EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	3 November 2020
Case	A-009-2020
Appellant	Polynt S.p.A., Italy
Appeal received on	28 September 2020
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 42(1) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	*Dossier evaluation – Follow-up to a compliance check – Cease of manufacture – Legal certainty – Proportionality*
Contested Decision	CCH-D-2114512482-58-01/F
Language of the case	English

Background

On 18 December 2017, pursuant to Article 41 of the REACH Regulation, the Agency adopted a decision following a compliance check of the Appellant's dossier for the substance esterification products of 1,3-dioxo-2-benzofuran-5-carboxylic acid with nonan-1-ol (ECHA List number 941-303-6; the 'Substance'). In that decision, the Agency requested the Appellant to update its registration dossier. Amongst others, the Agency requested information on a sub-chronic toxicity study (90-day), oral route (Section 8.6.2. of Annex IX to the REACH Regulation, test method: OECD test guideline 408).

On 3 January 2019, the Appellant updated its registration dossier. The Appellant sought to fulfil the information requirement for a 90-day sub-chronic toxicity study by a read-across adaptation. On 3 May 2019, the Appellant informed the Agency that it had ceased manufacture the Substance.

On 30 June 2020, after the follow-up evaluation of the Appellant's dossier update pursuant to Article 42(1) of the REACH Regulation, the Agency adopted the Contested Decision, by which it rejected the Appellant's read-across adaptation. The Agency concluded that the Appellant's registration dossier still does not comply with Section 8.6.2. of Annex IX to the REACH Regulation and reiterated that the Appellant is required to submit information on the 90-day sub-chronic toxicity study.

The Contested Decision states that '*the respective Member State competent authority (MSCA) and National enforcement authority (NEA) will be informed of this decision. They may consider*

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enforcement actions to secure the implementation of [the compliance check decision of 18 December 2017] and exercise the powers reserved to them under Article 126 of Regulation No 1907/2006 (penalties for non-compliance) for the period during which the registration dossier was not compliant'.

Remedy sought by the Appellant

The Appellant requests that the Board of Appeal annuls the Contested Decision and orders the Agency to pay the costs of the appeal proceedings.

Pleas in law and main arguments

The Appellant argues that the Agency breached Articles 42(1) and 50 of the REACH Regulation as it continued with the follow-up evaluation decision-making procedure and adopted the Contested Decision after the Appellant had informed the Agency that it ceased to manufacture the Substance in accordance with Article 50(2) of the REACH Regulation.

The Appellant claims that the Agency may not request any further information if the registrant of a substance has ceased manufacture or import in accordance with Article 50(2) or (3) of the REACH Regulation. This applies to any compliance check procedure under Article 41 of the REACH Regulation. The Appellant argues that, by considering that the Appellant could not rely on Article 50(2) of the REACH Regulation during the follow-up evaluation of its dossier update under Article 42(1) of the REACH Regulation, the Agency breached the principle of legal certainty and the principle of legitimate expectations.

The Appellant argues that the Agency breached the principle of proportionality as it addressed the Contested Decision to the Appellant instead of the other registrant that had not ceased manufacture the Substance. Furthermore, the disadvantages caused to the Appellant by the possible enforcement actions of the national enforcement authority are disproportionate.

The Appellant argues that the Agency breached the principle of good administration as it failed to provide the Appellant an opportunity to be effectively heard on the interpretation of the Article 50(2) of the REACH Regulation.

The Appellant also argues that the Agency made an error of assessment as it failed to examine carefully and impartially all the relevant information that the Appellant submitted in its read-across adaptation on 3 January 2019.

Finally, the Appellant argues that the Substance is no longer manufactured in the European Union. By requiring that the Appellant submits further information on the Substance, the Agency therefore breached Articles 5 and 6 of the REACH Regulation.

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