ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

24 March 2020

(Dossier evaluation – Compliance check – Read-across – Error of assessment – Alternative metabolic pathways – Conflict of opinion with another European Union body – Legal certainty – Right to good administration)

Case number	A-006-2018
Language of the case	English
Appellants	Emerald Kalama Chemical B.V., the Netherlands Lanxess Deutschland GmbH, Germany Valtris AO Belgium NV (previously Ineos Chloro Toluenes Belgium NV), Belgium
Representative	Raminta Dereskeviciute McDermott Will & Emery UK LLP, United Kingdom
Intervener	PETA International Science Consortium Ltd., United Kingdom
Contested Decision	CCH-D-2114378524-42-01/F of 18 December 2017 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; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation')

THE BOARD OF APPEAL

composed of Ioannis Dimitrakopoulos (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Sakari Vuorensola (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

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Background to the dispute

1. On 14 July 2010, Emerald Kalama Chemical B.V. registered benzaldehyde (EC No 202-860-4, CAS No 100-52-7).

2. On 5 and 23 November 2010, Lanxess Deutschland GmbH and Ineos Chloro Toluenes Belgium NV respectively also registered benzaldehyde.

3. On 1 August 2018, Ineos Chloro Toluenes Belgium NV was renamed Valtris AO Belgium NV.

4. In its registration dossier, Emerald Kalama Chemical B.V., the lead registrant for benzaldehyde and one of the Appellants, sought to fulfil the information requirements for pre-natal developmental toxicity ('PNDT') studies in the first and second species (Section 8.7.2. of Annex IX and Section 8.7.2. of Annex X to the REACH Regulation; the 'two PNDT studies'), and an extended one-generation reproductive toxicity study ('EOGRTS'; Section 8.7.3. of Annex X to the REACH Regulation) by means of read-across adaptations pursuant to Section 1.5. of Annex XI of the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise).

5. On 16 October 2015, the Agency initiated a compliance check of the lead registrant's dossier.

6. On 26 April 2016, the lead registrant updated its dossier with further justifications for the read-across adaptations.

7. On 9 November 2015, the Agency notified a draft decision to the lead registrant in accordance with Article 50(1) (the 'initial draft decision').

8. On 13 June 2016, the Agency adopted a compliance check decision (the 'June 2016 Decision') in accordance with Article 51(6).

9. The June 2016 Decision requested the lead registrant to submit, amongst other information, the two PNDT studies and the EOGRTS.

10. On 13 September 2016, the lead registrant filed an appeal before the Board of Appeal contesting the June 2016 Decision.

11. On 12 October 2016, the Executive Director of the Agency withdrew the June 2016 Decision as the lead registrant had not been able to comment on the initial draft decision due to the unavailability of a key member of the lead registrant's staff for medical reasons.

12. On 20 October 2016, the lead registrant withdrew its appeal contesting the June 2016 Decision.

13. On 10 February 2017, the Agency initiated a new compliance check of the lead registrant's dossier for benzaldehyde.

14. On 28 April 2017, the Agency notified a draft decision to the lead registrant in accordance with Article 50(1). The draft decision rejected the read-across adaptations proposed and requested the lead registrant to submit, amongst other information, the two PNDT studies and the EOGRTS.

15. On 4 June 2017, the lead registrant submitted comments on the draft decision. In its comments, the lead registrant agreed that the data to support its read-across adaptations was '*somewhat limited*'. The lead registrant proposed conducting a toxicokinetics study following OECD test guideline ('TG') 417 in order to demonstrate that the read-across adaptations are valid and that no further pre-natal developmental toxicity and reproductive toxicity testing on benzaldehyde is needed. However, no

changes were made to the information requests in the draft decision following the Appellants' comments.

16. On 20 July 2017, the Agency notified the draft decision to the Member State competent authorities ('MSCAs') for their comments. Proposals for amendment were received from three MSCAs.

17. On 22 September 2017, the lead registrant submitted comments on the proposals for amendment.

18. Between 24 and 26 October 2017, the Member State Committee (the 'MSC') reached unanimous agreement on the Contested Decision. The MSC did not modify the draft decision following consideration of the proposals for amendment.

19. On 18 December 2017, the Agency adopted the Contested Decision in accordance with Article 51(6).

20. The Contested Decision rejects the lead registrant's read-across adaptations and requests the addressees of the Contested Decision to update their registration dossiers by 25 June 2020 with, amongst other things, the following information:

'*[PNDT] study (Annex IX, Section 8.7.2; test method: EU B.31/OECD TG 414) in a first species (rats or rabbits), oral route with the registered substance;*

[PNDT] study (Annex X, Section 8.7.2; test method: EU B.31/OECD TG 414) in a second species (rats if first species was rabbits or rabbits if first species was rats), oral route with the registered substance;

[EOGRTS] (Annex IX/X, Section 8.7.3; test method: OECD TG 443) in rats, oral route, with the registered substance, specified as follows:

- *Ten weeks premating exposure duration for the parental (P0) generation;*
- *Dose level setting shall aim to induce some toxicity at the highest dose level;*
- *Cohort 1A (Reproductive toxicity); and*
- *Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.'*

21. On 3 August 2018, after filing the present appeal, the lead registrant submitted an update to its dossier. The update provided more information in support of the read-across adaptations.

