EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 14 FEBRUARY 2023
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-012-2021

(Dossier evaluation – Compliance check – Column 2 of Section 9.2. of Annex VIII – PBT/vPvB assessment – Annex XIII)

Factual background

The appeal concerns a compliance check of the registration for the substance reaction mass of 2,6-Bis[(dimethylamino)methyl]-4-(1-{3-[(dimethylamino)methyl]-4-hydroxyphenyl}-1-methylethyl)phenol and 4-(1-{3,5-Bis[(dimenthylamino)methyl]-4-hydroxyphenyl}-1-methylethyl)-2,6-bis[(dimethylamino)methyl]phenol.[1]

By the Contested Decision, the Agency required the Appellant to submit information on water, soil and sediment simulation testing and the identification of degradation products. That information was requested on the basis of Column 2 of Section 9.2. of Annex VIII. At the time the Contested Decision was adopted – i.e. on 26 August 2021 – that provision provided that *'further degradation testing shall be considered if the [CSA] according to Annex I indicates the need to investigate further the degradation of the substance'.*

The Contested Decision also requested the Appellant to provide information on bioaccumulation in aquatic species on the basis of Sections 0.6.1. and 4. of Annex I and Section 2.1. of Annex XIII.

Main findings of the Board of Appeal

Request for information on bioaccumulation in aquatic species

The Board of Appeal annulled the requirement in the Contested Decision to provide information on bioaccumulation in aquatic species.

The Board of Appeal found that, based on the version of the REACH Regulation applicable at the time the Contested Decision was adopted, i.e. on 26 August 2021, the Agency was not competent to request that information in a compliance check decision from registrants at the 10 to 100 tonnes per year tonnage band (Annex VIII level), such as the Appellant.

Requests for information on degradation

The Board of Appeal dismissed the appeal in so far as it concerned the requests to provide information on the three degradation simulation studies and the identification of degradation products.

[1] EC number 947-794-3 (the **Substance**).

The Board of Appeal found that the Agency had demonstrated in the Contested Decision that there is a need to further investigate degradation within the meaning of Column 2 of Section 9.2. of Annex VIII. A decision, based on the available information, that a substance is a potential persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substance justifies a request for additional information on degradation under Column 2 of Section 9.2. of Annex VIII.

The Board of Appeal found that, in the present case, the Agency did not commit an error in deciding that the Substance is a potential PBT or vPvB substance. Specifically, the Agency did not commit an error in deciding that additional information is required to conclude whether the Substance has persistent (P) or very persistent (vP) properties. In this respect, the Board of Appeal found that the Appellant's conclusion that the Substance is vP, based solely on screening studies, does not constitute a PBT and vPvB assessment as set out in Annex XIII.

The Board of Appeal also found that the Agency did not commit an error in deciding that the Substance may have bioaccumulative (B) or very bioaccumulative (vB) properties based on the Substance's ionisation and surface-active properties.

The Board of Appeal rejected the Appellant's argument that, since there is negligible release of the Substance into the environment and there is no risk posed by the Substance, no additional information is required on degradation under Column 2 of Section 9.2. of Annex VIII. A conclusion on whether a substance is a PBT or vPvB substance is required irrespective of the exposure based on its current uses. This is supported by Section 4.0.1. of Annex I.

The Board of Appeal found that under a compliance check verifying compliance with the information requirements in Annexes VII to X, the Agency verifies whether a registration dossier includes information on the intrinsic properties of a substance and is not obliged to assess the risks posed by that substance. As a general rule, the Agency is not obliged to take into account information on exposure and risk, unless exceptions are provided for in the REACH Regulation. The Board of Appeal found that Column 2 of Section 9.2. of Annex VIII is not such an exception obliging the Agency to take information on exposure and risk into account.

The Board of Appeal also found that the Agency may request information on the identification of degradation products under Column 2 of Section 9.2. of Annex VIII. That provision refers to the need to investigate further the degradation of a substance which includes the process of degradation and the identification of the degradation products of that substance. In addition, degradation testing includes the identification of degradation products. In this respect, the degradation simulation studies requested in the Contested Decision all allow for the identification of degradation or transformation products.
