EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 25 SEPTEMBER 2018 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-007-2017

(Substance evaluation – Dossier Evaluation – Compliance check – Choice of procedure – Procedural rights – Extended one-generation reproductive toxicity study (EOGRTS))

Factual background

The appeal concerns an ECHA decision on the substance evaluation of 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol (EC No 204-279-1, CAS No 118-82-1; the 'Substance'). The Appellant requests the annulment of the Contested Decision in so far as it requires the Appellant to provide information on an extended one-generation reproductive toxicity study (OECD TG 443; 'EOGRTS').

The Appellant had registered the Substance at the 10 to 100 tonnes per year tonnage band. For registration purposes it is therefore subject to the requirements of Annexes VI to VIII to the REACH Regulation. The Contested Decision was also addressed to companies that had registered the Substance at the 100 to 1 000 tonnes per year tonnage band. For registration purposes those companies are therefore subject to the requirements of Annexes VI to IX to the REACH Regulation.

Main findings of the Board of Appeal

The Board of Appeal found that, pursuant to Annexes VIII and IX to the REACH Regulation, the EOGRTS in the form set out in the Contested Decision may be a registration requirement for all addressees of the Contested Decision. Pursuant to Article 41 of the REACH Regulation, that study could therefore be required by the Agency following a compliance check from all, some, or none of the registrants of the Substance. In this case, however, the Agency requested the study under substance evaluation. All addressees of a substance evaluation decision are required to pay a share of the costs incurred in complying with that decision.

The Board of Appeal found that when requesting standard information for registration purposes under the substance evaluation procedure, rather than the compliance check procedure, the Agency must be able to demonstrate, amongst other things, that the rights of all registrants of the substance concerned are not prejudiced by the Agency's choice of procedure.

In the present case, if the Agency had requested an EOGRTS under the compliance check procedure pursuant to Annex IX from those registrants registering the Substance at 100 to 1 000 tonnes per year only, the registrant at 10 to 100 tonnes per year tonnage band would not have been required to pay a share of the costs related to the performance of that study. As a result, the rights of the Appellant had been prejudiced by the Agency's decision to request the EOGRTS under substance evaluation rather than following a compliance check. Under the Contested Decision the Appellant could be required to pay a share of the costs of the EOGRTS whilst it may not need that information for registration purposes.

However, registrants at the 10 to 100 tonnes per year tonnage band may, pursuant to Annex VIII, also be required to provide information on an EOGRTS for registration purposes. Registrants may propose performing an EOGRTS at the Annex VIII level, instead of a screening study (OECD TG 421 or 422), if there are '*serious concerns about the potential for adverse effects on fertility or development*'.

The Contested Decision does not contain any assessment of whether there were such '*serious concerns*'. In addition, there has been no compliance check of the registrants' registration dossiers at any time regarding this information requirement. It is therefore not known whether the EOGRTS should be provided under Annex VIII in the present case. As a result, if the substance evaluation decision was addressed only to the registrants at the 100 to 1 000 tonnes per year tonnage band their rights may also have been prejudiced.

Without knowing which of the registrants of the Substance are required to provide information on an EOGRTS for registration purposes, it is not known which of those registrants would be required to pay a share of the costs of the study in order to meet their registration obligations. The Agency did not therefore take into consideration all the relevant factors and circumstances of this particular case. As a result, the rights of some of the registrants may have been prejudiced by the Agency's decision to request the EOGRTS under substance evaluation rather than dossier evaluation. The requirement to perform an EOGRTS was therefore annulled and the case remitted to the Agency for further action.