Procedure before the Board of Appeal

22. On 19 March 2018, the Appellants filed this appeal.

23. On 22 May 2018, the Agency filed its Defence.

24. On 10 August 2018, the Appellants filed their observations on the Defence and replied to questions from the Board of Appeal.

25. On 13 December 2018, the Agency filed its observations on the Appellants' observations on the Defence.

26. On 19 December 2018, PETA International Science Consortium Ltd. ('PISC') was granted leave to intervene in support of the Appellants.

27. On 5 February 2019, the Chairman of the Board of Appeal at the time – Mercedes Ortuño – designated Ioannis Dimitrakopoulos to act in the present case as the Chairman of the Board of Appeal, pursuant to the fourth 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, as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.5.2016, p. 4; the 'Rules of Procedure').

28. On 6 March 2019, PISC filed its statement in intervention.

29. On 12 April 2019, the Appellants and the Agency filed their respective observations on the statement in intervention.

30. On 24 June 2019, the Appellants and the Agency respectively replied to questions from the Board of Appeal.

31. On 13 September 2019, the Chairman of the Board of Appeal – Antoine Buchet – designated Sakari Vuorensola to act in the present case as the Legally Qualified Member of the Board of Appeal, pursuant to the first subparagraph of Article 3(2) of the Rules of Procedure.

32. On 25 September 2019, a hearing was held at the Appellants' request. At the hearing, the Parties and the Intervener made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

33. In the Notice of Appeal, the Appellants request the Board of Appeal to annul the Contested Decision in its entirety and to remit the case to the competent body of the Agency for re-evaluation. However, during these appeal proceedings the Appellants clarified that they are seeking annulment of the Contested Decision only insofar as it requests the two PNDT studies and the EOGRTS.

34. The Appellants also request the Board of Appeal to order the refund of the appeal fee.

35. In the alternative, the Appellants request the Board of Appeal to extend the deadline for submitting the requested information to the Agency to at least 36 months or take such other or further measures as justice may require.

36. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

37. According to the Appellants, the properties of benzaldehyde (or the 'target substance') for pre-natal developmental toxicity and reproductive toxicity can be predicted from the properties of benzoic acid, benzyl alcohol and sodium benzoate (or the 'source substances').

38. The Appellants raise several pleas in law against the requirements in the Contested Decision to provide information on the two PNDT studies and the EOGRTS.

39. The Intervener additionally argues that, by imposing a request to conduct vertebrate animal tests on a substance which is used as an ingredient in cosmetic products, the Contested Decision '*requires the Appellants to violate the marketing and animal testing ban*' under Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 342, 22.12.2009, p. 59; the 'Cosmetics Regulation').

40. The Board of Appeal will first examine the admissibility of the Intervener's claim.

Admissibility of the Intervener's arguments related to the use of benzaldehyde as an ingredient in cosmetic products

41. One of the registered uses of benzaldehyde is as an ingredient in cosmetic products. However, neither the Appellants nor the Agency raised any pleas or arguments as regards the use of benzaldehyde as an ingredient in cosmetic products in the Notice of Appeal or the Defence respectively.

42. Arguments regarding the use of benzaldehyde as an ingredient in cosmetic products were first raised by the Intervener.

43. Under Article 8(3) of the Rules of Procedure, an intervener must accept the proceedings before the Board of Appeal as it finds them at the time of the intervention (Case A-022-2013, *REACheck Solutions*, Decision of the Board of Appeal of 15 March 2016, paragraph 47). Article 8(3) of the Rules of Procedure does not preclude an intervener from raising arguments different from those used by the party it is supporting, insofar as they do not alter the framework of the dispute, as defined by the parties (see, to this effect, judgment of 14 March 2013, *Fresh Del Monte Produce* v *Commission*, T-587/08, EU:T:2013:129, paragraphs 536 to 538, and judgment of 15 June 2005, *Regione autonoma della Sardegna* v *Commission*, T-171/02, EU:T:2005:219, paragraphs 152 to 153).

44. The Intervener's claim that the Contested Decision is in breach of the Cosmetics Regulation constitutes a legal plea not contained in the Notice of Appeal. This plea is based on a new fact (the use of benzaldehyde as an ingredient in cosmetic products), which was not referred to in the Notice of Appeal. This plea is not closely related, in law and in fact, to any of the pleas put forward by the Appellants and therefore goes beyond the framework of the dispute as defined by the parties.

45. The Intervener's plea that the Contested Decision is in breach of the Cosmetics Regulation is therefore rejected as inadmissible.

46. The Board of Appeal will next examine the pleas raised by the Appellants. These pleas will be grouped and addressed as follows:

    1. Error of assessment in rejecting the proposed read-across adaptations, and breaches of the principle of proportionality and '*the letter and spirit of [the] REACH [Regulation] with regard to animal welfare'*;
    2. Breach of the Agency's obligation to avoid conflicts of opinion with other European Union ('EU') bodies;
    3. Breach of the requirement for the Contested Decision to be coherent with the Agency's other activities;
    4. Breach of the principle of good administration;
    5. Breach of the principle of legal certainty; and
    6. Imposition of an unreasonable deadline to provide the requested information (Section 6 below).

