EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	17 October 2022
Case	A-009-2022
Appellants	Nouryon Functional Chemicals B.V., the Netherlands ARKEMA GmbH, Germany PERGAN Hilfsstoffe für industrielle Prozesse GmbH, Germany United Initiators GmbH, Germany
Appeal received on	8 September 2022
Subject matter	A decision taken by the European Chemicals Agency ('the Agency') pursuant to Article 41 of the REACH Regulation[2]
Keywords	*Dossier evaluation – Compliance check – Section 8.7.3. of Annex IX – Error of assessment – Legal certainty – Legitimate expectations – Principle of proportionality – Powers of the Agency*
Contested Decision	CCH-D-2114597796-22-01/F
Language of the case	English

Background and remedy sought by the Appellants

On 8 June 2022, the Agency adopted the Contested Decision following the compliance check of the Appellants' registration dossiers for Di-tert-butyl 1,1,4,4-tetramethyltetramethylene diperoxide (the **Substance**)[3].

According to the Contested Decision, the Appellants are required to submit information on several studies, including an extended one-generation reproductive toxicity study (**EOGRTS**; Column 1 of Section 8.7.3. of Annex IX; test method: OECD TG 443) to be performed on rats, by the oral route, with the following specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce systemic toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;
- Cohorts 2A and 2B (Developmental neurotoxicity); and
- Investigations on learning and memory function as described in paragraph 37 of the OECD TG 426.

[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 201-128-1.

The Appellants request the Board of Appeal to annul the Contested Decision insofar as it requires information on the EOGRTS.

They also request the Board of Appeal to order the Agency to refund the appeal fee and take such other or further measures as justice may require.

Pleas in law and main arguments

In support of their appeal the Appellants raise the following pleas in law. According to the Appellants, the Agency:

– made errors of assessment;
– failed to take into account all available and relevant information;
– breached the principles of legal certainty and legitimate expectations;
– breached Section 8.7.3. of Annex IX;
– breached Articles 41 and 25;
– breached the principle of proportionality; and
– exceeded its competence.

The Appellants support their pleas in law with the following main arguments.

First, the Appellants argue that the Agency erred in its assessment and failed to take all available and relevant information into account (i) in concluding that the available studies would indicate a need to conduct the EOGRTS, and (ii) by requesting additional investigations of developmental neurotoxity and learning and memory function.

According to the Appellants, the Agency erred:

- in considering that the available studies would indicate such adverse effects that lead to the need to investigate further the potential reproductive toxicity effects of the Substance;
- in concluding that the findings from the available studies would constitute such concern for thyroid related mode of action that triggers the need for additional cohorts 2A and 2B to investigate the developmental neurotoxicity; and
- in basing its request for investigations on learning and memory function on studies which are subject to several scientific and technical limitations.

Second, the Appellants argue that the Agency breached Section 8.7.3. of Annex IX, the principle of proportionality and Article 25 as it (i) failed to examine the necessity of both the EOGRTS and the additional cohorts 2A and 2B, and (ii) disregarded the alternative tiered approach proposed by the Appellants. According to the Appellants, the Agency may request an EOGRTS under Section 8.7.3. of Annex IX only after examining whether such study is necessary and the most appropriate one to investigate the potential reproductive toxicity properties of the respective substance.

The Appellants also argue that the Agency breached the principles of legal certainty and legitimate expectations as it deviated from its own guidance documents with regard to the triggers for the EOGRTS and the additional cohorts 2A and 2B.

The Appellants further argue that the Agency exceeded its competence and breached Section 8.7.3. of Annex IX and Article 41 by requesting investigations on learning and memory function. According to the Appellants, the Agency was not empowered to request these investigations as part of the EOGRTS because possibility for such extension is not provided for in Section 8.7.3. of Annex IX.

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