Appeal to indicate that "no further testing is required for the substance".

[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.

Pleas in law and main arguments

The Agency adopted the Contested Decision on 3 June 2020 following a compliance check of the Appellant's dossier for the substance disodium 4,4'-bis[(4-anilino-6-morpholino-1,3,5-triazin-2-yl)amino]stilbe ne-2,2'- disulphonate (EC No 240-245-2; CAS 16090-02-1; the 'Substance').

The Appellant argues that the requirements in sections B and C of the Contested Decision do not take into account all the supporting data the Appellant provided on the requirements of the tests, in particular:

- For the cytogenicity study in mammalian cells (OECD TG 473) or the in vitro micronucleus study (OECD 487) and the in vitro gene mutation study in mammalian cells (OECD TG 476 or 490), the Appellant claims that existing studies (including an OECD 473) performed by other entities show no mutagenicity nor clastogenic effects.

- Regarding the screening test (OECD TG 422) and the pre-natal developmental toxicity study (OECD TG 414), the Appellant claims that existing studies on three read-across chemicals did not show any adverse effects either in reproductive performance or in foetuses.

- Regarding the sub-chronic toxicity study (90-day), oral route, the Appellant claims that an OECD TG 407 (repeated dose 28-day oral toxicity study) and another two-week repeated dose toxicity study on a read-across chemical (CAS No 16470-24-9) do not show any adverse effects, meaning that no classification is required for the Substance. The Appellant further argues that the effects of a chronic (two-year) study observed on female reproductive organs and in the serum were not considered toxicologically relevant.

- Regarding the requirement for long-term toxicity testing on aquatic invertebrates, the Appellant refers to experimental data from an OECD TG 202 (acute toxicity test) and claims that it is "equally valid for meeting the data requirements". The Appellant also refers to an existing OECD TG 211 (long-term toxicity study) and a QSAR prediction showing that the Substance can already be classified as "aquatic chronic category 3" without performing any new tests.

- Finally, regarding the long-term toxicity testing on fish, the Appellant argues that the results of the two OECD TG 204 (14-day) tests, including with a read-across analogue and a long-term toxicity test on fish with the same analogue showed no need for classification. The Appellant also contends that a long-term toxicity test on fish would be only required if the chemical safety assessment showed the need to investigate further. Consequently, according to Column 2 of Annex IX, this requirement can be waived.

In arguing that the tests required in sections B and C of the Contested Decision are not necessary, the Appellant also submits that animal welfare should be appropriately considered.

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