ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 27 SEPTEMBER 2022
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-005-2021

(Dossier evaluation – Compliance check – Section 9.2. of Annex IX to the REACH Regulation – Identification of degradation products)

Factual background

This appeal concerned a compliance check of the registration for the substance N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide).[1]

The Appellant's registration dossier contained adaptations to omit the degradation simulation testing required under Section 9.2.1. of Annex IX to the REACH Regulation.[2] The Appellant also sought to omit the requirement to provide information on the identification of degradation products under Section 9.2.3. of Annex IX on the basis of an adaptation under Column 2 of Section 9.2. of Annex IX.

By the Contested Decision, the Agency required the Appellant to submit information on, amongst other things, the identification of degradation products (Section 9.2.3. of Annex IX), using an appropriate test method. The Contested Decision recommends the use of OECD test guideline 308. The Agency rejected in the Contested Decision the Appellant's adaptation under Column 2 of Section 9.2. of Annex IX.

Main findings of the Board of Appeal

In its Decision of 27 September 2022, the Board of Appeal upheld the appeal and annulled the requirement in the Contested Decision to provide information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX.

The Board of Appeal found that the degradation simulation studies and the identification of degradation products required under Column 1 of Section 9.2. of Annex IX are standard information requirements.

The obligation for registrants to fulfil the information requirements under Column 1 of Section 9.2. of Annex IX does not depend upon an assessment, under Column 2 of Section 9.2. of Annex IX[3], of whether the chemical safety assessment (CSA) indicates a need for that information. An assessment of the CSA is necessary only for the purposes of deciding whether a registrant is required to submit information on biotic degradation testing, which is further or additional to the standard information requirements under Column 1 of Section 9.2. of Annex IX.

[1] EC No 251-118-6; CAS No 32588-76-4.

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1). All references to Articles or Annexes hereinafter concern the REACH Regulation unless stated otherwise.

[3] Column 2 of Section 9.2. of Annex IX provides: '*Further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. […]*'.

Consequently, contrary to the Appellant's arguments, the Agency did not act *ultra vires* in requesting in the Contested Decision information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX.

However, the Board of Appeal accepted the Appellant's argument that the Agency misinterpreted and misapplied Column 1 of Section 9.2.3. of Annex IX by requesting information on the identification of degradation products on its own through *any* study it considered appropriate.

The Board of Appeal found that the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX, as a standard information requirement, is dependent on the degradation testing required under Annexes VII to IX.

To comply with Column 1 of Section 9.2.3. of Annex IX, a registrant must provide (i) information on the identification of the degradation products resulting from the standard information requirements on degradation set out in Column 1 of Section 9.2.1. of Annex IX and in Column 1 of Section 9.2.2.1. of Annex VIII, or (ii) an acceptable adaptation under Column 2 of the corresponding provisions or Annex XI.

In the present case, the Appellant had not provided in its registration dossier information on the degradation simulation studies required under Column 1 of Sections 9.2.1. of Annex IX, or the study on hydrolysis required in Column 1 of Section 9.2.2.1. of Annex VIII. Instead, the Appellant relied on the specific adaptations in Column 2 of Annexes VIII and IX to omit those information requirements.

The Board of Appeal found that the Agency is required to examine the validity of the adaptations submitted by the Appellant before deciding whether it can request the Appellant to provide information on those standard information requirements and, therefore, information on the identification of degradation products formed in those studies under Column 1 of Section 9.2.3. of Annex IX.

In the present case, the Agency did not examine whether the Appellant's adaptations under Section 9.2.2.1. of Annex VIII or Section 9.2.1. of Annex IX were acceptable. It was therefore not possible to determine whether there is a data-gap for those endpoints. Only if the adaptations submitted by the Appellant were deemed by the Agency to be inadequate could the Agency require the Appellant to provide, as standard information, one or more of those studies and information on the identification of the degradation products formed in those studies. Therefore, the scope of the information to be provided under Column 1 of Section 9.2.3. of Annex IX had not been determined.

The Board of Appeal therefore annulled the Contested Decision insofar as it requires information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX and remitted the case to the competent body of the Agency for further action.
