EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 9 SEPTEMBER 2015 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-004-2014

(Substance evaluation - UVCB – Misuse of power - Proportionality - Equal treatment)

Factual background

Following the substance evaluation of medium-chain chlorinated paraffins (hereinafter the 'Substance' or 'MCCP') by the United Kingdom competent authority (hereinafter the evaluating Member State Competent Authority' or 'eMSCA'), the European Chemicals Agency (hereinafter the 'Agency') adopted a decision requesting additional information from the Appellants[1] in order to clarify *inter alia* whether the Substance is persistent, bioaccumulative and toxic (hereinafter 'PBT'). The Appellants requested the Board of Appeal to set aside the Contested Decision.

Main findings of the Board of Appeal

In its Decision of 9 September 2015, the Board of Appeal observed that the Substance, as registered by the Appellants, contains many constituents with varying chlorine content and with a range of carbon chain lengths. The Board of Appeal also noted that the substance evaluation identified several carbon chain length and chlorine content combinations present in the Substance that potentially meet the PBT screening criteria (hereinafter the 'potentially PBT combinations'). It was therefore appropriate to generate further information to clarify this PBT concern. Taking into account that the Substance is a complex UVCB and that no single representative test material for all compositions of the Substance exists, the Board of Appeal found that it was appropriate in the present case to follow a 'constituents-based fractionation testing approach'. This approach is to conduct testing on test materials that are broadly representative of the potentially PBT combinations on the basis of likely physico-chemical properties, whilst recognising that the test materials themselves are not commercial products. The Board of Appeal noted in this respect that the approach followed by the Agency is not novel for the assessment of this type of substance and that the Appellants themselves cite data in their registrations for test materials with specific chain lengths and chlorination levels. The Board of Appeal also found that the Agency did not exceed its margin of appreciation when defining the test materials in the present case and did not misuse its powers.

In addition, the Board of Appeal rejected the Appellants' claim that the Agency was bound by law and previous practice to request testing on constituents only if the constituent in question exceeds 0.1% w/w. In light of the objectives of the REACH Regulation regarding the protection of human health and the environment, the importance of identifying substances with PBT properties, and the complex composition of the Substance, the Board of Appeal agreed with the Agency that, in the case at issue, the additivity of the effects related to the PBT properties of similar isomers of the Substance justify considering the sum of isomers within a specified carbon chain length and chlorine content as being a relevant

[1] The nine Appellants are: Altair Chimica SpA, Caffaro Industrie SpA, Fortischem a.s., Ineos Chlorvinyls Limited, Ineos Enterprises France Z.I., Kaustik Europe B.V., Leuna-Tenside GmbH, Prakash Chemicals Europe B.V., Química del Cinca, S.L.

concentration for PBT assessment. The Board of Appeal also found that the approach followed in the present case is consistent with the Agency Guidance on Information Requirements and Chemical Safety Assessment.

In relation to the Appellants' pleas regarding tests requested in the Contested Decision, the Board of Appeal found that the Appellants' arguments demonstrate a difference of scientific opinion between them and the Agency but do not demonstrate an error of assessment on the part of the Agency. The Board of Appeal found that it is apparent from the draft substance evaluation report, the Contested Decision and the other written submissions in this case that the eMSCA and the Agency examined, carefully and impartially, and took into consideration, all relevant information on the Substance. This included, importantly, the comments submitted by the Appellants during the substance evaluation procedure. Furthermore, the Board of Appeal found that the detailed scientific assessment, reasoning, and conclusions given by the eMSCA and the Agency were well founded, justified and address the arguments put forward by the Appellants. The Board of Appeal also found that the testing requested and the test materials chosen by the Agency in the Contested Decision were proportionate.

The Board of Appeal also rejected the Appellants' claim that registrants who submitted registration dossiers after the draft decision was notified to the MCCP registrants for their comments should have also been addressees of the Contested Decision. The Board of Appeal observed that the interpretation suggested by the Appellants would lead to discrimination against these new registrants, who would not have had the same opportunity to exercise their rights of defence and to participate on an equal footing in the substance evaluation procedure. In addition, the Board of Appeal noted that the interpretation suggested by the Appellants could lead to an endless loop whereby the whole substance evaluation procedure would restart each time a new dossier is submitted during the period between the preparation of the draft decision and the adoption of the final decision. The Board of Appeal considered that none of the above situations could have been the intention of the legislator as they would raise concerns regarding equality, due process, legal certainty and jeopardise the achievement of the primary objectives of the REACH Regulation. The Board of Appeal concluded that, in addressing the Contested Decision only to the registrants with active registrations at the time the draft decision was notified, the Agency did not breach the principle of equal treatment.

The Board of Appeal also dismissed the other pleas put forward by the Appellants which concerned *inter alia* the breach of animal welfare requirements and the principle of good administration.

In consideration of all the above, the Board of Appeal dismissed the appeal in its entirety. Having regards to the suspensive effect of appeals, the Appellants were requested to submit the information required in the Contested Decision within three years from the date of the notification of the Board of Appeal's decision in the present case.

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.