1. Error of assessment in rejecting the proposed read-across adaptations, and breaches of the principle of proportionality and '*the letter and spirit of [the] REACH [Regulation] with regard to animal welfare*'

Arguments of the Appellants

47. In its registration dossier, the lead registrant sought to adapt the information requirements for the two PNDT studies and the EOGRTS by means of read-across adaptations pursuant to Section 1.5. of Annex XI.

48. The Appellants argue that, contrary to the Agency's conclusion in the Contested Decision, the properties of benzaldehyde for pre-natal developmental toxicity and reproductive toxicity can be predicted by read-across from the source substances for the following reasons:

    (i) the available toxicokinetics studies indicate that benzaldehyde is metabolised rapidly into benzoic acid and therefore the '*systemic human health toxicity*' of benzaldehyde is driven by benzoic acid;

    (ii) whilst benzaldehyde may also be metabolised into benzylmercapturic acid under some circumstances, this secondary metabolic pathway only becomes relevant '*at high, non-biologically relevant doses which saturate the primary pathways*' and therefore would only be relevant at doses which are '*well above any real world exposure situation for humans*'; and

    (iii) the possibility that benzaldehyde could, in addition to its primary and secondary metabolic pathways, be metabolised into other substances via other metabolic pathways is purely theoretical.

49. In order to address shortcomings in the available toxicokinetics data, the Appellants proposed that, following '*a tiered-approach*', they would conduct an OECD TG 417 toxicokinetics study. According to the Appellants, the OECD TG 417 study would demonstrate that benzaldehyde is rapidly metabolised into benzoic acid. The OECD TG 417 study would therefore confirm that the two PNDT studies and the EOGRTS on benzaldehyde are not needed.

50. The Appellants also argue that a recently published toxicokinetics study, Hoffman and Hanneman (2017)[1], provides additional evidence that benzaldehyde is rapidly metabolised into benzoic acid. According to the Appellants, the Hoffman and Hanneman (2017) study demonstrates that the properties of benzaldehyde for pre-natal developmental toxicity and reproductive toxicity can be predicted from the data available on the source substances.

51. Consequently, the Agency should have accepted the read-across adaptations proposed in the lead registrant's dossier and concluded that further animal tests are not necessary. As the Agency failed to '*adequately consider*' the proposed read-across adaptations, the Contested Decision is vitiated by an error of assessment, and breaches the principle of proportionality and '*the letter and spirit of [the] REACH [Regulation] with regard to animal welfare*'.

[1] T. Hoffman and W. Hanneman, *Physiologically-based pharmacokinetic analysis of benzoic acid in rats, guinea pigs and humans: Implications for dietary exposures and interspecies uncertainty*, 2017 Computational Toxicology 3, pp. 19 – 32.

Arguments of the Agency

52. The Agency argues that the read-across adaptations in the lead registrant's dossier do not meet the requirements set out in Section 1.5. of Annex XI for the following reasons:

    (i) the Appellants have not established that the metabolism of benzaldehyde into benzoic acid would be sufficiently rapid and complete to exclude the systemic bioavailability of, and exposure to, benzaldehyde;

    (ii) the Laham and Potvin (1987) study[2] provided by the Appellants shows that benzaldehyde may also be metabolised into benzylmercapturic acid in amounts that may have an impact on the toxicity profile of benzaldehyde; and

    (iii) benzaldehyde may also form other metabolites in addition to benzoic acid and benzylmercapturic acid and these alternative metabolites may be toxicologically relevant.

53. According to the Agency, the existence of secondary metabolic pathways does not preclude read-across from the primary metabolite to a target substance. However, the formation of secondary metabolite(s) may have an impact on the toxicity profile of the target substance and this possibility has to be considered and addressed if a read-across adaptation is applied. In the present case, the Appellants failed to address the potential concerns related to secondary metabolic pathway(s) in their read-across adaptations for benzaldehyde.

54. The Agency also argues that an OECD TG 417 study does not require prior approval from the Agency and therefore the Appellants could have conducted this study at any time. In any event, the results of an OECD TG 417 study could not, on their own, justify the read-across adaptations as new data on toxicokinetics cannot *'remove the established fact'* that systemic exposure to benzaldehyde occurs.

55. The Agency argues that the Hoffman and Hanneman (2017) study could not be taken into account in the Contested Decision as it was not submitted in the lead registrant's dossier or during the compliance check decision-making procedure. In any event, the Hoffman and Hanneman (2017) study focuses on the toxicokinetics of benzoic acid and does not provide clarity on the toxicokinetics of benzaldehyde.

Findings of the Board of Appeal

56. Articles 6 and 7 provide a general obligation for manufacturers or importers of substances on their own, in mixtures or in articles in quantities of one tonne or more per year to register their substances with the Agency.

