ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 6 JUNE 2023
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-001-2022

Dossier evaluation – Compliance check – Competence of the Agency – Error of assessment – Compliance with the relevant test methods – Article 13 – In vitro gene mutation in bacteria – In vitro cytogenicity in mammalian cells – In vitro micronucleus study – Long-term aquatic toxicity testing on fish – Degradation simulation testing in surface water, soil and sediment – Non-extractable residues – Identification of degradation products)

1. Factual background

The appeal concerns a compliance check of the registration for the substance 4,4'-(9H-fluoren-9-ylidene)bis(2-chloroaniline).[1]

By the Contested Decision, the Agency required the Appellant to submit information on:

(i) *In vitro* gene mutation study in bacteria (Section 8.4.1. of Annex VII to the REACH Regulation[2], test method: EU B.13/14 / OECD TG 471) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 (**Information Requirement 1**),

(ii) *In vitro* cytogenicity study in mammalian cells (Section 8.4.2. of Annex VIII; OECD TG 473) or *in vitro* micronucleus study (Section 8.4.2. of Annex VIII; OECD TG 487) (**Information Requirement 2**),

(iii) Long-term toxicity testing on fish (Column 2 of Section 9.1.3. of Annex VIII and Section 9.1.6. of Annex IX; OECD TG 210) (**Information Requirement 3**),

(iv) Simulation testing on ultimate degradation in surface water (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.2. of Annex IX; test method: EU C.25 / OECD TG 309); non-extractable residues (**NERs**) must be quantified (**Information Requirement 4**),

(v) Soil simulation testing (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.3. of Annex IX; test method: EU C.23 / OECD TG 307); NERs must be quantified (**Information Requirement 5**),

(vi) Sediment simulation testing (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.4. of Annex IX; test method: EU C.24 / OECD TG 308; NERs must be quantified (**Information Requirement 6**), and

(vii) Identification of degradation products (Column 2 of Section 9.2. of Annex VIII and Section 9.2.3. of Annex IX; OECD TG 307 and/or 308 and/or 309) (**Information Requirement 7**).

The Appellant requested the Board of Appeal to annul each of those information requirements.

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[1] EC number 407-560-9 (the **Substance**).

[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.

2. Main findings of the Board of Appeal

2.1. Information Requirements 1 and 2

To fulfil Section 8.4.1. of Annex VII and Section 8.4.2. of Annex VIII, the Appellant included in its registration dossier the results of studies that had been carried out according to the version of the relevant test guidelines applicable at the time those studies were carried out.

In the Contested Decision, the Agency decided that there was a data gap in relation to those information requirements because the results of the studies submitted by the Appellant did not cover parameters added by subsequent amendments to the relevant test methods.

The Board of Appeal found that, to comply with the first subparagraph of Article 13(3), a registrant must respect the version of the relevant test method laid down in the Test Methods Regulation[3] that is applicable at the time it submitted its registration or updated its registration to the tonnage band under which the information requirement in question is required.

In relation to Section 8.4.1. of Annex VII and Section 8.4.2. of Annex VIII, the Board of Appeal concluded that the studies submitted by the Appellant were not carried out according to the version of the test guideline that was applicable at the time the Appellant was required to comply with those information requirements. Therefore, those studies were not carried out in accordance with the first subparagraph of Article 13(3).

The Board of Appeal then examined whether the information submitted by the Appellant could nonetheless be a valid source of information on the intrinsic properties of the Substance under the second subparagraph of Article 13(3).

In relation to Column 1 of Section 8.4.1. of Annex VII and Column 1 of Section 8.4.2. of Annex VIII, the Board of Appeal found that the information submitted by the Appellant was not sufficient to meet those standard information requirements for the purposes of the second subparagraph of Article 13(3), in conjunction with the requirements of Annex XI.

However, the Board of Appeal found that the Agency committed an error in rejecting the Appellant's adaptation under Column 2 of Section 8.4.2. of Annex VIII. Consequently, the Board of Appeal annulled Information Requirement 2.

2.2. Information Requirement 3

2.2.1. Requirement at the Annex VIII level

Under the version of the REACH Regulation applicable at the time the Contested Decision was adopted – i.e. on 25 October 2021 – Column 2 of Section 9.1.3. of Annex VIII provided that *'the long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble […].'*

It was not disputed that the Substance is poorly water soluble. However, the Appellant argued that the Agency committed an error in requesting that information. According to the Appellant, long-term toxicity testing on fish was not necessary due to the uses of the Substance and the fact that, in its opinion, a long-term study on invertebrates is the most appropriate study in the present case.

[3] Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 142, 31.5.2008, p. 1).

The Board of Appeal firstly found that there is no provision in the REACH Regulation allowing for the omission of aquatic toxicity testing on fish based on an available study, or studies, on invertebrates only.

The Board of Appeal also 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. The Agency is not, in general, obliged to take into account information on uses, 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 into account information on uses.

The Board of Appeal therefore concluded that the Appellant had not provided an adequate justification for not carrying out a long-term aquatic toxicity study on fish under Column 2 of Section 9.1.3. of Annex VIII despite the fact that the Substance is poorly water soluble.

2.2.2. Requirement at the Annex IX level

The Board of Appal noted that since the Agency did not commit an error in requiring the Appellant to provide information on a long-term aquatic toxicity study on fish under Column 2 of Section 9.1.3. of Annex VIII (see above), under Article 12(1)(c) and (d), registrants of the Substance at both the Annex VIII and Annex IX level are required to provide that information.

The Board of Appeal therefore found that, even if the Agency had made an error in requesting the information under Annex IX, the Appellant would still need to submit that information. Consequently, the Appellant's pleas related to the request for information under Column 1 of Section 9.1.6. of Annex IX were rejected by the Board of Appeal as ineffective.

2.3. Information Requirements 4 to 7

The Board of Appeal found that the Agency did not commit an error in requesting Information Requirements 4 to 7 from registrants of the Substance under Annex VIII and Annex IX.

2.3.1. Requirements at the Annex VIII level

The Board of Appeal found that the Agency did not err in concluding 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. Furthermore, the Agency did not commit an error in deciding that the Substance is a potential PBT or vPvB substance.

2.3.2. Requirements at the Annex IX level

The Board of Appeal found that the information requirements under Column 1 of Section 9.2. of Annex IX are standard information requirements which oblige registrants to provide, and allow the Agency to require, information on the degradation of the substance at issue .

Therefore, the requirement to submit the information on degradation at the Annex IX level is not dependent on a demonstration that there is a need for that information, for example because the substance in question is a potential PBT or vPvB substance. The information on degradation under Column 1 of Section 9.2. of Annex IX must be submitted unless the registrant submits an acceptable specific adaptation under Column 2 of the corresponding provision or an acceptable general adaptation under Annex XI.

In addition, the Agency did not commit an error in rejecting the Appellant's adaptation under Column 2 of Section 9.2.1.2 of Annex IX (Information Requirement 4).

2.3.3. Information on NERs

The Appellant also contested the requirement to provide information on the quantification of NERs in the degradation simulation studies.

In relation to the soil and sediment simulation testing, the Board of Appeal found that the Agency did not commit an error in requiring the quantification of NERs as that requirement is found in the relevant test methods set out in Test Methods Regulation.

However, in relation to the simulation testing on ultimate degradation in surface water, the Board of Appeal found that there is no requirement to provide information on NERs in the relevant test method set out in the Test Methods Regulation. Therefore, the Agency exceeded its competence in requesting that information.

Consequently, the Board of Appeal annulled the requirement to provide information on NERs in the simulation testing on ultimate degradation in surface water.

2.4. Conclusion on the appeal

The Board of Appeal dismissed the appeal in so far as it concerned Information Requirements 1, 3, 5, 6 and 7.

Information Requirement 2 was annulled in its entirety and Information Requirement 4 was partially annulled in so far is required the Appellant to provide information on NERs.

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.
