EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 10 MAY 2022 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case A-002-2021

(Substance evaluation – Error of assessment – Good administration – Proportionality)

Factual background

The appeal concerned a decision on the substance evaluation of diuron (EC number 206-354-4; CAS number 330-54-1).

On 10 June 2016, the Agency adopted a substance evaluation decision on diuron requesting the Appellants to provide information on a Fish Sexual Development Test ('FSDT'; test method: OECD test guideline ('TG') 234) due to a concern regarding endocrine disruption in the environment (the 'first substance evaluation decision').

Following an evaluation of the information submitted by the Appellants in response to the first substance evaluation decision, the evaluating Member State Competent Authority (the 'eMSCA') considered that there was insufficient information to conclude that diuron is not an endocrine disruptor due to the (anti)androgenic and (anti)estrogenic ('EA') modes of action. In addition, the eMSCA concluded that there was a concern related to the thyroid mode of action.

To address those concerns, on 26 October 2020, the Agency adopted the Contested Decision requesting the Appellants to provide information on a Larval Amphibian Growth and Development Assay ('LAGDA'; OECD TG 241).

The Appellants requested the Board of Appeal to annul the Contested Decision.

Main findings

In its decision of 10 May 2022, the Board of Appeal confirmed that the Agency is required to take into consideration all the relevant factors and circumstances of the case at issue.

Although, the Agency may fix cut-off points for the submission of new information in a decision-making procedure, it must nonetheless take into account any substantial new information that arises after that cut-off point. The Board of Appeal also confirmed that the Agency is required to take into account all substantial new information during a decision-making procedure irrespective of the means used to bring that information to its attention. However, the means of transmission chosen must ensure that the Agency is informed in a clear and comprehensive way. Substantial new information could therefore be submitted by a registrant in the form of a dossier update.

The Board of Appeal, however, rejected the Appellants' claim that the Agency made an error of assessment and breached the right to good administration in the present case by failing to take into account certain information that was published during the decision-making procedure. In particular, the Board of Appeal noted that the Appellants did not submit to the Agency any substantial new information during the decision-making procedure. Furthermore, the Agency and the eMSCA were not required to monitor the availability of new scientific publications relevant to the substance evaluation in question.

The Board of Appeal also rejected the Appellants' claim that the Agency disregarded in its assessment the suitability of the LAGDA for examining the thyroid mode of action. This was considered by the Agency in the Contested Decision. Furthermore, the LAGDA was adopted by the OECD and is included in the Test Methods Regulation[1]. According to the LAGDA, as included in the Test Methods Regulation, that test method is capable of examining the concern related to the thyroid mode of action. The Board of Appeal is not competent to decide on the legality of the Test Methods Regulation, which is a Commission regulation.

In its decision, the Board of Appeal decided that the Agency breached the principle of proportionality by failing to demonstrate that the requested information is necessary to examine the endocrine disruption concern related to the EA modes of action. The Board of Appeal found that the Agency had failed to demonstrate that, based on the available information, there is a potential hazard and therefore a potential risk, related to the EA modes of action. Specifically, the results of the FSDT submitted by the Appellants in response to the first substance evaluation decision did not demonstrate any endocrine disruption mediated adverse effects. Furthermore, the Agency did not present any evidence which would suffice on its own to contradict the FSDT findings and maintain the concern. The Contested Decision was therefore annulled in so far as it concluded that there is a concern related to the EA modes of action.

The Board of Appeal would have been competent to replace the Contested Decision with a decision seeking to clarify the concern related to the thyroid mode of action, which was the other mode of action identified in the Contested Decision. However, before replacing an Agency decision, the Board of Appeal must examine whether the available evidence allows it to do so. The Board of Appeal must also bear in mind the procedure for adopting Agency decisions under the substance evaluation process, and in particular the role of the various actors in that process.

In the present case, the Appellants agreed that it is necessary to clarify the concern related to endocrine disruption in the environment through the thyroid mode of action. However, the Appellants argued that the LAGDA is not appropriate to clarify that concern.

The Board of Appeal noted that the appropriateness of the LAGDA to meet the objectives of the Contested Decision had been assessed on the basis of potential hazards related to the EA modes of action and the thyroid mode of action. The possibility of requesting the LAGDA to clarify the thyroid mode of action only had not been examined in the process leading to the adoption of the Contested Decision. More specifically, the Agency had not assessed the relevance and appropriateness of alternative testing methods to the LAGDA in assessing only the thyroid mode of action.

Therefore, considering the procedure for adopting Agency decisions under the substance evaluation process, and in particular the role of the various actors in that procedure, the Board of Appeal decided that the case must be remitted to the Agency for further action.

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[1] Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 142, 31.5.2008, p. 1).