EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 12 JANUARY 2021 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case A-007-2019

(Substance evaluation – Error of assessment – Potential risk – Improved risk management measures – Proportionality – Article 25)

Factual background

The appeal concerned a decision of the European Chemicals Agency (the 'Agency') on the substance evaluation of ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate (EC No 700-242-3, CAS No 62037-80-3; the 'Substance').

In a carcinogenicity study in rats with the Substance, tumours were observed in the liver, in the pancreas and in Leydig cells. Based on the results of that study, the Agency concluded that there is a concern for carcinogenicity.

To clarify the concern, the Agency requested the Appellant to provide information on a carcinogenicity study in mice (OECD test guideline 451). The Appellant requested the Board of Appeal to annul that request.

Main findings of the Board of Appeal

In its Decision of 12 January 2021, the Board of Appeal dismissed the appeal.

The Board of Appeal rejected the Appellant's claim that the Agency made an error of assessment in concluding that there is a carcinogenicity concern based on the available information on the Substance. In particular, the Board of Appeal rejected the Appellant's claim that the tumours observed in the carcinogenicity study in rats are not relevant to humans because, according to the Appellant, those effects were induced by the peroxisome proliferator-activated receptor alpha ('PPARα') mode of action.

According to the CLP Regulation[1], substances which have induced tumours in studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumour formation is not relevant for humans.

It was undisputed between the parties that liver tumours in rodents caused solely by the PPARα mode of action are not relevant to humans. However, the Appellant did not demonstrate that the PPARα mode of action was the only mode of action responsible for the tumour formation in the carcinogenicity study in rats.

In addition, the Appellant did not demonstrate that the tumours in the pancreas and in Leydig cells observed in the carcinogenicity study in rats were caused by the PPARα mode of action. The Board of Appeal added that, even if the tumours in the pancreas and in Leydig cells were caused via the PPARα mode of action and this is not relevant to humans, the Appellant had not demonstrated that the PPARα mode of action is the sole mode of action linked to the formation of those tumours.

[1] Section 3.6.1.1. of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

The Board of Appeal rejected the Appellant's claim that the Agency made an error of assessment in concluding that there are similarities between the Substance and another substance capable of justifying a concern for carcinogenicity. The information on the other substance was used to support the Agency's argument that there may be more than one mode of action responsible for the tumours in the carcinogenicity study in rats and that the results from that study may be relevant to humans. The Board of Appeal added that the potential exposure to the Substance for the environment, the general population and workers, coupled with the results of the carcinogenicity study in rats, were sufficient to demonstrate a potential risk and justify the request for the carcinogenicity study in mice.

The Board of Appeal also rejected the Appellant's claim that the Agency committed an error of assessment in concluding that the requested information could lead to improved risk management measures. According to the CLP Regulation, since there is currently one carcinogenicity study on the Substance, the Agency has '*limited evidence*' only regarding the carcinogenic potential of the Substance. To have '*sufficient evidence of carcinogenicity*', and therefore the possibility to classify the Substance as a Category 1B carcinogen, there would need to be, at least, two studies.

Under Article 57(a) of the REACH Regulation, if the results of the carcinogenicity study in mice, coupled with the existing evidence, lead to a classification of the Substance as a Category 1B carcinogen, the Substance may subsequently be included in Annex XIV of the REACH Regulation ('*List of substances subject to authorisation*'). Substances included in Annex XIV may be subject to the authorisation process leading to controls on their use and eventually they may be phased out.

In addition, prior to inclusion in Annex XIV, the Substance would need to be included on the candidate list of substances of very high concern under Article 59 of the REACH Regulation. The identification of a substance as being of very high concern serves to improve information for the public and professionals as to the risks incurred. Consequently, such identification is a means of enhancing the protection of human health and the environment. Inclusion on the candidate list is therefore an improved risk management measure in itself.

The Board of Appeal rejected the Appellant's claims that the Agency breached Article 25 of the REACH Regulation regarding animal testing as a last resort and the principle of proportionality. In particular, the Agency had clearly considered alternatives to animal testing and the Appellant did not demonstrate that there are less onerous alternatives available which can clarify the carcinogenicity concern and that would avoid animal testing.

Following the Board of Appeal's Decision, the Appellant is required to provide the carcinogenicity study in mice by 21 October 2024.

NOTE: The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 91(1) of the REACH Regulation and Article 77(1) of the Biocidal Products Regulation. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.

Unofficial document, not binding on the Board of Appeal

The full text of the decision is available on the Board of Appeal's section of ECHA's website: http://echa.europa.eu/about-us/who-we-are/board-of-appeal