

# DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

# 7 September 2021

(Dossier evaluation – Compliance check – Admissibility – Weight-of-evidence adaptation – Animal welfare – Duties of the Agency)

Case number A-008-2020

Language of the case English

**Appellant** Sustainability Support Service (Europe) AB, Sweden

Contested Decision CCH-D-2114512168-54-01/F of 3 June 2020, adopted by the

European Chemicals Agency (the 'Agency') pursuant to Article 41 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 BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

#### **Decision**

## **Background to the dispute**

- 1. This appeal concerns a compliance check of the Appellant's registration dossier for the substance disodium 4,4'-bis[(4-anilino-6-morpholino-1,3,5-triazin-2-yl)amino] stilbene-2,2'-disulphonate (EC No 240-245-2, CAS No 16090-02-1; the 'Substance').
- 2. The Appellant registered the Substance at the 100 to 1 000 tonnes per year tonnage band. The Appellant submitted information separately from the other registrants of the Substance under Article 11(3) of the REACH Regulation (all references to Articles or Annexes hereinafter concern the REACH Regulation unless stated otherwise).
- 3. In its registration dossier, the Appellant sought to fulfil the following information requirements by means of adaptations based on the weight of evidence ('weight-of-evidence adaptations') in accordance with Section 1.2. of Annex XI:
  - screening for reproductive/developmental toxicity (Section 8.7.1. of Annex VIII),
  - sub-chronic toxicity study (90-day) (Section 8.6.2. of Annex IX),
  - pre-natal developmental toxicity study in a first species (Section 8.7.2. of Annex IX),
  - long-term toxicity testing on fish (Section 9.1.6.1. of Annex IX),
  - *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Section 8.4.2. of Annex VIII), and
  - long-term toxicity testing on aquatic invertebrates (Section 9.1.5. of Annex IX).
- 4. On 4 February 2019, the Agency initiated a compliance check of the Appellant's registration dossier under Article 41.
- 5. On 24 April 2019, the Agency notified a draft decision to the Appellant under Article 50(1). In that draft decision, the Agency rejected the adaptations referred to in paragraph 3 above, in particular because those adaptations did not satisfy the requirements of Section 1.2. of Annex XI, no robust study summaries had been provided for the source studies, and the supporting information provided was neither reliable nor relevant.
- 6. On 29 May 2019, the Appellant submitted comments on the draft decision. The Agency subsequently revised the draft decision and notified the revised draft decision to the competent authorities of the Member States under Article 51(1).
- 7. On 3 June 2020, as no proposals for amendment were submitted by the competent authorities of the Member States, the Agency adopted the Contested Decision under Article 51(3).

#### The Contested Decision

8. In the Contested Decision, the Agency assessed the information contained in the Appellant's registration dossier against the relevant requirements of the REACH Regulation and concluded that there were several data-gaps in that registration dossier. The Contested Decision consequently provides:

'Based on Article 41 [...], ECHA requests that you submit the information listed in [...] C.2, C.3 and C.4 below by <u>4 January 2021</u> and all other information listed below by 10 December 2021.

[...]

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

- 1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) with the Substance;
- 2. Only if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. is obtained, In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method OECD TG 476 or TG 490) with the Substance;
- 3. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method OECD 422) in rats, oral route with the Substance;
- C. Requirements applicable to all the Registrants subject to Annex IX of REACH
- 1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the Substance;
- 2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;
- 3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211) with the Substance;
- 4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance.'

# **Procedure before the Board of Appeal**

- 9. On 3 September 2020, the Appellant filed this appeal.
- 10. On 9 November 2020, the Agency submitted its Defence.
- 11. On 8 January 2021, the Appellant submitted its observations on the Defence.
- 12. On 22 February 2021, the Agency submitted observations on the Appellant's observations on the Defence.
- 13. On 30 November 2020, Spyridon Merkourakis and Ángel M. Moreno, alternate members of the Board of Appeal, were designated to act, respectively, as technically and legally qualified members of the Board of Appeal in this case. They were designated, respectively, in accordance with the first and second subparagraphs 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').
- 14. On 26 April 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

- 15. The Appellant requests the Board of Appeal to:
  - annul the Contested Decision insofar as it requires the Appellant to submit information to fulfil the information requirements listed under points B. and C. of the Contested Decision (see paragraph 8 above), and
  - confirm that no further testing is required for the Substance.
- 16. The Agency requests the Board of Appeal to dismiss the appeal as inadmissible or, in the alternative, as manifestly unfounded. In its observations on the Appellant's observations on the Defence, the Agency also requests the Board of Appeal to dismiss the pleas in law submitted by the Appellant in its observations on the Defence as inadmissible or, in the alternative, as manifestly unfounded.

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#### Reasons

#### 1. Admissibility of the appeal

### Relevant legislation

# 17. Article 92(2) provides:

'The appeal, together with the statements of the grounds thereof, shall be filed in writing to the Agency within three months of the notification of the decision to the person concerned, or in the absence thereof, of the day on which it became known to the latter, unless otherwise provided in this Regulation.'

18. Article 6(1) of the Rules of Procedure provides:

'The notice of appeal shall contain:

- (a) the name and address of the appellant;
- (b) where the appellant has appointed a representative, the name and the business address of the representative;
- (c) an address for service, if different from those under points (a) and (b);
- (d) the reference of the decision which is being contested and the remedy sought by the appellant;
- (e) the pleas in law and the arguments of fact and law relied on;
- (f) where appropriate, the nature of any evidence offered and a statement explaining the facts for which the evidence is offered in support;
- (g) where appropriate, an indication as to what information in the notice of appeal is to be regarded as confidential and why;
- (h) an indication whether the appellant agrees that service is to be effected on him or, where appropriate, on his representative by telefax, e-mail or other technical means of communication.'
- 19. Article 11(1) of the Rules of Procedure provides:

'The grounds on which an appeal shall be ruled inadmissible shall include the following:

- (a) the notice of appeal is not in compliance with the requirements set out in Article 6(1)(a) to (d) and (2) and Article 9 of this Regulation;
- (b) the appellant has exceeded the time limit for submitting an appeal as set out in Article 92(2) [...];
- (c) the appeal is not brought against a decision referred to in Article 91(1) of [the REACH Regulation] or Article 77(1) of Regulation (EU) No 528/2012;
- (d) the appellant is neither an addressee of the decision contested by the appeal nor able to establish direct and individual concern according to Article 92(1) [...]'

## **Arguments of the Parties**

20. The Agency 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. The Agency argues that the list of inadmissibility grounds under Article 11(1) of the Rules of Procedure is not exhaustive. According to the Agency, an appeal can therefore be declared inadmissible if the notice of appeal does not contain the pleas in law and the arguments of fact and law relied on in accordance with Article 6(1)(e) of the Rules of

- Procedure, despite the fact that this requirement is not listed expressly in Article 11(1) of the Rules of Procedure.
- 21. The Appellant did not provide any observations on the admissibility of its appeal.

- 22. To decide on the Agency's objection to the admissibility of the appeal, it is necessary to determine, first, whether the absence of pleas in law or arguments of fact or law is a valid ground to dismiss an appeal as inadmissible. Second, in the affirmative, it is necessary to determine whether the Appellant submitted any pleas in law or arguments of fact or law.
- 23. Article 11(1) of the Rules of Procedure establishes a list of grounds on which an appeal shall be ruled inadmissible. The absence of pleas in law or arguments of fact or law is not mentioned among the grounds that are listed under that provision.
- 24. However, the list established under Article 11(1) of the Rules of Procedure is not exhaustive. The use of the verb 'include' in the introductory sentence of that provision shows that it does not exclude the possibility to consider other grounds of inadmissibility.
- 25. Under Article 92(2) of the REACH Regulation and Article 6(1)(e) of the Rules of Procedure, an appellant must set out the grounds of its appeal, that is to say the pleas in law and the arguments of fact or law on which it relies. In essence, an appellant must set out the reasons why it considers that the contested decision is vitiated by an error.
- 26. The procedure before the Board of Appeal is adversarial in nature. The subject of a case before the Board of Appeal is determined by the grounds of appeal put forward by the appellant (see judgment of 20 September 2019, T-125/17, BASF Grenzach v ECHA, EU:T:2019:638, paragraphs 61 and 65).
- 27. The adversarial nature of the appeal procedure is reflected in Article 6(1)(e) of the Rules of Procedure. In the absence of comprehensible grounds of appeal, the Agency is not in a position to dispute the merits of the appeal, and the Board of Appeal is not in a position to exercise its powers of review.
- 28. Therefore, 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, to this effect, Case A-004-2011, *Kronochem*, Decision of the Board of Appeal of 7 October 2011, paragraph 47).
- 29. In the present case, the Notice of Appeal is laconic. However, it contains three comprehensible grounds on the basis of which the Appellant considers the Contested Decision to be vitiated by error. In essence, the Appellant argues that:
  - the Agency has not considered in an objective manner any of the supporting data provided by the Appellant or the Appellant's comments on the draft decision,
  - the information provided by the Appellant in its registration dossier and in its comments on the draft decision is sufficient to fulfil the requirements of the REACH Regulation, and
  - the Contested Decision raises ethical issues as regards animal welfare due to the studies on vertebrate animals that are required by that Decision.
- 30. Therefore, the arguments provided in the Notice of Appeal are sufficiently detailed to constitute grounds of appeal within the meaning of Article 92(2) of the REACH Regulation and Article 6(1)(e) of the Rules of Procedure.
- 31. The Agency's objection to the admissibility of the appeal must consequently be rejected.

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# 2. Admissibility of pleas and evidence submitted after the first exchange of written pleadings

# Relevant legislation

- 32. Article 12 of the Rules of Procedure provides:
  - '1. No further evidence may be introduced after the first exchange of written pleadings unless the Board of Appeal decides that the delay in offering the evidence is duly justified.
  - 2. No new plea in law may be introduced after the first exchange of written pleadings unless the Board of Appeal decides that it is based on new matters of law or of fact that come to light in the course of the proceedings.

[...]'

# **Arguments of the Parties**

- 33. In its observations on the Defence, the Appellant argues that the Agency:
  - should have accepted the adaptations contained in the Appellant's registration dossier as it accepted a related adaptation from the lead registrant of the Substance, and
  - exceeded its powers and violated Article 41 by limiting, in the Contested Decision, the means by which the Appellant can comply with the standard information requirements.
- 34. The Agency argues that the pleas submitted by the Appellant in its observations on the Defence, and the evidence submitted in support of those pleas, are inadmissible under Article 12 of the Rules of Procedure. According to the Agency, those pleas and that evidence are new, and no explanation has been given for their late submission.
- 35. The Appellant did not provide any observations on the admissibility of the pleas and evidence it submitted in its observations on the Defence.

- 36. First, Article 12(2) of the Rules of Procedure provides that no new plea in law may be introduced after the first exchange of written pleadings unless the Board of Appeal decides that it is based on new matters of law or of fact that come to light in the course of the proceedings.
- 37. In the first place, in its observations on the Defence, the Appellant argues that the Contested Decision breached Article 25. This argument constitutes a reformulation of the Appellant's plea concerning animal welfare, which was set out in the Notice of Appeal. It cannot be considered to be a new plea. The Agency's argument must therefore be rejected in this regard.
- 38. In the second place, in its observations on the Defence, the Appellant argues that the Agency should have accepted the adaptations contained in the Appellant's registration dossier as it accepted a related adaptation from the lead registrant of the Substance. In addition, according to the Appellant, the Agency exceeded its powers and violated Article 41 by limiting the means by which the Appellant can fulfil the standard information requirements.
- 39. The two pleas referred to in the previous paragraph are not contained in the Notice of Appeal and must be considered to be new pleas. The Appellant has not explained the reasons for their late submission. Furthermore, those two new pleas are not

- based on new matters of law or of fact that came to light in the course of the present appeal proceedings. They must therefore be rejected as inadmissible.
- 40. Second, Article 12(1) of the Rules of Procedure provides that no further evidence may be introduced after the first exchange of written pleadings unless the Board of Appeal decides that the delay in offering the evidence is duly justified.
- 41. The Appellant attached to its observations on the Defence a document entitled 'Justification towards the requirements posted by ECHA'. That document contains references to scientific studies and information which, according to the Appellant, show that the Appellant's registration dossier complies with the information requirements in Annexes VII, VIII and IX. Furthermore, in the same document, the Appellant declares that it is now ready to consider testing for pre-natal developmental toxicity should the adaptation proposed for this endpoint not be considered to be sufficient by the Agency.
- 42. The document in question contains new evidence which was not submitted with the Notice of Appeal. Furthermore, the Appellant did not provide any justification for the delay in offering this evidence. Therefore, this document must be rejected as inadmissible.

#### 3. Substance of the case

- 43. As stated in paragraphs 29 above, in the Notice of Appeal the Appellant raises the following three pleas in support of its appeal:
  - the Agency has not considered in an objective manner any of the supporting data provided by the Appellant or the Appellant's comments on the draft decision (first plea),
  - the information provided by the Appellant in its registration dossier and in its comments on the draft decision is sufficient to fulfil the requirements of the REACH Regulation (second plea), and
  - the Contested Decision raises ethical issues as regards animal welfare and breaches Article 25 (third plea).
- 44. Each of these pleas will be examined in turn.
  - 3.1. First plea: The Agency has not considered in an objective manner any of the supporting data provided by the Appellant or the Appellant's comments on the draft decision

#### **Arguments of the Parties**

- 45. The Appellant argues that the Agency did not consider objectively the supporting data it provided or its comments on the draft decision.
- 46. The Agency disputes the Appellant's arguments.

### Findings of the Board of Appeal

47. The right to good administration, which is codified in Article 41 of the Charter of Fundamental Rights of the European Union, requires the Agency to examine carefully and impartially all the relevant aspects of the individual case, to gather all the factual and legal material necessary for the exercise of its discretion, and to ensure the proper conduct and the efficiency of the procedures it was implementing (see judgment of 3 October 2019, BASF v ECHA, T-805/17, EU:T:2019:723, paragraph 57; judgment of 3 October 2019, BASF and REACH & colours v ECHA, T-806/17, ECLI:EU:T:2019:724, paragraph 75). The Agency's assessment of all the relevant

aspects of the individual case must be carried out as thoroughly as possible on the basis of the principles of scientific excellence, transparency, and independence (see judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 172; see also Joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others*, Decision of the Board of Appeal of 23 February 2021, paragraph 123).

- 48. In the present case, the Appellant submitted comments on the draft decision in accordance with Article 50(1) (see paragraph 6 above). In the Contested Decision, the Agency replied to the Appellant's comments, addressed the reliability and relevance of the studies submitted by the Appellant, and provided endpoint specific justifications for rejecting the Appellant's adaptations. 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.
- 49. The first plea must therefore be rejected.
  - 3.2. Second plea: The information provided by the Appellant in its registration dossier and in its comments on the draft decision is sufficient to fulfil the requirements of the REACH Regulation

# **Arguments of the Parties**

- 50. First, the Appellant argues that the weight-of-evidence adaptations contained in its registration dossier and in its comments on the draft decision are sufficient to comply with the relevant information requirements in Annexes VII, VIII and IX, and that the Agency erred in rejecting those adaptations.
- 51. Second, as regards long-term toxicity testing on fish (Section 9.1.6.1. of Annex IX), the Appellant argues that under Section 9.1. of Annex IX, long-term toxicity testing on fish is only required if the chemical safety assessment shows the need to investigate further the aquatic toxicity of the registered substance. As the Appellant's chemical safety assessment does not show such a need, such testing is not required for the purposes of the registration of the Substance.
- 52. The Agency disputes the Appellant's arguments.

- 53. By the first part of the second plea, the Appellant argues, in essence, that the adaptations contained in its registration dossier comply with the requirements of Section 1.2. of Annex XI.
- 54. In the course of the proceedings before the Board of Appeal, an appellant cannot confine itself to claiming that the result of the assessment on which the 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 that decision is based (see *BASF Grenzach* v *ECHA*, cited in paragraph 26 above, paragraph 86 of the judgment).
- 55. In the present case, the Appellant confines itself to claiming that its adaptations should have been accepted, without providing any arguments to show that the Agency made an error of assessment.
- 56. The first part of the first plea must therefore be rejected.
- 57. By the second part of second plea, the Appellant argues, in essence, that it is not required to submit any aquatic toxicity testing on fish under Column 1 of

- Section 9.1.6. of Annex IX because its chemical safety assessment does not show that there is a need to do so.
- 58. That argument is based on a misinterpretation of Column 2 of Section 9.1. of Annex IX. That provision does not allow registrants to omit information on one of the three studies listed in Column 1 of Section 9.1.6. of Annex IX. Instead, Column 2 of Section 9.1. of Annex IX requires registrants to submit information on a further study than one of the three studies listed in Column 1 of Section 9.1.6. of Annex IX, if the chemical safety assessment indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond what any one of those three studies would do (see Case A-011-2018, Clariant Plastics & Coatings (Deutschland), Decision of the Board of Appeal of 4 May 2020, paragraphs 175 and 179).
- 59. Therefore, even assuming that the Appellant's chemical safety assessment is correct and complete, the fact that that chemical safety assessment does not show a need for further testing does not allow the Appellant to omit the information required under Column 1 of Section 9.1.6. of Annex IX.
- 60. The second part of the second plea must therefore also be rejected, and with it the second plea in its entirety.

# 3.3. Third plea: The Contested Decision raises ethical issues as regards animal welfare and breaches Article 25

#### **Arguments of the Parties**

- 61. The Appellant argues that the Contested Decision fails to take into account the welfare of vertebrate animals, as required in particular by Article 25, insofar as the Contested Decision requires testing on vertebrate animals.
- 62. The Agency disputes the Appellant's arguments.

- 63. In the present case, the Agency concluded in the Contested Decision that the Appellant's registration dossier contains data-gaps under, amongst others, Sections 8.7.1. and 8.6.2. of Annex VIII and Sections 8.7.2. and 9.1.6.1. of Annex IX. The Appellant has not shown that this conclusion is vitiated by an error (see paragraphs 53 to 60 above).
- 64. The consequences of this conclusion flow directly from the REACH Regulation. Pursuant to Article 10(a)(vi), read in conjunction with the relevant provisions of Annexes VIII and IX, the Appellant is obliged to submit either information on the studies at issue, or acceptable adaptations.
- 65. As a consequence, the Agency was neither required nor empowered to consider whether it is consistent with Article 25 for the Appellant to be required to submit this information (see *Clariant Plastics & Coatings (Deutschland)*, cited in paragraph 58 above, paragraph 51 of the decision).
- 66. The third plea must therefore be rejected as unfounded.

#### 4. Result

- 67. The Appellant requests the Board of Appeal to partially annul the Contested Decision and confirm that no further testing is required for the Substance.
- 68. First, as all the Appellant's pleas have been rejected, the Appellant's request to partially annul the Contested Decision must be rejected.
- 69. Second, as regards the Appellant's request to confirm that no further testing is required for the Substance, the Agency concluded, without committing an error, that the Appellant's registration dossier contains data-gaps and that the adaptations submitted by the Appellant are not acceptable.
- 70. Therefore, the Appellant's dossier must be brought into compliance with the relevant information requirements. The Appellant is obliged to submit information on the required studies, within the time limits specified under Article 41(3), unless it provides acceptable adaptations within the same time limits. Consequently, the Appellant's request to confirm that no further testing is required must be rejected.
- 71. As all the Appellant's pleas and requests have been rejected, the appeal must be dismissed.

# Refund of the appeal fee

72. 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**

- 73. The Contested Decision required the Appellant to submit the following information by 4 January 2021, which is seven months and one day from the date of notification of the Contested Decision:
  - pre-natal developmental toxicity study in a first species (Section 8.7.2. of Annex IX) (rat or rabbit),
  - long-term toxicity testing on aquatic invertebrates (Section 9.1.5. of Annex IX), and
  - long-term toxicity testing on fish (Section 9.1.6.1. of Annex IX).
- 74. The Contested Decision also required the Appellant to submit the following information by 10 December 2021, which is one year, six months and seven days from the date of notification of the Contested Decision:
  - *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Section 8.4.2. of Annex VIII),
  - in case of a negative result in Section 8.4.1. of Annex VII and Section 8.4.2. of Annex VIII: *in vitro* gene mutation study in mammalian cells (Section 8.4.3. of Annex VIII),
  - screening for reproductive/developmental toxicity (Section 8.7.1. of Annex VIII),
     and
  - sub-chronic toxicity study (90-day) (Section 8.6.2. of Annex IX).

- 75. Under Article 91(2), an appeal has suspensive effect. The deadlines set in the Contested Decision for the information requirements contested in the present proceedings must therefore be calculated starting from the date of the notification of the present decision of the Board of Appeal to the Parties.
- 76. The information referred to in paragraph 73 above must therefore be provided by 8 April 2022.
- 77. The information referred to in paragraph 74 above must therefore be provided by 14 March 2023.

On those grounds,

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hereby:

- 1. Dismisses the appeal.
- 2. Decides that information on the following studies must be provided by 8 April 2022:
  - pre-natal developmental toxicity study in a first species (Section 8.7.2. of Annex IX) (rat or rabbit),
  - long-term toxicity testing on aquatic invertebrates (Section 9.1.5. of Annex IX), and
  - long-term toxicity testing on fish (Section 9.1.6.1. of Annex IX).
- 3. Decides that information on the following studies must be provided by 14 March 2023:
  - in vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Section 8.4.2. of Annex VIII),
  - in case of a negative result in Section 8.4.1. of Annex VII and Section 8.4.2. of Annex VIII: *in vitro* gene mutation study in mammalian cells (Section 8.4.3. of Annex VIII),
  - screening for reproductive/developmental toxicity (Section 8.7.1. of Annex VIII), and
  - sub-chronic toxicity study (90-day) (Section 8.6.2. of Annex IX).
- 4. Decides that the appeal fee is not refunded.

Antoine BUCHET Chairman of the Board of Appeal

Alen MOČILNIKAR Registrar of the Board of Appeal