

**SUMMARY OF DECISION OF 25 SEPTEMBER 2018 OF THE BOARD OF APPEAL OF  
THE EUROPEAN CHEMICALS AGENCY****Case number: A-008-2017**

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

*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 Appellants request the annulment of the Contested Decision in so far as it requires them to provide information on an extended one-generation reproductive toxicity study (OECD TG 443; 'EOGRTS') and soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD TG 307). Alternatively, the Appellants request the annulment of the Contested Decision insofar as it requires additional testing parameters for both studies.

The Appellants had registered the Substance at the 100 to 1 000 tonnes per year tonnage band. For registration purposes they are therefore subject to the requirements of Annexes VI to IX to the REACH Regulation. The Contested Decision was also addressed to a company that had registered the Substance at the 10 to 100 tonnes per year tonnage band. For registration purposes that company is therefore subject to the requirements of Annexes VI to VIII 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 latter registrant 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 registrant at 10 to 100 tonnes per year tonnage band 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.

The Board of Appeal dismissed the appeal as regards the requirement to provide information on soil simulation testing. However, the Board of Appeal annulled the requirement to use 20 °C during the test for the identification of potential metabolites on the grounds that it was disproportionate. The Board of Appeal decided that the kinetic and metabolite identification parts of the soil simulation testing should both be performed at 12 °C.

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**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. 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.

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*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>*