57. Registrants must submit a registration dossier containing all the information required by the REACH Regulation. In accordance with Article 10(a)(vi) and (vii), this includes information on the intrinsic properties of a substance in accordance with the requirements of Annexes VII to X (the 'testing Annexes').

58. A registrant may meet those requirements by submitting information on the relevant study (Column 1 of the relevant section of the testing Annexes). In the alternative, a registrant may submit a specific adaptation (under Column 2 of the relevant section of the testing Annexes, where applicable) or a general adaptation (under Annex XI).

59. The lead registrant has not submitted information on the relevant studies required under Column 1 of Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X (PNDT studies in a first and second species and EOGRTS respectively). Instead, the lead

[2] *S*. Laham and M. Potvin, *Biological Conversion of Benzaldehyde to Benzylmercapturic Acid in the Sprague-Dawley Rat*, 1987 Drug and Chemical Toxicology 10:3–4, pp. 209 – 225.

registrant has submitted read-across adaptations in accordance with Section 1.5. of Annex XI.

60. Pursuant to Section 1.5. of Annex XI, an information requirement set out in the testing Annexes can be met by means of a read-across adaptation from data available on structurally similar reference substance(s) when the physicochemical, toxicological and ecotoxicological properties of the target substance and the reference substance(s) '*are likely to be similar or follow a regular pattern as a result of structural similarity*'.

61. When relying on a read-across adaptation, it is for the registrant to establish that the adaptation complies with the requirements set out in Section 1.5. of Annex XI. It is not the task of the Agency to develop or improve the adaptation on the registrant's behalf (see Case A-005-2016, *Cheminova,* Decision of the Board of Appeal of 30 January 2018, paragraph 86).

62. The task of the Agency in the compliance check process under Article 41 is to examine whether the evidence provided by the registrant demonstrates that a read-across adaptation meets the requirements set out in Section 1.5. of Annex XI. If the Agency finds that the read-across adaptation proposed by a registrant does not comply with the requirements set out in Section 1.5. of Annex XI, the Agency is required to reject the adaptation and request the registrant to fulfil the relevant information requirement set out in the testing Annexes (see, to this effect, Case A-017-2014, *BASF*, Decision of the Board of Appeal of 7 October 2016, paragraph 76).

63. When an appellant argues that the Agency committed an error of assessment, the Board of Appeal must examine whether the Agency has examined carefully and impartially all the relevant facts of the individual case, and whether those facts support the conclusions that the Agency drew from them (see, by analogy, judgment of 19 January 2012, *Xeda International and Pace International* v *Commission*, T-71/10, EU:T:2012:18, paragraph 71; see Case A-006-2017, *Climax Molybdenum*, Decision of 11 December 2018, paragraph 38).

64. The Board of Appeal will examine whether the arguments put forward by the Appellants are capable of demonstrating that the Agency made an error of assessment when it rejected the read-across adaptations in the lead registrant's dossier (see, by analogy, judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638, paragraph 89).

65. The Contested Decision finds that the read-across adaptations contained in the lead registrant's dossier do not satisfy the requirements set out in Section 1.5. of Annex XI.

66. The Appellants argue that this finding is incorrect for several reasons (see paragraphs 48 to 50 above). However, none of the Appellants' arguments suffice to establish that the Contested Decision is vitiated by an error of assessment.

67. First, the available toxicokinetics studies show that benzaldehyde can be metabolised into at least two substances, benzoic acid and benzylmercapturic acid. It is also possible that benzaldehyde might, in addition to benzoic acid and benzylmercapturic acid, be metabolised into other substances.

68. It is undisputed that the existence of alternative metabolic pathways does not preclude the application of a read-across adaptation based on common metabolites. However, if any such alternative metabolic pathways exist, they must be taken into account and adequately addressed in a read-across justification.

69. In the present case, the possible formation of other metabolites, and the toxicological effects that the alternative metabolic pathways of benzaldehyde may have, were not adequately addressed in the read-across adaptations proposed in the lead registrant's dossier. Consequently, the Appellants have failed to establish that the metabolism of

benzaldehyde would be so rapid and complete as to allow a read-across from the source substances to benzaldehyde. The aim of a compliance check under Article 41 is to verify whether the registration dossier includes information on the intrinsic properties of a substance in accordance with the testing Annexes, not to assess the risks posed by a substance in specific exposure conditions. Therefore, the Appellants' argument that benzaldehyde would metabolise into benzylmercapturic acid only at high doses, cannot call into question the legality of the Contested Decision.

70. Second, as stated in the Contested Decision, the studies provided by the Appellants show significant differences between the toxicological properties of benzaldehyde and benzoic acid. At comparable doses, benzaldehyde (at 800 mg/kg of body weight per day) caused severe toxicological effects in rats, for example death, effects on the brain, and necrosis of the liver[3], whilst benzoic acid (at 750 mg/kg of body weight per day) caused no effects in rats[4].

71. The Appellants have failed to establish why the properties of benzaldehyde for pre-natal developmental toxicity and reproductive toxicity could be predicted from the source substances despite these differences in the toxicological profile of benzaldehyde and benzoic acid.

