EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

14 December 2021

(Substance evaluation – Admissibility – Simulation testing on ultimate degradation in surface water – ^{14}C-radiolabelling)

Case number	A-007-2021
Language of the case	English
Appellant	Global Product Compliance (Europe) AB, Sweden
Intervener	Federale Overheidsdienst Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu, Belgium
Contested Decision	Decision of 15 February 2021 on the substance evaluation of N-[4-[9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl] acetamide, adopted by the European Chemicals Agency (the 'Agency') under Article 46 of 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; the 'REACH Regulation') The Contested Decision was notified to the Appellant under annotation number SEV-D-2114541764-45-01/F

THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman), Nikolaos Georgiadis (Technically Qualified Member and Rapporteur) and Ángel M. Moreno (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. This appeal concerns a request for further information pursuant to the evaluation of the substance N-[4-[9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl] acetamide (EC No 267-636-0, CAS No 67905-17-3; the 'Substance').

2. The Substance was included in the Community rolling action plan for substance evaluation in 2019 due to initial grounds for concern relating to its potential persistent, bioaccumulative and toxic ('PBT') or very persistent and very bioaccumulative ('vPvB') properties. The competent authority of Belgium, the Federale Overheidsdienst Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu (the 'eMSCA'), was appointed to carry out the evaluation in 2019.

3. On 13 March 2020, the eMSCA submitted to the Agency a draft decision. The draft decision required further information on the Substance in accordance with Articles 46(1) and 52(1) of the REACH Regulation (all references to Articles or Annexes hereinafter concern the REACH Regulation unless stated otherwise).

4. On 16 April 2020, the Agency notified the draft decision to the registrants of the Substance and invited them to comment in accordance with Article 50(1). The draft decision requested the registrants of the Substance to carry out simulation testing on ultimate degradation in surface water (OECD TG 309/EU C.25) or, should that test not be technically feasible, simulation testing in soil (OECD TG 307/EU C.23) on the Substance.

5. On 29 June 2020, the Appellant submitted comments on the draft decision.

6. On 29 October 2020, the draft decision, together with the Appellant's comments, was notified to the competent authorities of the Member States.

7. On 30 November 2020, the competent authorities of the Netherlands and of Finland made proposals for amendment in accordance with Articles 51(2) and 52(2). The competent authority of the Netherlands subsequently revised its proposal on 11 December 2020. In accordance with those proposals for amendment, the registrants of the Substance should be required, amongst other things, to carry out simulation testing on ultimate degradation in surface water (OECD TG 309/EU C.25) or, should that test not be technically feasible, simulation testing in sediment (OECD TG 308/EU C.24) on the Substance.

8. On 4 January 2021, the Appellant submitted comments on the proposals for amendment in accordance with Articles 51(5) and 52(2).

9. On 25 January 2021, the Member State Committee reached unanimous agreement.

10. On 15 February 2021, the Agency adopted the Contested Decision in accordance with Articles 51(6) and 52(2).

Contested Decision

11. According to the Contested Decision, it is necessary to determine whether the Substance, including its transformation and/or degradation products, is PBT or vPvB.

12. The Contested Decision therefore requires the registrants of the Substance, including the Appellant, to submit the following information by 21 November 2022:

    '*Simulation testing on ultimate degradation in surface water: Aerobic mineralisation in surface water – simulation biodegradation test, test method EU C.25./ OECD TG 309 […], on the Substance, specified as follows:*

- *a pelagic test using EU representative surface water with a suspended solids concentration of approximately 15 mg_{dw}/L (but not outside the range of 10 to 20 mg_{dw}/L);*
- *at a test temperature of 12°C;*
- *the test must also be performed with sterile control;*
- *using a concentration appropriate to also successfully identify and quantify possibly formed transformation and/or degradation products. Moreover test concentrations used must not exceed the solubility limit of the Substance in the test medium;*
- *concentration of the test substance must be measured at appropriate intervals during the study so that a reliable primary degradation half-life can be determined;*
- *transformation and/or degradation products must be identified and quantified at every sampling time at a concentration of ≥ 1% w/w, unless reasonably justified otherwise;*
- *transformation and/or degradation products of which concentrations are continuously increasing should also be considered;*
- *using the ^{14}C radiolabelled Substance with the radiolabel located in the most stable part of the molecule. However according to the OECD TG 309, the most stable part does not necessarily include the relevant functional moiety of the molecule (that can be related to a specific property such as toxicity, bioaccumulation, etc.). If this is the case, it may be appropriate to use a test substance, which is 14C-labelled, in the functional part in order to follow the elimination of the specific property;*
- *a mass balance must be provided;*
- *the total amount of non-extractable residues (NER) must be quantified and the reporting of results must include a scientific justification of the used extraction procedures and solvents.*

If it can be demonstrated by sound justification that simulation testing in surface water is not technically feasible (i.e.: impossible to analytically quantify the parent compound), the following test is required instead:

Sediment simulation testing; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/ OECD TG 308 […], on the Substance, specified as follows:

- *at a test temperature of 12°C;*
- *the test must also be performed with sterile control;*
- *under aerobic conditions;*
- *using a concentration appropriate to also successfully identify and quantify possibly formed transformation and/or degradation products;*
- *transformation and/or degradation products must be identified and quantified at every sampling time at a concentration of ≥ 1 % w/w, unless reasonably justified otherwise;*
- *transformation and/or degradation products of which concentrations are continuously increasing should also be considered;*
- *using the ^{14}C radiolabelled Substance with the radiolabel located in the most stable part of the molecule;*
- *a mass balance must also be provided;*

- *the total amount of non-extractable residues (NER) must be quantified and the reporting of results must include a scientific justification of the used extraction procedures and solvents.*

However if a high enough test concentration in water can be established to follow the degradation of parent compound (thus expected to allow the determination whether the degradation half-life of the parent compound exceeds the P (vP) criterion), the OECD TG 309 is still required, and cannot be replaced by performing [sic] OECD TG 308. The reason that the degradation products cannot be sufficiently investigated is not a valid argument for not performing a water simulation test.'

Procedure before the Board of Appeal

13. On 14 May 2021, the Appellant filed this appeal.

14. On 9 July 2021, Ángel M. Moreno, alternate member of the Board of Appeal, was designated to act as a legally qualified member of the Board of Appeal in this case, in accordance with the second subparagraph of Article 3(2) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; the 'Rules of Procedure').

15. On 19 July 2021, the Agency submitted its Defence.

16. On 3 September 2021, the eMSCA was granted leave to intervene in support of the Agency.

17. On 1 October 2021, the Intervener submitted its statement in intervention.

18. On 21 October 2021, the Agency and the Appellant submitted their respective observations on the statement in intervention.

19. On 27 October 2021, the Board of Appeal closed the written procedure. Neither of the Parties requested a hearing to be held in the present case and the Board of Appeal considered that a hearing was not necessary.

Forms of order sought

20. The Appellant requests the Board of Appeal to annul the Contested Decision and to confirm that the testing required by the Contested Decision should be carried out without radiolabelling.

21. The Agency requests the Board of Appeal to dismiss the appeal as inadmissible or, in any event, as unfounded.

Reasons

1. Admissibility of the appeal

Arguments of the Parties and the Intervener

22. The Agency, supported by the Intervener, objects to the admissibility of this appeal on the grounds that the Notice of Appeal does not contain any plea in law or arguments of fact or law, as required by Article 6(1)(e) of the Rules of Procedure.

Findings of the Board of Appeal

23. An appeal may be declared inadmissible if the appellant does not set out in a comprehensible manner the grounds of its appeal, that is to say the pleas in law and the arguments of fact or law on which it relies (see Case A-008-2020, *Sustainability Support Services (Europe)*, decision of the Board of Appeal of 7 September 2021, paragraph 28).

24. In the present case, the Notice of Appeal is laconic. However, it sets out the form of order sought by the Appellant and contains two comprehensible grounds on the basis of which the Appellant challenges the Contested Decision. In essence, the Appellant argues that:

- the Agency failed to take the Appellant's comments to the draft decision into account and to consider those comments objectively (first plea), and
- it is not necessary to use radiolabelling for the substance when carrying out the testing required by the Contested Decision (second plea).

25. The Agency's objection to the admissibility of the appeal must consequently be rejected.

2. Substance of the case

26. Each of the Appellant's pleas (see paragraph 24 above) will be examined in turn.

2.1. First plea: The Agency failed to take the Appellant's comments to the draft decision into account and to consider those comments objectively

Arguments of the Parties

27. The Appellant argues that the Agency did not consider objectively the supporting data it provided or its comments on the draft decision, thereby breaching Articles 46 and 50.

Findings of the Board of Appeal

28. The Agency must examine carefully and impartially all the relevant aspects of the individual case (see *Sustainability Support Services (Europe)*, cited in paragraph 23 above, paragraph 47 of the decision). It must also provide an adequate statement of reasons as to why the essential arguments put forward by a party cannot be upheld (Case A-013-2016, *BASF Personal Care and Nutrition*, decision of the Board of Appeal of 12 December 2017, paragraph 70).

29. The Contested Decision states that the Appellant's comments were taken into account (pp. 22-23) and provides the reasons why the Agency was not persuaded by those comments (pp. 12, 13, 15, 17 and 18).

30. The Appellant does not specify which of its comments were left unaddressed by the Agency. Similarly, the Appellant does not provide any evidence that the Agency lacked objectivity in the assessment of its comments.

31. The first plea must therefore be rejected.

2.2. Second plea: It is not necessary to use radiolabelling for the Substance when carrying out the OECD TG 309 test required by the Contested Decision

Arguments of the Parties

32. The Appellant argues that it is not necessary to use radiolabelling for the substance when carrying out the testing required by the Contested Decision.

33. Specifically, according to the Appellant, the degradation products which will be formed in the test system can already be predicted by reference to substances which are similar to the Substance, namely 1,4-bis[(4-methylphenyl)amino]-9,10-anthraquinone (CAS No 128-80-3) and N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl]acetamide (CAS No 67905-17-3). The Appellant argues that there is no need to use radiolabelling in order to identify those degradation products. Therefore, according to the Appellant, the Agency committed an error in that regard and exceeded its powers.

Findings of the Board of Appeal

34. The Contested Decision requires the Appellant to submit information on simulation testing on ultimate degradation in surface water (OECD TG 309/EU C.25) or, should that test not be technically feasible, simulation testing in sediment (OECD TG 308/EU C.24) in order to determine the half-life of the Substance. In the conduct of that study, the Appellant is additionally required to radiolabel the molecules of the substance in order to identify the transformation and/or degradation products formed in the test.

35. The Appellant does not argue that the testing required by the Contested Decision is unnecessary as such. However, it argues that it is not necessary to radiolabel the molecules of the Substance, as the relevant transformation and/or degradation products can be predicted based on available information on other substances.

36. A request for further information under Article 46 is necessary if the substance at issue poses a potential risk for human health or the environment, it is necessary to clarify that risk, and there is a realistic possibility that the information requested allows improved risk management measures to be taken (see judgment of 16 December 2020, *3v Sigma* v *ECHA*, T-176/19, EU:T:2020:621, paragraph 44, and Case A-007-2019, *Chemours Netherlands*, decision the Board of Appeal of 12 January 2021, paragraph 38). These requirements must be fulfilled not only as regards the request for a study as such, but also as regards any specific additional requirements imposed for the conduct of that study.

37. According to the Contested Decision, it is necessary to radiolabel the molecules of the Substance in order to identify the transformation and/or degradation products formed in the test. This, in turn, is necessary because the Substance may form unknown transformation and/or degradation products which may show that the substance is PBT or vPvB.

38. The Appellant asserts that it is not necessary to radiolabel the molecules of the Substance as the relevant transformation and/or degradation products formed in the test can be predicted based on available information on other substances.

39. However, in the context of the adversarial proceedings before the Board of Appeal, an appellant cannot confine itself to claiming that the result of the assessment on which a contested decision is based should have been different. It falls to the appellant to put forward arguments to show the existence of errors vitiating the scientific assessment on which the contested decision is based (see judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638, paragraph 86, and Joined Cases A-016-2019 to A-029-2019*, Lubrizol France and Others*, decision of the Board of Appeal of 23 February 2021, paragraph 104).

40. The Appellant does not provide any information capable of demonstrating that the transformation and/or degradation products formed in the test by the Substance can be predicted based on information on the transformation and/or degradation products formed by the other substances to which it refers. Furthermore, the Appellant does not explain why it considers that the degradation products of those substances are the only ones – or even the main ones – which may be formed in the test with the Substance. Consequently, the Appellant has not put forward any arguments to show the existence of errors vitiating the scientific assessment on which the Contested Decision is based.

41. The second plea must therefore be rejected.

3. Result

42. As all the Appellant's pleas have been rejected, the appeal must be dismissed.

Refund of the appeal fee

43. Under Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to the REACH Regulation (OJ L 107, 17.4.2008, p. 6), the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the appeal is dismissed, the appeal fee is not refunded.

Effects of the Contested Decision

44. The Contested Decision required the Appellant to submit information on simulation testing on ultimate degradation in surface water (OECD TG 309/EU C.25) or, should that test not be technically feasible, simulation testing in sediment (OECD TG 308/EU C.24), using the methods specified in the Contested Decision, by 21 November 2022. That deadline corresponds to one year, nine months and six days after the date of notification of the Contested Decision.

45. Under Article 91(2), an appeal has suspensive effect. The deadline set in the Contested Decision must therefore be calculated starting from the date of the notification of the present decision of the Board of Appeal to the Parties. The information required in the Contested Decision must therefore be submitted by 20 September 2023.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that information required in the Contested Decision must be provided by 20 September 2023.**
3. **Decides that the appeal fee is not refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal