ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

9 November 2021

(Dossier evaluation – Compliance check – Tonnage downgrade – Cut-off point for considering dossier updates – Substantial new information – Duties of the Agency – Proportionality – Article 25)

Case numbers	Joined Cases A-006-2020 and A-007-2020
Language of the cases	English
Appellants	BASF Colors & Effects GmbH, Germany (A-006-2020) BASF SE, Germany (A-007-2020)
Representatives	Christoph Rung and Michael Wenzel Rittershaus Rechtsanwälte, Germany
Interveners	PETA International Science Consortium Ltd, United Kingdom Cruelty Free Europe, Belgium Both represented by: David Thomas, Advocates for Animals, United Kingdom
Contested Decision	Decision of 1 April 2020 on a compliance check of the registration dossiers for the substance reaction product of [29H, 31 H-phthalocyaninato (2-)-N29, N30, N31, N32] zinc, sulphuric acid and caustic soda, 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 Contested Decision was notified to the Appellants under annotation numbers CCH-D-2114505954-46-01/F and CCH-D-2114505954-44-01/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

Background to the dispute

1. This appeal concerns the compliance check of the Appellants' registration dossiers for the substance reaction product of [29H, 31 H-phthalocyaninato (2-)-N29, N30, N31, N32] zinc, sulphuric acid and caustic soda (EC No 939-524-8; the 'Substance').

2. Both Appellants registered the Substance at the tonnage band of 100 to 1000 tonnes per year. The Appellants are the only registrants of the Substance.

3. On 11 March 2019, the Agency started a compliance check of each of the Appellants' registration dossiers in accordance with Article 41 of the REACH Regulation (all references to Articles or Annexes hereinafter concern the REACH Regulation unless stated otherwise).

4. On 27 June 2019, the Agency notified a draft decision to each of the Appellants in accordance with Article 50(1).

5. On 9 July 2019, each Appellant updated its registration dossier by changing the tonnage band of its registration from 100 to 1000 tonnes per year to 10 to 100 tonnes per year (the 'tonnage downgrades').

6. On 10 July 2019, the Agency acknowledged those tonnage downgrades by adopting completeness check decisions in accordance with Articles 20(2) and 22(3).

7. On 2 August 2019, the Appellants submitted comments on the draft decision in accordance with Article 50(1).

8. Regarding the tonnage downgrades, both Appellants stated:

   '[The Appellants] registered the substance in the tonnage band < 1000 t/y for both legal entities. The decision for this high tonnage was based on a positive business forecast. However, the production volumes were far below 1000 t/y and an upward trend was not expected. According to this fact, [the Appellants] submitted a dossier update and reduced the tonnage band to < 100 t/y for both legal entities. Please consider this reduced tonnage band in the final decision.

   Moreover it was planned for both legal entities to cease manufacturing in 2020. Please also consider this fact and the reduced tonnage band in the final decision.'

9. On 19 September 2019, the Agency sent a communication to the Appellants. In that communication the Agency stated:

   '*[…] Please note, you have already received a dossier evaluation draft decision related to this registration dossier. Please note that neither a change of the joint submission's tonnage band, nor a change of your individual tonnage band will have an individual impact on the decision-making process of this draft decision. ECHA's evaluation of your registration dossier is based on the specific tonnage band at which your substance was registered at the time the draft decision was submitted to you*. *[…]*'

10. On 9 January 2020, the Agency notified the draft decision to the competent authorities of the Member States in accordance with Article 51(1).

11. On 1 April 2020, as no proposals for amendment were submitted by the competent authorities of the Member States, the Agency adopted the Contested Decision in accordance with Article 51(1). The Contested Decision was notified to the Appellants under annotation numbers CCH-D-2114505954-46-01/F and CCH-D-2114505954-44-01/F.

The Contested Decision

12. The Contested Decision states:

'Based on Article 41 […], [the Agency] requests that you submit the information listed below by the deadline of 7 July 2022.

[…]

C. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. In vivo genotoxicity study to be selected according to the following scenarios:

a. If the test results of request B.1 [in vitro cytogenicity study in mammalian cells or in vitro micronucleus study with the Substance] are negative:

In vivo mammalian alkaline comet assay (Annex IX, Section 8.4., column 2; test method OECD TG 489) in rats, oral route, on the following tissues: liver, glandular stomach and duodenum, with the Substance

OR

Transgenic rodent somatic and germ cell gene mutation assays (Annex IX, Section 8.4., column 2; test method EU 8.58./OECD TG 488) in transgenic mice or rats, oral route on the following tissues: liver and glandular stomach and duodenum, with the Substance; duodenum must be harvested and stored for up to 5 years. The duodenum must be analysed if the results of the glandular stomach and of the liver are negative or inconclusive.

b. If the test results of request B.1 [in vitro cytogenicity study in mammalian cells or in vitro micronucleus study with the Substance] are positive:

In vivo mammalian alkaline comet assay (Annex IX, Section 8.4., column 2; test method OECD TG 489) in rats, oral route, on the following tissues: liver, glandular stomach and duodenum, with the Substance

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211) with the Substance

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance

4. Identification of degradation products (Annex IX, Section 9.2.3.) using an appropriate test method with the Substance

[…]

Appendix D: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

[…]

[The Agency] took into account your comments [on the draft decision] and did not amend the requests.

You submitted comments concerning a request for a tonnage band change and an indication of a future cease of manufacture. The Agency does not take into account updates of volumes in its decision making (see ECHA's Practical Guide).

[…].'

Procedure before the Board of Appeal

13. On 29 June 2020, the Appellants filed these appeals.

14. On 3 September 2020, the Agency filed its Defences in both cases.

15. On 9 September 2020, Sakari Vuorensola, 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').

16. On 28 September 2020, the Board of Appeal joined the appeals for the purposes of the written and oral parts of the procedure, and the final decision.

17. On 9 November 2020, the Appellants submitted their observations on the Defences.

18. On 7 December 2020, Cruelty Free Europe and PETA International Science Consortium Ltd were granted leave to intervene in support of the Appellants.

19. On 25 January 2021, the Agency submitted its observations on the Appellants' observations on the Defences.

20. On 3 February 2021, the Interveners jointly submitted a statement in intervention.

21. On 11 March 2021, the Agency submitted its observations on the statement in intervention. The Appellants did not submit observations on the statement in intervention.

22. On 26 March 2021, the Agency replied to questions from the Board of Appeal.

23. On 26 May 2021, 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 Appellants, the Agency and the Interveners' representatives made oral submissions and responded to questions from the Board of Appeal.

Forms of order sought

24. The Appellants request the Board of Appeal to:

    - annul the Contested Decision insofar as it concerns the information requirements set out in Annex IX, and
    - order the refund of the appeal fees.

25. In the alternative, the Appellants request a reasonable extension of the deadline set in the Contested Decision for the submission of the requested information.

26. The Agency requests the Board of Appeal to dismiss the appeals as unfounded.

Reasons

27. The appeals are limited to section C of the Contested Decision, which concerns the information requirements set out in Annex IX.

28. In support of their appeals, the Appellants raise the following plea in law: The Agency breached substantive requirements of the REACH Regulation and the principle of proportionality, including the principle of testing on vertebrate animals only as a last resort under Article 25(1), by failing to take into account the Appellants' tonnage downgrades.

Relevant legislation

29. Article 12 ('*Information to be submitted depending on tonnage*') provides:

> '*1. The technical dossier referred to in Article 10(a) shall include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following:*
>
> *[…]*
>
> *(c) the information specified in Annexes VII and VIII for substances manufactured or imported in quantities of 10 tonnes or more per year per manufacturer or importer;*
>
> *(d) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annex IX for substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer;*
>
> *[…]*
>
> *2. As soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer shall inform the Agency immediately of the additional information he would require under paragraph 1. Article 26(3) and (4) shall apply adapted as necessary.*
>
> *[…]'*

30. Article 22 ('*Further duties of registrants*') provides:

> '*1. Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency in the following cases:*
>
> *[…]*
>
> *(c) changes in the annual or total quantities manufactured or imported by him or in the quantities of substances present in articles produced or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;*
>
> *[…]*
>
> *The Agency shall communicate this information to the competent authority of the relevant Member State.'*

31. Article 50 (‘*Registrants' and downstream users' rights*’) provides:

‘1. The Agency shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 46) and the Agency (for decisions taken under Articles 40 and 41) shall take any comments received into account and may amend the draft decision accordingly.

2. If a registrant has ceased the manufacture or import of the substance, or the production or import of an article, or the downstream user the use, he shall inform the Agency of this fact with the consequence that the registered volume in his registration, if appropriate, shall be put to zero and no further information may be requested with respect to that substance, unless the registrant notifies the restart of the manufacture or import of the substance or the production or import of the article, or the downstream user notifies the restart of the use. The Agency shall inform the competent authority of the Member State in which the registrant or downstream user is located.

3. The registrant may cease the manufacture or import of the substance or the production or import of the article, or the downstream user the use, upon receipt of the draft decision. In such cases, the registrant, or downstream user, shall inform the Agency of this fact with the consequence that his registration, or report, shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration or report. The Agency shall inform the competent authority of the Member State in which the registrant or downstream user is located.

[…]’

Arguments of the Parties and Interveners

32. The Appellants argue that the Agency was required to take the tonnage downgrades into account. According to the Appellants, those tonnage downgrades were notified to the Agency during the compliance check process and the REACH Regulation does not define any cut-off point that would allow the Agency to disregard new facts in that process. The Agency's strict application of the cut-off point, on the grounds of administrative efficiency, was too inflexible.

33. The Appellants further argue that they referred to the updates of their registration dossiers, and therefore to the tonnage downgrades, in their comments on the draft decision. Following those tonnage downgrades, the Agency could not request the Appellants to provide any information set out in Annex IX.

34. The Interveners argue that the Agency had an obligation to take into account the tonnage downgrades to which the Appellants referred in their comments on the draft decision. After considering the information provided by the Appellants, the Agency should not have requested any information set out in Annex IX.

35. The Agency disputes the Appellants' and Interveners' arguments. The Agency argues that the REACH Regulation precludes it from taking into account a tonnage downgrade after a draft compliance check decision is received by the registrant concerned. The only tonnage downgrade which the Agency can take into account during a compliance check process is a cessation of manufacture or import under Article 50(2) and (3). In any event, a tonnage downgrade does not constitute substantial new information that the Agency must take into account after a draft compliance check decision is received by the registrant concerned. In addition, the Agency argues that it must refuse to take into account a tonnage downgrade after the receipt by the registrant concerned of a draft compliance check decision in order to prevent that registrant from using tonnage downgrade as a means to escape its responsibilities.

Findings of the Board of Appeal

1. The REACH Regulation does not preclude the Agency from taking into account tonnage downgrades during a compliance check process

36. The Appellants argue that the REACH Regulation does not define a cut-off-point authorising the Agency to disregard new facts, such as the tonnage downgrades at issue in the present cases, during a compliance check process.

37. The Agency argues that, under Article 50(2) or (3), the cessation of manufacture or import is the only tonnage downgrade which the Agency can take into account during a compliance check process. The Agency argues that it has no discretion in that regard and that it is legally precluded from taking into account a tonnage downgrade after the receipt by the registrant concerned of a draft decision during a compliance check process. This argument must be rejected for the following reasons.

38. First, there is no provision in the REACH Regulation that excludes, explicitly or implicitly, the possibility for the Agency to take into account a tonnage downgrade other than a cessation of manufacture or import during a compliance check process.

39. Article 22 sets out rules concerning updates of registration dossiers, including changes of tonnage band occurring after the registration of the substance concerned. Article 22(1) provides that updates must be made without undue delay. However, this provision does not set out the consequences of such updates when they are made during a compliance check process. In particular, this provision does not exclude the possibility for the Agency to take into account a tonnage downgrade during a compliance check process.

40. Article 50(2) and (3) set out the consequences of a cessation of manufacture or import as regards, first, the change of status of the registration concerned, and second, the impossibility to request further information on the substance concerned. However, Article 50(2) and (3) do not regulate the consequences of any other change of tonnage band. As other changes of tonnage band do not entail such specific consequences, they do not need to be regulated specifically. A cessation of manufacture or import differs fundamentally from any other change of tonnage band.

41. The consequences of a tonnage downgrade other than a cessation of manufacture or import are not set out in Article 50(2) and (3). They flow from Article 12 and Annexes VII to X. Under those provisions, the information requirements to be fulfilled by a registrant depend on the tonnage band of the registration. After a tonnage downgrade, a registration remains valid and active, and the Agency remains empowered to request further information. The information requirements to be fulfilled by a registrant are, however, based on a lower tonnage band, corresponding to fewer information requirements.

42. By contrast, it is clear from the wording of Article 50(2) and (3) that the scope of those provisions is limited to the cessation of manufacture or import and does not concern the possibility or impossibility for the Agency to take into account other tonnage downgrades during a compliance check process.

43. Contrary to the Agency's argument, the fact that Article 50(2) and (3) address only cessations of manufacture or import does not mean that the Agency is legally precluded from taking into account a tonnage downgrade during a compliance check process. Such an interpretation of Article 50(2) and (3) would constitute an exception to the obligation of the Agency to take into consideration all the relevant factors and circumstances of the situation the act was intended to regulate (see Case A-005-2016, *Cheminova*, decision of the Board of Appeal of 30 January 2018, paragraph 128). Therefore, such an interpretation of Article 50(2) and (3) would have to be based on clear and unequivocal provisions of the REACH Regulation. It cannot be deduced from the absence of any mention of tonnage downgrades other than cessations of manufacture or import in those provisions.

44. Second, a compliance check process does not begin with the receipt of the draft decision, but with the start of the compliance check under Article 41(1). As a first step in the compliance check process, under Article 41(1), the Agency examines the registration and proceeds with a series of verifications. As a second step in the compliance check process, within twelve months of the start of the examination referred to in Article 41(1), the Agency prepares a draft compliance check decision under Article 41(3).

45. If the Agency's position were correct, based on its interpretation of Article 50(2) and (3) the Agency would be legally precluded from taking into account any tonnage downgrade during the entire compliance check process, since Article 50(2) and (3), taken together, cover the entire compliance check process, both before and after the receipt of a draft decision by the registrant concerned.

46. However, in its submissions in the present proceedings, the Agency explained that it may take into account tonnage downgrades occurring between the start of a compliance check process and the receipt of the draft decision by the registrant concerned. Therefore, under its current practice, the Agency is not legally precluded from taking into account tonnage downgrades during the entire compliance check process.

47. Consequently, the Agency's own practice shows that the choice of the moment of receipt by the registrant concerned of the draft compliance check decision under Article 50(1) as the cut-off point after which a tonnage downgrade is not taken into account is the result of a decision taken by the Agency, rather than a legal requirement stemming from the REACH Regulation (see Case A-001-2018, *BrüggemannChemical*, decision of the Board of Appeal of 9 April 2019, paragraph 45).

48. It follows from the reasons set out in paragraphs 38 to 47 above that the Agency is not legally required to refuse to take into account a tonnage downgrade after the receipt by the registrant concerned of a draft decision in a compliance check process. The refusal to take into account a tonnage downgrade after the receipt by the registrant concerned of a draft decision in a compliance check process was based on an administrative cut-off point established and implemented by the Agency in exercising its discretion.

2. The Agency must take into account substantial new information after an administrative cut-off point

49. Establishing and implementing an administrative cut-off point in a decision-making process with the aim of ensuring administrative efficiency may fall within the Agency's margin of discretion (see Case A-001-2014, *CINIC Chemicals Europe,* decision of the Board of Appeal of 10 June 2015, paragraphs 76 and 78).

50. However, in order to ensure that it has exercised its discretion correctly when establishing and implementing the administrative cut-off point, the Agency must balance the need for administrative efficiency with other relevant considerations (*CINIC Chemicals Europe,* cited in the previous paragraph, paragraph 78). In particular, the Agency, when exercising its discretion, must take into consideration all the relevant factors and circumstances of the situation the act was intended to regulate. The Agency's refusal to take into account dossier updates after the draft decision has been sent to the registrant under Article 50(1) could lead to a situation in which the final decision adopted by the Agency is not based on all relevant factors and circumstances (see *BrüggemannChemical*, cited in paragraph 47 above, paragraph 67).

51. 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 (see *BrüggemannChemical*, cited in paragraph 47 above, paragraph 69).

3. The tonnage downgrades constituted substantial new information which the Agency was required to take into account during the compliance check process

52. In the present cases, the Agency did not provide for any possibility to take into account a tonnage downgrade as a substantial new information after the receipt by the registrant concerned of the draft compliance check decision. This is because the Agency considered that such a possibility was legally excluded by the REACH Regulation (see paragraph 37 above). However, as stated in paragraph 48 above, there is no such legal requirement in the REACH Regulation, and the Agency's refusal to take into account the tonnage downgrades after the receipt by the Appellants of the draft decision was based on an administrative cut-off point. Therefore, it is necessary to determine whether, in the present cases, the tonnage downgrades constituted substantial new information that the Agency was required to take into account after the administrative cut-off point.

53. At the hearing, the Agency argued that the tonnage downgrades did not constitute substantial information because they did not fulfil the information requirements addressed in section C of the draft decision. The Agency also argued that the tonnage downgrades did not constitute new information because the Appellants did not respect their obligation to update their registration dossiers without undue delay under Article 22(1)(c). These arguments must be rejected for the following reasons.

54. First, 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 (see paragraph 51 above). As this limitation constitutes an exception to a general obligation of the Agency, this limitation must be applied strictly (see, to this effect and by analogy, judgments of 10 November 2016, *Baštová*, C-432/15, EU:C:2016:855, paragraph 59, and of 27 September 2017, *Puškár*, C-73/16, EU:C:2017:725, paragraph 38; see also Case A-006-2016, *SI Group UK and Others*, decision of the Board of Appeal of 6 June 2018, paragraph 64).

55. Second, under Article 12 and Annexes VII to X, the tonnage band determines the information requirements to be fulfilled by the registrant concerned. A tonnage downgrade therefore constitutes information that can substantially modify the content of a decision by which the Agency verifies that the registrant concerned has fulfilled the relevant information requirements. In particular, a lower tonnage band can substantially modify the assessment by the Agency of the need to request information involving tests on vertebrate animals (see, to this effect, *CINIC Chemicals Europe*, cited in paragraph 49 above, paragraphs 84 and 103).

56. In the present cases, if the Agency had taken into account the tonnage downgrades, this could have led the Agency to consider only the information requirements under Annex VIII, and not the information requirements under Annex IX. Therefore, contrary to the Agency's argument, the tonnage downgrades constituted substantial information.

57. The conclusion that the tonnage downgrades constituted substantial information is not called into question by the Agency's argument that those tonnage downgrades did not aim to fulfil the information requirements addressed in the draft decision (see paragraph 53 above). The tonnage downgrades concerned the applicability of the information requirements addressed in the draft decision and were therefore relevant to the Agency's decision.

58. Third, as regards whether the tonnage downgrades constituted new information, the tonnage downgrades occurred after the receipt by the Appellants of the draft decision, that is to say, after the administrative cut-off point established by the Agency. Irrespective of the grounds on which those tonnage downgrades were decided, such information was not known until the Appellants updated their registration dossiers. Therefore, the tonnage downgrades constituted new information.

59. The conclusion that the tonnage downgrades constituted new information is not called into question by the Agency's arguments for the following reasons.

60. In the first place, the Agency's argument relating to an alleged breach of the Appellants' obligations under Article 22(1)(c) (see paragraph 53 above) has no bearing on the present cases. In the present cases, it is only relevant to determine whether the tonnage downgrades constituted substantial new information during the compliance check process. It is however not relevant, to decide on the present appeals, to determine whether the Appellants have updated their registration dossiers without undue delay as required under Article 22(1)(c). Although the tonnage downgrades may have been based on considerations dating to a period occurring before the administrative cut-off point and might therefore be considered as being unduly delayed under Article 22(1)(c), those tonnage downgrades occurred after the receipt by the Appellants of the draft compliance check decision. They therefore constituted new information which the Agency was required to take into account.

61. In the second place, it is necessary to reject the Agency's argument that the tonnage downgrades did not constitute new information because the Appellants continued to be bound by the obligation to fulfil the information requirements under Annexes VII to

IX as they had initially registered the Substance in the tonnage band of 100 to 1000 tonnes per year, corresponding to Annex IX.

62. It is not disputed that registrants must submit a registration dossier containing all the information required by the REACH Regulation (see Case A-006-2018, *Emerald Kalama Chemical and Others*, decision of the Board of Appeal of 24 March 2020, paragraph 57). Similarly, it is not disputed that the registration dossier of a substance must be updated as required under Article 22(1).

63. However, the objective of a compliance check under Article 41 is not to review the history of a registration dossier with the aim of identifying retroactively the time periods during which a registrant might have been in breach of the obligations described in the previous paragraph. In particular, the objective of a compliance check under Article 41 is not to verify that updates under Article 22(1) were made without undue delay. The Agency's powers in a compliance check under Article 41 aim, first, at identifying the potential data-gaps in the registration dossier under evaluation at the time of the adoption of the compliance check decision and, second, at requiring the submission of the information needed to fill those potential data-gaps.

64. Article 41 empowers the Agency to request a registrant to fill, within adequate time limits, the data-gaps of its registration dossier, as identified at the time of the adoption of the compliance check decision. In adopting a compliance check decision, the Agency must take into account all the relevant factors and circumstances of the individual case at hand. This assessment also concerns substantial new information which comes to light during the compliance check process after an administrative cut-off point (see paragraphs 50 and 51 above).

65. Therefore, the fact that the Appellants initially registered the Substance at a higher tonnage band does not authorise the Agency to refuse to take into account the tonnage downgrades that occurred after the receipt by the Appellants of the compliance check draft decision.

66. It follows from the reasons set out in paragraphs 54 to 65 above that, in the present cases, the tonnage downgrades constituted substantial new information which should have been taken into account by the Agency.

4. The tonnage downgrades must be subject to an individual assessment by the Agency

67. The Agency argues that it must refuse to take into account a tonnage downgrade after the receipt by the registrant concerned of a draft compliance check decision in order to prevent that registrant from using tonnage downgrade as a means to escape its responsibilities (see paragraph 35 above). This argument must be rejected for the following reasons.

68. 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 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).

69. The Agency therefore had a duty to examine each of the present cases individually. In particular, the Agency was required to assess the tonnage downgrades made by the Appellants after receiving the draft compliance check decision.

70. First, the Agency cannot presume that a registrant which downgrades its tonnage band after receiving a draft compliance check decision uses that tonnage downgrade as a means to escape its responsibilities. Such a presumption would be in contradiction with the duty of the Agency to examine each case individually.

71. Second, a systematic and absolute refusal to take into account any tonnage downgrade after the receipt by the registrant concerned of a draft compliance check decision constitutes a breach by the Agency of its duty to assess each case individually.

72. A tonnage downgrade that amounts to an abuse of procedure cannot constitute substantial new information that the Agency is required to take into account after an administrative cut-off point in a compliance check process. A tonnage downgrade may amount to an abuse of procedure if it is not based on objective industrial or commercial considerations.

73. The objective of a compliance check under Article 41 is not to identify retroactively the time periods during which a registrant was in breach of its registration obligations (see paragraph 63 above). Nevertheless, the annual volumes of the substance produced by that registrant since its registration are relevant to assess the objective industrial or commercial considerations justifying a tonnage downgrade. Therefore, in determining whether a tonnage downgrade relies on objective industrial or commercial considerations, the Agency may examine – among other factors – the correlation between the tonnage downgrade and the annual production volumes of the substance at issue in the period preceding that tonnage downgrade.

74. In the present cases, the Agency did not carry out an individual assessment of each of the tonnage downgrades made by the Appellants and did not determine whether those tonnage downgrades relied on objective industrial or commercial considerations or were primarily triggered by the receipt of the draft compliance check decision and therefore amounted to an abuse of procedure.

75. Therefore, the Agency did not establish that it had a legitimate reason to refuse to take into account those tonnage downgrades during the compliance check process that led to the adoption of the Contested Decision.

76. The refusal by the Agency to assess the tonnage downgrades made by the Appellants after receiving the draft compliance check decision might lead the Appellants to perform unnecessary studies on vertebrate animals. By refusing to take into account substantial new information after the administrative cut-off point in the compliance check process, the Agency therefore breached its duty to ensure that the Appellants carry out studies on vertebrate animals only as a last resort under Article 25(1).

5. Result

77. It follows from the reasons set out in paragraphs 36 to 76 above that, in each of the present cases, the Agency failed to take into account substantial new information after the administrative cut-off point in the compliance check process under Article 41 and therefore breached, first, its duty to take into consideration all the relevant factors and circumstances of the case and, second, its duty to avoid animal testing under Article 25(1).

78. Therefore, the Appellants' plea must be upheld and the Contested Decision annulled.

79. The Contested Decision is annulled insofar as it concerns information requirements set out in Annex IX. The cases are remitted to the competent body of the Agency for further action.

Refund of the appeal fees

80. 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 (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 appeals have been decided in favour of the Appellants, the appeal fees must be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Contested Decision insofar as it concerns the information requirements set out in Annex IX of the REACH Regulation.**
2. **Remits the cases to the competent body of the Agency for further action.**
3. **Decides that the appeal fees are refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal