

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

## 13 August 2024

(Dossier evaluation – Compliance check – Tonnage downgrade – Right to good administration)

Case number A-001-2023

Language of the case English

**Appellant** BASF SE, Germany

**Contested Decision** Decision of 3 November 2022 on a compliance check of the

registration for the substance 1,6-dichlorohexane, adopted by the European Chemicals Agency under Article 41 of the

**REACH Regulation** 

The Contested Decision was notified to the Appellant under

annotation number CCH-D-2114616073-60-01/F

## THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman and Rapporteur), Nikolaos Georgiadis (Technically Qualified Member), and Sakari Vuorensola (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

#### Decision

#### 1. Background to the dispute

- 1. This appeal concerns the compliance check of the registration for the substance 1,6-dichlorohexane (the **Substance**).<sup>1</sup>
- 2. In 2013, the Appellant registered the Substance at the 100 to 1 000 tonnes per year tonnage band, which corresponds to the volume of manufacture or import referred to in Annex IX to the REACH Regulation.<sup>2</sup>
- 3. On 4 June 2021, the Agency initiated a compliance check process under Article 41.
- 4. On 13 January 2022, the Agency notified to the Appellant a draft decision in accordance with Articles 41(3) and 50(1). The Appellant did not submit comments on the draft decision.
- 5. On 18 May 2022, the Appellant updated its registration dossier by changing the tonnage band of its registration from 100 to 1 000 tonnes per year to 10 to 100 tonnes per year (the **tonnage downgrade**), which corresponds to the volume of manufacture or import referred to in Annex VIII.
- 6. On 20 May 2022, the Agency acknowledged the tonnage downgrade by adopting a completeness check decision in accordance with Articles 20(2) and 22(3).
- 7. On 21 June 2022, the Agency sent a letter to the Appellant concerning the tonnage downgrade. In that letter, the Agency informed the Appellant that since the decision of the Board of Appeal in Joined Cases A-006-2020 and A-007-2020³ the Agency may carry out an assessment to determine whether a tonnage band downgrade made during a dossier evaluation procedure relies on objective industrial or commercial considerations or whether it was primarily triggered by the receipt of the draft dossier evaluation decision and therefore amounted to an abuse of procedure which would result in unduly avoiding information requirements necessary to protect human health or the environment.
- 8. The Agency stated further in that letter that the information provided by the Appellant was insufficient to carry out such an assessment and invited the Appellant to submit data, with supporting documentary evidence, regarding the volume of the Substance that had been imported/manufactured in the calendar year preceding the tonnage downgrade that is to say, in 2021.
- 9. On 28 June 2022, the Appellant submitted data on the volume of the Substance it had produced in 2021. In addition, the Appellant justified its tonnage downgrade as follows:

'In the past years, a significant part of this volume (> 100 t/y) was always dedicated to one single external customer that used this substance as a monomer, requiring us to have a full registration in the 100-1000 t/y tonnage band.

The situation changed very recently, after negotiations about future deliveries of [the Substance] with our customer. As a result, the external customer announced a reduction in the future demand for [the Substance], which will no longer exceed 100 t/y. This situation triggered our decision to downgrade the REACH-Dossier to 10-100 t/y [...]'.

<sup>&</sup>lt;sup>1</sup> EC No 218-491-7; CAS No 2163-00-0.

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.

Decision of the Board of Appeal of 9 November 2021, BASF Colors & Effects and BASF, Joined Cases A-006-2020 and A-007-2020.

- 10. On 1 September 2022, the Agency notified the draft compliance check decision to the competent authorities of the Member States in accordance with Articles 50(1) and 51(1).
- 11. On 3 November 2022, as no proposals for amendment were submitted to the Agency by the competent authorities of the Member States, the Agency adopted the Contested Decision in accordance with Article 51(3). The Contested Decision was notified to the Appellant and to another registrant, wherein they were both identified as registrants to which Annex IX is applicable.
- 12. On 4 November 2022, the Appellant asked the Agency to clarify why it was listed in the Contested Decision as a registrant to which Annex IX is applicable.
- 13. On 25 November 2022, the Agency replied to the Appellant that the Agency had not taken into account the tonnage downgrade as the data submitted by the Appellant showed that during the calendar year preceding the tonnage downgrade it was still operating at the 100 to 1 000 tonnes per year tonnage band.

## 2. Contested Decision

- 14. The Contested Decision requires the Appellant to submit, by 8 August 2025, information on studies to fulfil several information requirements under Annexes VII, VIII and IX.
- 15. Appendix 2 to the Contested Decision, on the procedure, states the following:

'[The Agency] notes that during the decision-making process one registrant [the Appellant] addressed by this decision changed its registration to a lower tonnage band and provided data on the production volume for the preceding year (2021). However, that tonnage band change is not considered for this decision-making process as the data shows that within the preceding year the registrant was still operating at the higher tonnage band'.

## 3. Procedure before the Board of Appeal

- 16. On 24 January 2023, the Appellant filed this appeal.
- 17. On 27 March 2023, the Agency submitted its Defence.
- 18. On 10 May 2023, the Appellant submitted its observations on the Defence.
- 19. On 26 June 2023, the Agency submitted its observations on the Appellant's observations on the Defence.
- 20. On 27 July 2023, the Board of Appeal requested the Appellant to provide documentary evidence related to its appeal. The Appellant submitted the requested information on 4 September 2023.
- 21. On 4 April 2024, Sakari Vuorensola, alternate member of the Board of Appeal, was designated to replace Marijke Schurmans in this case in accordance with the first subparagraph of Article 3(2) of the Rules of Procedure.<sup>4</sup>
- 22. On 21 May 2024, a hearing was held as the Board of Appeal considered it necessary in accordance with Article 13(1) of the Rules of Procedure. The hearing was held by video-conference in accordance with Article 13(7) of the Rules of Procedure. At the hearing, the Parties made oral submissions and responded to questions from the Board of Appeal.

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).

## 4. Form of order sought

- 23. The Appellant requests the Board of Appeal to:
  - annul the Contested Decision insofar as the Appellant is identified as an addressee to which Annex IX is applicable,
  - amend the Contested Decision to the effect that the Appellant is identified as an addressee to which Annex VIII is applicable as the highest annex to the REACH Regulation, and
  - order the refund of the appeal fee.
- 24. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

#### 5. Assessment of the case

- 25. The Appellant challenges the Contested Decision insofar as that decision finds that Annex IX applies to it. The Appellant does not challenge the Contested Decision as regards the application of Annexes VII and VIII. Therefore, the scope of the present appeal is limited to the applicability to the Appellant of the information requirements under Annex IX.
- 26. In support of its appeal, the Appellant raises two pleas, alleging that the Agency:
  - breached its duty to examine each case individually and thereby violated the Appellant's right to good administration as set out in Article 41 of the Charter of Fundamental Rights of the European Union<sup>5</sup> (the **Charter**), and
  - breached Article 41.
- 27. To decide on the present case, it is appropriate to examine, first, whether the Agency breached Article 41, and second, whether the Agency breached its duty to examine each case individually and thereby violated the Appellant's right to good administration as set out in Article 41 of the Charter.

## 5.1. Breach of Article 41

Arguments of the Parties

- 28. The Appellant argues that the Agency breached Article 41 by failing to properly take into account the tonnage downgrade.
- 29. According to the Appellant, the completeness check decision of 20 May 20226 restricted the Appellant's ability to legally manufacture or import the Substance to a maximum of 100 tonnes per year. Therefore, according to the Appellant, under Article 12(1)(c), the Appellant was only required to fulfil the information requirements under Annex VIII. Consequently, the Appellant argues that at the time of the adoption of the Contested Decision the Agency could not require the Appellant to provide information under Annex IX.
- 30. The Appellant further argues that after the completeness check decision of 20 May 2022 the Agency was prevented from assessing the relevance of the tonnage downgrade for the ongoing compliance check process.
- 31. The Agency disputes the Appellant's arguments. The Agency argues that a completeness check decision under Article 20(2) does not involve an assessment of the quality or adequacy of the data or justifications submitted by the registrant(s) concerned. Therefore, according to the Agency, the completeness

<sup>&</sup>lt;sup>5</sup> OJ C 83, 30.3.2010, p. 389.

<sup>&</sup>lt;sup>6</sup> See paragraph 6 above.

check decision of 20 May 2022 could not prevent the Agency from assessing the tonnage downgrade as regards its relevance for the compliance check process leading to the Contested Decision.

## Findings of the Board of Appeal

- 32. To decide on this plea, it is necessary to determine, first, whether the Agency was entitled to verify the relevance of the tonnage downgrade for the compliance check process leading to the Contested Decision, and second, whether the Agency had already proceeded to that verification in the completeness decision of 20 May 2022.
  - (a) Power of the Agency to verify the relevance of the tonnage downgrade
- 33. A change in the tonnage band at which a substance is registered during a compliance check process constitutes information that must be taken into account by the Agency as the volume of manufacture or import of a substance determines the number and nature of the information requirements to be fulfilled under Annexes VII to X.<sup>7</sup>
- 34. Where a registrant downgrades the tonnage band at which a substance is registered after the receipt by that registrant of a draft decision in the process leading to the adoption of a compliance check decision under Article 41, the Agency may assess the relevance of that information for the ongoing compliance check process.<sup>8</sup>
- 35. Therefore, the Agency was entitled to verify, in the present case, whether the tonnage downgrade made by the Appellant on 18 May 2022 was relevant for the compliance check process that led to the Contested Decision.
  - (b) Exercise by the Agency of its power to verify the relevance of the tonnage downgrade
- 36. Concerning the completeness check process, Article 20(2) provides that '[t]he Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 10 and 12 [...] have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted' (emphasis added).
- 37. Article 22(3) provides that `[t]he Agency shall undertake a completeness check according to Article 20(2) first and second subparagraphs of each updated registration'.
- 38. Concerning the compliance check process, Article 41(1)(a) and (b) provide:
  - 'The Agency may examine any registration in order to verify any of the following:
  - (a) that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;
  - (b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI'.

See, to this effect, BASF Colors & Effects and BASF, cited in footnote 3, paragraphs 54, 55 and 58 of the decision.

<sup>8</sup> *Ibidem*, paragraph 74 of the decision.

- 39. In a completeness check under Article 20(2), the Agency's assessment is limited to determining that all the information required for a registration is present in the registration and is meaningful.<sup>9</sup> In a compliance check under Article 41(1), the Agency's assessment extends to determining the quality and the adequacy of that information and related justifications in order to verify that the standard information requirements under the REACH Regulation have been fulfilled.<sup>10</sup>
- 40. In the present case, the Agency acknowledged the tonnage downgrade made by the Appellant on 18 May 2022 by adopting, on 20 May 2022, a completeness check decision under Article 22(3) and Article 20(2). In conformity with those provisions, the decision of 20 May 2022 did not contain any assessment of the quality and adequacy of the tonnage downgrade.
- 41. After the completeness check decision of 20 May 2022, the Agency invited the Appellant on 21 June 2022 to provide information on the tonnage downgrade. <sup>11</sup> That information concerned the justifications for the tonnage downgrade. It was based on the information and justifications provided by the Appellant on 28 June 2022 that the Agency assessed the quality and adequacy of the tonnage downgrade to verify its relevance for the ongoing compliance check process.
- 42. That assessment by the Agency fell outside the scope of the completeness check decision of 20 May 2022. Consequently, the completeness check decision of 20 May 2022 did not deprive the Agency of its power to verify the relevance of the tonnage downgrade during the compliance check process leading to the Contested Decision. Therefore, the Agency did not breach Article 41 in proceeding to that verification in the framework of the compliance check process leading to the Contested Decision.
- 43. The Appellant's plea regarding the breach of Article 41 must therefore be rejected as unfounded.

# 5.2. Article 41 of the Charter and the breach of the Agency's duty to examine each case individually

Arguments of the Parties

- 44. The Appellant argues that the Agency breached the principle of good administration, as set out in Article 41 of the Charter, because it did not proceed to a proper individual assessment of the present case.
- 45. First, the Appellant argues that the Agency cannot presume that a tonnage downgrade made after receiving a draft compliance check decision is used by a registrant to escape its responsibilities, thereby amounting to an abuse of procedure. According to the Appellant, this approach contradicts the Agency's duty to examine each case individually and is not in line with the findings of the Board of Appeal in its decision in Joined Cases A-006-2020 and A-007-2020.
- 46. The Appellant argues that the tonnage downgrade was not used to avoid the submission of information necessary to protect human health or the environment. The Appellant argues that Articles 10(a) and 12 list the information requirements to be fulfilled by a registrant depending on the tonnage band of the registration. According to the Appellant, the objective of a compliance check under Article 41 is not to identify retroactively whether a registrant might have breached its obligations to submit a registration dossier containing all the information required by the REACH Regulation and to update that dossier under Article 22(1).

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Decision of the Board of Appeal of 23 March 2018, REACheck Solutions, A-011-2017, paragraph 47.

<sup>&</sup>lt;sup>10</sup> See, to this effect, decision of the Board of Appeal of 23 February 2021, *Lubrizol France and Others*, Joined Cases A-016-2019 to A-029-2019, paragraph 120.

<sup>&</sup>lt;sup>11</sup> See paragraphs 7 and 8 above.

- 47. The Appellant further argues that, since the Contested Decision is addressed to another registrant at the Annex IX level, 12 the removal of the Appellant as an addressee at the Annex IX level will not hinder the submission of the required information nor be detrimental to the protection of human health or the environment.
- 48. Second, the Appellant argues that the Agency erred in limiting its assessment of the tonnage downgrade to the sole aspect of the volume of the Substance manufactured or imported in the calendar year preceding the tonnage downgrade. According to the Appellant, such an approach contradicts the findings of the Board of Appeal in its decision in Joined Cases A-006-2020 and A-007-2020.
- 49. The Appellant further argues that the volume of a substance produced in the calendar year preceding a tonnage downgrade is not a reliable indicator of the current industrial or commercial motivations of a company downgrading its tonnage band. According to the Appellant, specific factual circumstances in a particular year may force a company to massively reduce its production, as in the present case.
- 50. Third, the Appellant argues that it demonstrated the objective industrial or commercial considerations that led to the tonnage downgrade. According to the Appellant, the Agency did not take this substantial new information into account and therefore did not properly exercise its margin of discretion.
- 51. The Agency disputes the Appellant's arguments.
- 52. First, the Agency argues that it did not presume that the tonnage downgrade was abusive but proceeded to an individual assessment of that tonnage downgrade as this could have substantially modified the scope and content of the Contested Decision.
- 53. The Agency further argues that a tonnage downgrade can also modify the list of registrants required to fill the data gaps identified in a final compliance check decision. According to the Agency, this could affect the obligations of the company downgrading its tonnage band vis-à-vis the other registrants still operating at the higher tonnage band as regards the data and cost sharing rules under Article 53.
- 54. Second, the Agency argues that many of the reasons given by a registrant for downgrading its tonnage band can be seen as industrial or commercial considerations. As a result, the Agency's practice is to first assess a tonnage downgrade based on the volume manufactured or imported in the previous calendar year. If a registrant demonstrates that it operated at the lower tonnage band in the calendar year preceding its tonnage downgrade, the Agency takes that tonnage downgrade into account for the remainder of the compliance check process, irrespective of the reasons given for that tonnage downgrade. If the registrant fails to demonstrate that it operated at the lower tonnage band in the calendar year preceding its tonnage downgrade, the Agency will not consider that tonnage downgrade in the ongoing compliance check process.
- 55. The Agency argues that this practice is in line with both the REACH Regulation and the findings of the Board of Appeal in its decision in Joined Cases A-006-2020 and A-007-2020. According to the Agency, that decision states that the Agency can examine the annual production volumes of the substance at issue in the period preceding a tonnage downgrade. In this respect, according to the Agency, the limitation of the concerned period to the preceding calendar year is justified by the application of Articles 3(30), 6 and 12 of the REACH Regulation, read in conjunction with Article 1 of Commission Implementing Regulation

<sup>&</sup>lt;sup>12</sup> See paragraph 11 above.

(EU) 2019/1692.13

56. Third, the Agency argues that it did not ignore the information contained in the Appellant's letter of 28 June 2022. According to the Agency, the fact that in the calendar year preceding its tonnage downgrade the Appellant was operating at the higher tonnage band entitled the Agency to disregard that tonnage downgrade in the ongoing compliance check process.

### Findings of the Board of Appeal

- 57. To decide on this plea, it is necessary, first, to determine the Agency's duties in the assessment of a tonnage downgrade submitted by a registrant after the receipt by that registrant of a draft decision in the process leading to the adoption of a compliance check decision under Article 41. Second, it is necessary to determine whether the Agency breached those duties in adopting the Contested Decision.
  - (a) Duties of the Agency
- 58. There is no provision in the REACH Regulation that could be interpreted as preventing the Agency from assessing a tonnage downgrade submitted by a registrant after the receipt by that registrant of a draft decision in the process leading to the adoption of a compliance check decision under Article 41.<sup>14</sup>
- 59. Potential data gaps in a registration dossier under evaluation must be identified by the Agency with reference to the registration dossier as it exists at the time of the adoption of the compliance check decision under Article 41<sup>15</sup>, not at the time of the notification of the draft compliance check decision to the concerned registrant(s).
- 60. In this regard, whilst it falls within the Agency's discretion to set an administrative cut-off point in a decision-making process<sup>16</sup>, the Agency is required to take into account all relevant factors and circumstances of a particular case until the final decision is adopted.<sup>17</sup> After an administrative cut-off point, the Agency may exceptionally limit to substantial new information its obligation to take into account all relevant factors and circumstances of a particular case. For this reason, the Agency must have mechanisms in place to take into account substantial new information coming to light after that administrative cut-off point.<sup>18</sup>
- 61. A tonnage downgrade submitted by a registrant constitutes substantial new information that the Agency is required to take into account even when it occurs after the receipt by that registrant of a draft decision in the process leading to the adoption of a compliance check decision under Article 41<sup>19</sup>, unless the tonnage downgrade at issue amounts to an abuse of procedure.<sup>20</sup>

Commission Implementing Regulation (EU) 2019/1692 on the application of certain registration and data-sharing provisions of Regulation (EC) No 1907/2006 of the European Parliament and of the Council after the expiry of the final registration deadline for phase-in substances (OJ L 259, 10.10.2019, p. 12).

<sup>14</sup> See, to this effect, BASF Colors & Effects and BASF, cited in footnote 3, paragraphs 38 to 48 of the decision.

See, to this effect, decision of the Board of Appeal of 9 April 2019, BrüggemannChemical, A-001-2018, paragraph 45.

See, by analogy, decision of the Board of Appeal of 10 June 2015, CINIC Chemicals Europe, A-001-2014, paragraph 78.

<sup>&</sup>lt;sup>17</sup> See, to this effect, *BrüggemannChemical*, cited in footnote 15, paragraph 67 of the decision.

<sup>&</sup>lt;sup>18</sup> *Ibidem*, paragraph 69 of the decision.

<sup>&</sup>lt;sup>19</sup> See, to this effect, *BASF Colors & Effects and BASF*, cited in footnote 3, paragraphs 54 to 56 and 58 of the decision.

<sup>&</sup>lt;sup>20</sup> *Ibidem*, paragraph 72 of the decision.

- 62. The Agency may, after carrying out an individual assessment of the case,<sup>21</sup> disregard a tonnage downgrade submitted by a registrant after the receipt by that registrant of a draft decision in the process leading to the adoption of a compliance check decision under Article 41. The purpose of that individual assessment is to determine whether that tonnage downgrade relied on objective industrial or commercial considerations or whether it was primarily triggered by the receipt of the draft compliance check decision and therefore amounted to an abuse of procedure.<sup>22</sup>
- 63. In determining whether a tonnage downgrade relies on objective industrial or commercial considerations, the Agency may examine among other factors the correlation between that tonnage downgrade and the annual production volumes of the substance at issue in the period preceding that tonnage downgrade.<sup>23</sup>
  - (b) Breach of the Agency's duties in the present case
- 64. The Contested Decision states that the tonnage downgrade was not considered for the ongoing compliance check process as the Appellant was still operating at the higher tonnage band in the calendar year preceding the tonnage downgrade.<sup>24</sup>
- 65. The Agency therefore limited its assessment to the examination of the volume of the Substance produced by the Appellant in the calendar year preceding the tonnage downgrade, without considering any other factors. During the present proceedings, the Agency explained that limiting its assessment to this element reflects the practice put in place by the Agency following the decision of the Board of Appeal in Joined Cases A-006-2020 and A-007-2020.
- 66. For the following reasons, the assessment carried out by the Agency in the present case did not constitute the individual assessment which is required from the Agency to disregard a tonnage downgrade submitted by a registrant after the receipt by that registrant of a draft decision in the process leading to the adoption of a compliance check decision under Article 41.<sup>25</sup>
- 67. First, the volume of the Substance produced in the calendar year preceding the tonnage downgrade is only one of the elements that the Agency should consider when examining the correlation between that tonnage downgrade and the annual production volumes of the Substance in the period preceding that tonnage downgrade. For example, in the present case, the Agency did not take into account the volume of the Substance produced in 2022, as it limited its assessment to the year 2021.
- 68. In this respect, the argument of the Agency based on Articles 3(30), 6 and 12 of the REACH Regulation, read in conjunction with Article 1 of Commission Implementing Regulation (EU) 2019/1692, must also be rejected. Those legal provisions do not define the period preceding a tonnage downgrade submitted by a registrant after the receipt by that registrant of a draft decision in the process leading to the adoption of a compliance check decision under Article 41. Instead, those provisions are related to the method of calculation of the quantities of phase-in substances. Consequently, those legal provisions are not relevant to determine, in the present case, the correlation between the tonnage downgrade and the annual production volumes of the Substance in the period preceding that tonnage downgrade.

<sup>&</sup>lt;sup>21</sup> See, to this effect and by analogy, judgments of 3 October 2019, *BASF* v *ECHA*, T-805/17, EU:T:2019:723, paragraph 57, and *BASF* and *REACH* & colours v *ECHA*, T-806/17, EU:T:2019:724, paragraph 75.

<sup>&</sup>lt;sup>22</sup> See, to this effect, *BASF Colors & Effects and BASF*, cited in footnote 3, paragraph 74 of the decision.

<sup>&</sup>lt;sup>23</sup> BASF Colors & Effects and BASF, cited in footnote 3, paragraph 73 of the decision.

<sup>&</sup>lt;sup>24</sup> See paragraph 15 above.

<sup>&</sup>lt;sup>25</sup> See paragraphs 61 to 63 above.

- 69. Second, the examination of the objective industrial or commercial considerations based on which that tonnage downgrade was decided by the Appellant cannot be limited to the examination of the volume of the Substance produced in the calendar year preceding the tonnage downgrade.
- 70. In the present case, the Agency did not examine any other factors than the volume of the Substance produced in the calendar year preceding the tonnage downgrade. None of the reasons provided by the Appellant to justify the tonnage downgrade<sup>26</sup> were examined by the Agency. Those reasons cannot be disregarded solely on the ground that during the calendar year preceding the tonnage downgrade the Appellant was still operating at the 100 to 1 000 tonnes per year tonnage band.
- 71. Moreover, during the decision-making process leading to the adoption of the Contested Decision, the Agency did not inform the competent authorities of the Member States of the reasons provided by the Appellant to justify the tonnage downgrade, nor did it mention those reasons in the Contested Decision.<sup>27</sup>
- 72. Third, the Agency did not determine whether the tonnage downgrade, in the present case, amounted to an abuse of procedure. By limiting its assessment to the examination of the volume of the Substance produced in the calendar year preceding the tonnage downgrade, the Agency was not in a position to gather any evidence of a potential abuse of procedure on the part of the Appellant. In this respect, it was for the Agency to establish that the tonnage downgrade amounted to an abuse of procedure, and not for the Appellant to prove that there was no such abuse.<sup>28</sup>
- 73. If the Agency intends to disregard a tonnage downgrade submitted by a registrant after the receipt by that registrant of a draft decision in the process leading to the adoption of a compliance check decision under Article 41, it must have mechanisms in place to proceed to an individual assessment of that tonnage downgrade, to determine whether it amounts to an abuse of procedure. Such an assessment cannot be limited to the examination of the production volume of a substance in the calendar year preceding the tonnage downgrade.
- 74. In the present case, the Agency did not carry out an individual assessment of the tonnage downgrade and therefore breached the Appellant's right to good administration.
- 75. The Appellant's plea regarding the breach of Article 41 of the Charter and the breach of the Agency's duty to examine each case individually must therefore be upheld.

#### 6. Result

- 76. It follows from the reasons set out in paragraphs 57 to 75 above that the Agency failed to carry out an individual assessment of the tonnage downgrade and therefore breached the Appellant's right to good administration.
- 77. Therefore, the Appellant's plea regarding the breach of Article 41 of the Charter and the breach of the Agency's duty to examine each case individually must be upheld and the Contested Decision annulled insofar as it requires the Appellant to provide information under Annex IX.

<sup>&</sup>lt;sup>26</sup> See paragraph 9 above.

<sup>&</sup>lt;sup>27</sup> See paragraph 15 above.

<sup>&</sup>lt;sup>28</sup> See, to this effect and by analogy, judgment of 26 February 2019, *N Luxembourg 1 and Others*, C-115/16, EU:C:2019:134, paragraph 142, and judgment of 24 September 1996, *Dreyfus*, T-485/93, EU:T:1996:126, paragraph 68.

## 7. Refund of the appeal fee

78. In accordance with 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<sup>29</sup>, the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the Contested Decision has been partly annulled as regards the Appellant's obligations under Annex IX, the appeal fee must be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Annuls the Contested Decision insofar as the Appellant is identified as a registrant to which Annex IX to the REACH Regulation is applicable.
- 2. Remits the case to the competent body of the Agency for further action.
- 3. Decides that the appeal fee is refunded.

Antoine BUCHET Chairman of the Board of Appeal

Alen MOČILNIKAR Registrar of the Board of Appeal

<sup>&</sup>lt;sup>29</sup> OJ L 107, 17.4.2008, p. 6.