72. Third, the Agency could not consider the Hoffman and Hanneman (2017) study in the Contested Decision as this study was not included in the lead registrant's dossier and the Appellants did not raise it during the compliance check decision-making procedure leading to the Contested Decision. It follows from the reasons set out in paragraphs 67 to 71 above that the Agency was justified in concluding that the read-across adaptations in the lead registrant's dossier did not comply with Section 1.5. of Annex XI. Therefore, the Agency did not make an error of assessment when it rejected those adaptations.

73. In consequence of that finding, the Contested Decision was correct in identifying the data gaps under Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X in the lead registrant's dossier. Therefore, the Agency had no other choice but to require the lead registrant to bring its dossier into compliance by submitting information on the two PNDT studies and the EOGRTS, or adaptations that fulfil the requirements set out in Column 2 of the relevant sections of the testing Annexes or in Annex XI (see paragraphs 61 to 62 above).

74. The Appellants argue that, by requesting the two PNDT studies and the EOGRTS, the Agency, in addition to committing an error of assessment, breached the principle of proportionality and '*the letter and spirit of [the] REACH [Regulation] with regard to animal welfare*'. This is because carrying out an OECD TG 417 toxicokinetics study would be sufficient to demonstrate that the read-across adaptations in lead registrant's dossier comply with Section 1.5. of Annex XI.

75. However, the Contested Decision does not prevent the lead registrant from performing the OECD TG 417 study, or any other toxicokinetics study, and submitting improved adaptations instead of performing PNDT studies in a first and second species and an EOGRTS. Such improved adaptations would be assessed in accordance with the follow-up process under Article 42 (see judgment of 8 May 2018, *Esso Raffinage* v *ECHA*, T-283/15, EU:T:2018:263, currently under appeal before the Court of Justice, paragraph 62).

76. In any event, Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X oblige a registrant to carry out the two PNDT studies and the EOGRTS unless that registrant

[3] National Institutes of Health, *NTP Technical Report 378 on the Toxicology and Carcinogenesis*, Studies of Benzaldehyde, 1990.

[4] W. Kieckebusch and K. Lang, *The tolerability of benzoic acid in chronic feeding experiments*, 1960 Arzneimittelforschung 10, pp. 1001 – 1003.

demonstrates that an adaptation applies. In the present case, the Agency correctly concluded that the lead registrant's dossier contains data gaps under Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X.

77. As a consequence of the Agency's finding that there are data gaps in the lead registrant's dossier, the Agency had no other choice but to require the lead registrant to either perform the two PNDT studies and the EOGRTS or adapt these information requirements pursuant to Column 2 of the relevant sections of the testing Annexes or Annex XI (see *Climax Molybdenum,* cited in paragraph 63 above, paragraphs 120 to 121).

78. Therefore, the Agency did not breach the principle of proportionality or '*the letter and spirit of [the] REACH [Regulation] with regard to animal welfare*', when it required the lead registrant to bring its dossier into compliance with Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X (see *BASF*, cited in paragraph 62 above, paragraphs 83, 88 and 89).

79. It follows from the above that the Appellants' arguments alleging an error of assessment in relation to Section 1.5. of Annex XI, and breaches of the principle of proportionality and '*the letter and spirit of [the] REACH [Regulation] with regard to animal welfare*' must be rejected.

2. Breach of the Agency's obligation to avoid conflicts of opinion with other EU bodies

Arguments of the Appellants

80. The Appellants argue that the European Food Safety Authority ('EFSA') has treated '*benzyl substances as a grouped category*' and, based on '*the same dataset*' used in the lead registrant's dossier, EFSA has found that benzaldehyde is safe for use in food products.

81. The Appellants argue that, in rejecting the read-across adaptations in the lead registrant's dossier, the Agency contradicted EFSA's findings. According to the Appellants, the Agency therefore breached Article 95 as there was a conflict of opinion between EFSA and the Agency and the Agency did not work to resolve this conflict.

82. The Appellants argue that EFSA has been able to conduct '*human health hazard and risk assessments*' on benzaldehyde using data available on the source substances. It should therefore be possible to assess under the REACH Regulation the human health effects of benzaldehyde on the same basis.

Arguments of the Agency

83. The Agency argues that the studies requested in the Contested Decision are necessary for the Appellants to fulfil the standard information requirements set out in Annexes IX and X for registration purposes under the REACH Regulation.

84. According to the Agency, EFSA examined whether benzaldehyde presents a risk to the health of consumers from its use in food. The Agency assessed whether the lead registrant's dossier is compliant with the information requirements set out in the REACH Regulation '*with a view to evaluate whether testing must be required, and ultimately establishing the intrinsic properties and safety of [benzaldehyde] for human health for non-food uses and non-food exposure levels*'.

85. The Agency argues that EFSA has conducted a very different assessment of benzaldehyde than that conducted by the Agency. Therefore, the conclusions of EFSA are not of direct relevance to the Contested Decision and there is no conflict of opinion.

Findings of the Board of Appeal

86. Pursuant to Article 95, the Agency has to ensure early identification of potential sources of conflict between its opinions and opinions of any other EU body '*carrying out a similar task in relation to issues of common concern*'. Where the Agency identifies a potential source of conflict, it is obliged to contact the other EU body in question. If a fundamental conflict of opinion is confirmed to exist, the Agency and the other EU body must work together to solve the conflict or submit a joint document to the Commission clarifying '*the scientific and/or technical points of conflict*'.

87. The Appellants argue, in essence, that there was a conflict of opinion between the Agency and EFSA on the assessment of benzaldehyde. Therefore, the Agency should have worked together with EFSA in order to resolve this conflict of opinion. The Board of Appeal will examine whether the Agency and EFSA carried out '*a similar task*' and whether the Agency therefore was required to act under Article 95 in order to resolve a potential conflict of opinion.

88. In this regard, it must be observed that the duties of the Agency and EFSA are, in general, different (see judgment of 20 September 2019, *PlasticsEurope* v *ECHA*, T-636/17, EU:T:2019:639, currently under appeal before the Court of Justice, paragraph 65).

89. In its assessment of a substance intentionally added to food under Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law (OJ L 31, 1.2.2002, p. 1; 'the General Food Law Regulation'), EFSA evaluates the risks connected to a particular use, namely the risks incurred by the dietary exposure of consumers to a substance.

90. An EFSA finding that there is no such risk does not mean that the evaluated substance does not present any (other) concern to human health or to the environment or presuppose an overall analysis of the intrinsic properties of the substance (see *PlasticsEurope* v *ECHA*, cited in paragraph 88 above, paragraphs 64 and 67). By contrast, the registration obligation provided for by the REACH Regulation aims to improve the protection of human health and the environment through the identification of the intrinsic properties of chemical substances. To this effect, it requires the submission of specified information on the properties of the substance being registered. In the compliance check process under Article 41, the role of the Agency is to verify whether a registration dossier complies with the information requirements set out, primarily, in the testing Annexes (see paragraphs 56 to 62 above).

91. When conducting a compliance check, the Agency does not assess the risks that exposure to the chemical substance concerned may pose to human health and the environment.

92. In its evaluation under the General Food Law Regulation, EFSA assessed the risk posed by benzaldehyde when used as a food flavouring. Based on this assessment, EFSA concluded that benzaldehyde does not pose a risk to consumers at the estimated levels of intake as a food flavouring.

93. In the compliance check decision-making procedure leading to the Contested Decision, the Agency did not assess the risks that exposure to benzaldehyde poses to human health and to the environment. Instead, the Agency verified whether the information requirements set out in the testing Annexes were fulfilled in the lead registrant's dossier. The Agency found that the lead registrant's dossier did not fulfil the information requirements set out in the testing Annexes as the proposed read-across adaptations did not comply with Section 1.5. of Annex XI.

94. Therefore, there was no conflict of opinion between the Agency and EFSA that required the Agency to take action under Article 95 before adopting the Contested Decision.

95. In light of the above, the Agency and EFSA did not carry out a '*similar task*' within the meaning of Article 95. It follows that the Appellants' plea alleging a breach of Article 95 must be rejected.

3. Breach of the requirement for the Contested Decision to be coherent with the Agency's other activities

Arguments of the Appellants

96. The Appellants argue that, whilst Article 47 specifically requires coherence between the Agency's activities related to substance evaluation, that Article should also be applied to dossier evaluation by analogy '*in light of achieving the spirit and principles of [the] REACH [Regulation]*'.

97. The Appellants argue that the Agency should have been *'more coherent'* in its assessment on benzaldehyde and the source substances. The Agency should have also considered in the Contested Decision the read-across adaptations that had been submitted to the Agency for benzoic acid and benzyl alcohol registrations.

98. The Appellants argue that the Agency was not coherent in its activities as it rejected the read-across adaptations for the registration of benzaldehyde whilst it accepted similar read-across adaptations for both benzoic acid and benzyl alcohol. By failing to ensure the coherence of its activities, the Agency also breached the principle of equal treatment.

Arguments of the Agency

99. The Agency argues that Article 47 concerns only substance evaluation and cannot be applied by analogy to compliance checks.

100. The Agency argues that benzaldehyde is, in any event, '*objectively in a different situation*' than benzyl alcohol and benzoic acid. According to the Agency, the metabolism of benzyl alcohol to benzoic acid via benzaldehyde, as an intermediate metabolite, *'is limited by [the] metabolic capacity'* of the body. The internal exposure to benzaldehyde originating from the metabolism of benzyl alcohol is therefore limited. However, if the human body is exposed directly to benzaldehyde, the systemic availability of benzaldehyde may be much higher.

101. According to the Agency, a read-across therefore '*could be possible'* from benzoic acid to benzyl alcohol but not from benzoic acid to benzaldehyde.

Findings of the Board of Appeal

102. Article 47 is part of the '*Substance evaluation*' Chapter of the REACH Regulation. This Article requires that a substance evaluation is coherent with the Agency's previous activities on the same substance.

103. The present case, however, does not concern a substance evaluation. It concerns the compliance check of a registration dossier in accordance with Article 41 under the '*Dossier evaluation*' Chapter of the REACH Regulation.

104. Article 47, therefore, does not apply to the present case.

105. The requirement in Article 47 also cannot be applied to a compliance check of a registration dossier by analogy. This is due to the differences between the objectives of the substance evaluation and compliance check processes under the REACH Regulation. Whilst the compliance check of a registration dossier normally aims at verifying whether a registration dossier is complete (see paragraph 62 above), the objective of substance evaluation is to clarify the potential risks that a substance poses to human health or the environment (see Case A-005-2014, *Akzo Nobel and Others*, Decision of the Board of Appeal of 23 September 2015, paragraphs 56 to 58 and 77).

106. In performing its tasks under the REACH Regulation, the Agency is nonetheless required to take into consideration all the relevant factors and circumstances of the situation in question (see, by analogy, judgment of 7 March 2013, *Rütgers Germany and Others* v *ECHA*, T-96/10, EU:T:2013:109, paragraph 100; Case A-001-2018, *BrüggemanChemical*, Decision of the Board of Appeal of 9 April 2019, paragraph 67).

107. Consequently, when adopting the Contested Decision in the present case, the Agency was obliged to take into account the arguments of the Appellants as regards the read-across adaptations for benzoic acid and benzyl alcohol to the extent that these arguments were raised during the compliance check of benzaldehyde.

108. In its comments on the draft decision on benzaldehyde, the lead registrant referred to the read-across adaptation provided in the registration dossier for benzoic acid. The Agency took these comments into account in the Contested Decision. The Agency concluded that those comments did not demonstrate that the information requirements for benzaldehyde (for pre-natal developmental toxicity and reproductive toxicity) can be fulfilled by read-across from the source substances. The Appellants have not established that this finding was vitiated by an error.

109. The lead registrant did not refer, in its registration dossier for benzaldehyde or in its comments on the draft decision, to the read-across adaptation used and accepted in the registration dossier for benzyl alcohol. Therefore, the Agency was not required to take into account in the Contested Decision the read-across adaptation used and accepted in the registration dossier for benzyl alcohol.

110. In any event, the toxicokinetics and the metabolism of benzaldehyde may vary depending on whether the human body is exposed directly to benzaldehyde or to benzaldehyde originating from the metabolism of benzyl alcohol in the human body. Therefore, toxicological effects and the metabolic pathways of benzaldehyde may be different depending on its origin.

111. Moreover, as stated in paragraphs 67 to 72 above, the Agency was justified in concluding that the read-across adaptations in the lead registrant's dossier for benzaldehyde did not comply with Section 1.5. of Annex XI.

112. Consequently, the Agency's acceptance of the read-across adaptation from benzoic acid to benzyl alcohol cannot on its own call into question the legality of the rejection of the read-across adaptation proposed in the registration dossier for benzaldehyde.

113. It is therefore clear that the Agency has not failed to adopt a coherent approach in the evaluation of the adaptations concerning benzaldehyde, benzoic acid and benzyl alcohol.

114. As Article 47 does not apply to the present case and as the Agency, in any event, has not failed to be coherent in its different activities as regards benzaldehyde and the source substances, the Appellants' plea alleging a breach of the requirement for coherence of the Contested Decision with the Agency's other activities must be rejected.

4. Breach of the principle of good administration

Arguments of the Appellants

115. The Appellants argue that the Agency breached the duty of good administration by launching a new compliance check process only five months after the rectification of the June 2016 Decision.

116. The Agency did not give the Appellants adequate time to update the registration dossier considering the resource constraints caused by the 2018 REACH registration deadline and other regulatory requirements applying to other substances registered by the Appellants.

Arguments of the Agency

117. The Agency argues that, as the June 2016 Decision was rectified on procedural grounds only, the Agency had a duty to launch a compliance check again as soon as possible.

118. The Agency also argues that the Appellants did not raise the resource constraints issue during the compliance check decision-making procedure and that, in any event, on-going regulatory processes involving other substances do not constitute a valid reason to delay a compliance check.

Findings of the Board of Appeal

119. The principle of good administration, which is a general principle of EU law, is set out in Article 41 of the Charter of Fundamental Rights. It entails, in particular, a duty for the administration to examine carefully and impartially all the relevant aspects of the individual case and the right of the person concerned to be heard and to have an adequately reasoned decision (see judgment of 21 November 1991, *Technische Universität München*, C-269/90, EU:C:1991:438, paragraph 14).

120. The Appellants argue, in essence, that the Agency breached the principle of good administration by launching a new compliance check process too soon after rectifying a previous compliance check decision on the same registration dossier.

121. The June 2016 Decision was rectified by the Executive Director of the Agency because the lead registrant had been unable to comment on the draft decision due to the unavailability of a key member of the lead registrant's staff for medical reasons.

122. Both the June 2016 Decision and the Contested Decision concerned information that the lead registrant was obliged to submit in its registration dossier in 2010.

123. There was therefore no reason for the Agency to delay initiating a new compliance check on benzaldehyde. The Appellants' plea alleging a breach of the principle of good administration must therefore be rejected.

5. Breach of the principle of legal certainty

Arguments of the Appellants

124. The Appellants argue that the Contested Decision puts them in a position of legal uncertainty.

125. The Appellants argue that, if they continue to work on substantiating their read-across adaptations instead of conducting the requested testing on vertebrate animals, the Agency would examine the revised adaptations only after the deadline for providing the

requested information. If the Agency eventually rejected the revised adaptations it would notify the relevant enforcement authorities accordingly.

126. Therefore, the Appellants would face the risk of enforcement action(s) if they decided to work on substantiating their read-across adaptations instead of conducting the requested animal testing.

127. The Appellants argue that the Agency has failed to provide certainty on what would be '*acceptably fast*' metabolism for the read-across adaptations. The Appellants therefore do not know how to address this alleged deficiency in their read-across adaptations.

Arguments of the Agency

128. The Agency argues that the shortcomings of the read-across adaptations were clearly explained in the Contested Decision. According to the Agency, any revised read-across adaptations would be examined in a follow-up process under Article 42 and would be accepted if they met the requirements of Section 1.5. of Annex XI.

Findings of the Board of Appeal

129. The principle of legal certainty, which includes the principle of foreseeability (see *PlasticsEurope* v *ECHA*, cited in paragraph 88 above, paragraph 138), requires that every act of an administration which produces legal effects should be clear and precise so that the person concerned is able to know without ambiguity what its rights and obligations are and to take steps accordingly (see judgment of 1 October 1998, *Langnese-Iglo* v *Commission*, C-279/95 P, EU:C:1998:447, paragraph 78; see also *BrüggemanChemical*, cited in paragraph 106 above, paragraph 44). Those acts must be brought to the notice of those concerned in such a way that they can ascertain exactly the time at which the act comes into being and begins to have legal effects (see, by analogy, judgment of 22 January 1997, *Opel Austria* v *Council*, T-115/94, EU:T:1997:3, paragraph 124).

130. In order to comply with the Contested Decision, the Appellants can remedy the shortcomings in the lead registrant's dossier either by conducting the requested studies and submitting the results to the Agency or by submitting compliant adaptations. If the Appellants submit improved read-across adaptations, they will be assessed in accordance with the follow-up process under Article 42 (see paragraph 75 above).

131. A compliance check decision finding a data-gap in a registration dossier is a foreseeable consequence of a registrant proposing a read-across adaptation that does not comply with Section 1.5. of Annex XI. Whilst the Agency has to provide adequate grounds for such decisions, the registrant is responsible for complying with with the information requirements of the testing Annexes, either by conducting the respective studies or submitting compliant adaptations. It is not the task of the Agency to develop or improve the adaptation on a registrant's behalf (see paragraph 61 above).

132. In light of the above, the Appellants' plea alleging a breach of the principle of legal certainty must be rejected.

6. Imposition of an unreasonable deadline to provide the requested information

Arguments of the Appellants

133. The Appellants argue that the deadline in the Contested Decision for providing the requested information on the two PNDT studies and the EOGRTS is too short as it does not allow the three studies to be conducted sequentially. According to the Appellants, the studies should be conducted sequentially '*because should any study give a classifiable response there is no need to proceed to the next study*'.

Arguments of the Agency

134. The Agency argues that the deadline in the Contested Decision is appropriate because it allows the two PNDT studies to be conducted sequentially. Neither of the PNDT studies can lead to a classification that would be a valid ground for waiving the EOGRTS and *vice versa*. The EOGRTS can therefore be conducted in parallel to the two PNDT studies.

Findings of the Board of Appeal

135. The deadline imposed in the Contested Decision grants the Appellants 30 months and 7 days to provide the requested information. The Appellants argue that at least 36 months would be needed in order to conduct the three studies sequentially.

136. However, the Appellants did not identify any potential outcome from the two PNDT studies that would be a valid ground for waiving the EOGRTS. The Appellants have therefore not demonstrated the need to conduct the two PNDT studies and the EOGRTS sequentially.

137. The Appellants have therefore failed to demonstrate that the deadline imposed by the Contested Decision to provide the requested information would be insufficient.

138. The Appellants' plea alleging a failure to provide sufficient time to provide the requested information must therefore be rejected.

139. As all of the Appellants' pleas have been rejected, the present appeal is dismissed in its entirety.

Refund of the appeal fee

140. 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 shall 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

141. The Contested Decision required the Appellants to submit the requested information or, alternatively, any possible adaptation '*according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI*' by 25 June 2020, which is 30 months and 7 days from the date of its notification.

142. Pursuant to Article 91(2), an appeal has suspensive effect.

143. The Appellants must therefore provide the requested information on the two PNDT studies and the EOGRTS by 1 October 2022.

On those grounds,
THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal in its entirety.**
2. **Decides that the information on the PNDT studies (Annex IX, Section 8.7.2. and Annex X, Section 8.7.2.; test method: EU B.31/OECD TG 414) in first and second species and the EOGRTS (Annex X, Section 8.7.3; test method: OECD TG 443) must be submitted to the Agency by 1 October 2022.**
3. **Orders that the appeal fee will not be refunded.**

Andrew FASEY
On behalf of the Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal