EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 12 JULY 2016 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-009-2014

(Substance evaluation – Deviations from Test Guidelines)

Factual background

Following the substance evaluation of 1,1'-(ethane-1,2-diyl)bis[pentabromobenzene] (hereinafter the 'Substance') by the United Kingdom, the European Chemicals Agency (hereinafter the 'Agency') adopted a decision requesting certain registrants to provide additional information. In particular, the addressees of the Agency's Decision were requested to provide information on long-term toxicity to aquatic invertebrates, bioaccumulation in aquatic species, soil simulation, and sediment simulation.

In relation to long-term toxicity testing on aquatic invertebrates and bioaccumulation in aquatic species, the Agency's Decision (hereinafter the 'Contested Decision') requested information using the '*least pure form of the registered substance*'. In relation to soil simulation testing and sediment simulation testing, the Contested Decision required that the test material should be the '*purest form of the registered substance*' and should be radiolabelled.

The Appellants requested the Board of Appeal to either annul the Contested Decision or, amend the decision at least as to the deadline set for the dossier update.

Main findings of the Board of Appeal

In its Decision of 12 July 2016, the Board of Appeal dismissed the Appellants' arguments alleging that the Agency had made an error of assessment in finding that the structural similarity between the Substance and another substance (decaBDE) was relevant to assessing the concerns posed by the Substance. The Board of Appeal also dismissed the Appellants' plea that the Agency breached the duty to state reasons by not providing any justification for the statements in the Contested Decision related to the similarity of the Substance and decaBDE.

The Board of Appeal then examined the Appellants' arguments related to whether the Agency had identified grounds for concern in the Contested Decision which were sufficient to demonstrate the need for the information requested in the Contested Decision.

The Board of Appeal found that the structural similarity between the Substance and decaBDE is sufficient, coupled with the environmental exposure to the Substance, to demonstrate grounds for concern that the Substance may be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). The Board of Appeal found that the Agency had demonstrated the need for additional information from tests on long-term toxicity on aquatic invertebrates, bioaccumulation in aquatic species, soil simulation, and sediment simulation. The Appellants' claim was therefore dismissed.

The Board of Appeal also dismissed the Appellants' claim that information on long-term toxicity on aquatic vertebrates should have been addressed under the compliance check procedure rather than through substance evaluation. In reaching its finding the Board of Appeal

highlighted in particular that the information requested in the Contested Decision is relevant for all addressees of the Contested Decision. In addition, the Board of Appeal found that the concerns being investigated in this case are typical of those which should be investigated pursuant to substance evaluation as the Contested Decision is examining environmental effects holistically through the use of modified testing requirements.

The Board of Appeal found however that the Agency had failed to demonstrate the necessity of a request for information on vitellogenin induction. In particular, the Board of Appeal found that the study relied on by the Agency to justify this request provides, on its own, weak evidence of a concern and that the Agency had not provided any other justifications for this information request. As a result, the Board of Appeal found that, in relation to vitellogenin induction, the Agency had failed to demonstrate the necessity of the requested measure by setting out the '*grounds for considering that a substance constitutes a risk to human health or the environment*'. The Board of Appeal therefore found that the request for information on vitellogenin induction should be annulled and removed from the Contested Decision.

In relation to the requirements to provide information using the '*least pure form of the registered substance*' and the '*purest form of the registered substance*', the Board of Appeal found that, in the interests of legal certainty, the wording of the Contested Decision should be amended to clarify that only the compositions of the Substance registered by the addressees of that Decision should be subject to the testing required in the Contested Decision.

The Board of Appeal also found that the Agency failed, in light of the high level of purity of the Substance as registered by the addressees of the Contested Decision, to adequately state reasons as to why tests should be performed on the purest or least pure form of the Substance. The Board of Appeal therefore decided that all references to the purest or least pure form of the Substance shall be removed from the Contested Decision and that tests should be conducted on representative samples of the Substance as registered by the addressees of the Contested Decision.

In their appeal the Appellants also claimed that the soil simulation testing (modified OECD Test Guideline 307) and sediment simulation testing (modified OECD Test Guideline 308) requested in the Contested Decision would not have a realistic possibility of delivering the required information. The Appellants also argued that the requested tests are not expressed sufficiently clearly in the Contested Decision to allow the Appellants to know what is required to ensure compliance. These claims were however dismissed by the Board of Appeal. In particular, the Board of Appeal found that the Agency was in this case justified in deviating from some of the requirements of the OECD Test Guidelines. The Board of Appeal also found that, although the Contested Decision lacked clarity on certain aspects of the requested tests, this lack of clarity was not sufficient to justify an annulment of the Contested Decision.
