Announcement of appeal[1]

Published on	7 May 2024
Case	A-003-2024
Appellant	ARKEMA France S.A., France
Appeal received on	4 April 2024
Subject matter	A decision taken by the European Chemicals Agency under Article 42(1) of the REACH Regulation[2]
Keywords	*Dossier evaluation – Follow-up to a compliance check – Rectification of a decision by the Executive Director – Article 25*
Contested Decision	CCH-D-2114664303-53-01/F
Language of the case	English

Background and remedy sought by the Appellant

On 24 October 2017, the Agency adopted a compliance check decision under Article 41 (**the initial compliance check decision**) concerning the Appellant's registration for 1-chloro-2,3-epoxypropane (the **Substance**).[3] Following that decision, the Appellant carried out and submitted an extended one-generation reproductive toxicity study (**EOGRTS**) under Section 8.7.3. of Annex X.

On 9 March 2022, the Agency issued a first follow-up decision pursuant to Article 42(1). In this first follow-up decision, the Agency found that the Appellant had failed to comply with the initial compliance check decision because the EOGRTS was, in part, carried out incorrectly.

On 7 June 2022, the Appellant filed an appeal before the Board of Appeal seeking the annulment of the first follow-up decision. The Agency subsequently rectified the first follow-up decision by withdrawing it entirely. The Appellant withdrew its appeal and the case was closed on 22 August 2022.[4]

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[1] Announcement published in accordance with Article 6(6) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5).

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1). All references to Articles and Annexes concern the REACH Regulation unless stated otherwise.

[3] EC No 500-130-2; CAS No 55818-57-0.

[4] Decision of the Board of Appeal of 22 August 2022, *Arkema France,* case A-005-2022.

On 5 January 2024, the Agency adopted a new follow-up decision (the **Contested Decision**). In the Contested Decision, the Agency declared that the Appellant had failed to comply with the initial compliance check decision because the EOGRTS was, in part, carried out incorrectly. It also stated that the Appellant remains bound to provide the information set out in that decision, and that the national enforcement authorities will be informed.

The Appellant requests the Board of Appeal to annul the Contested Decision and order the Agency to refund the appeal fee.

Pleas in law and main arguments

In support of its appeal, the Appellant raises eight pleas in law.

First, according to the Appellant, the Contested Decision was adopted after the 30-day period foreseen in Article 93(1) for the rectification of the first follow-up decision. The Appellant also argues that the Agency acted *ultra vires* in adopting the Contested Decision which reiterates the same information requirements with, however, an amended statement of reasons.

Second, the Appellant argues that the Agency failed to provide a clear and unequivocal statement of reasons as required by Article 130.

Third, the Appellant argues that the Agency breached Articles 41 and 42 as well as the principle of legal certainty by stating, in both the first follow-up decision and the Contested Decision, that the EOGRTS should be carried out in application of certain guidelines dating from after the initial compliance check decision. In addition, the Appellant argues that the Agency committed errors insofar as it required the use of the highest possible dose level, failed to assess all available data on the substance, and did not demonstrate that the requested information had any realistic possibility to improve risk management measures. Finally, the Appellant argues that the Agency exceeded its competence by finding that the dose-levels used in the EOGRTS carried out by the Appellant were inadequate.

Fourth, the Appellant argues that the Agency breached Article 25(1) by requiring unnecessary animal testing.

Fifth, the Appellant argues that the Agency breached the principle of a fair trial and of the equality of arms as enshrined in Article 47 of the Charter of Fundamental Rights of the European Union and Article 6 of the European Convention on Human Rights by removing and amending parts of its statement of reasons in the first follow-up decision.

Sixth, according to the Appellant, the Agency breached the principle of proportionality and Article 41 and 42 of REACH read in conjunction with Article 25(1). In this respect, the Appellant argues that the submitted EOGRTS is in compliance with the initial compliance check decision, and that the Agency committed several errors in its scientific assessment.

Seventh, the Appellant argues that the Agency breached the duty of good administration and the duty to examine carefully and impartially all the relevant aspects of the case, breached the Appellant's legitimate expectations, created a situation of uncertainty for registrants, and failed to provide clear and reliable guidance on dose selection.

Eighth, according to the Appellant, the Agency committed manifest errors of assessment when reviewing the EOGRTS submitted by the Appellant.

Further information

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

https://echa.europa.eu/web/guest/regulations/appeals