EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

9 November 2021

(Follow-up to dossier evaluation – Article 42(1) of the REACH Regulation – Cessation of manufacture – Legal certainty – Proportionality – Read-across)

Case number	A-009-2020
Language of the case	English
Appellant	Polynt S.p.A., Italy
Representatives	Claudio Mereu and Selma Abdel-Qader Fieldfisher (Belgium) LLP, Belgium
Contested Decision	CCH-D-2114512482-58-01/F of 30 June 2020 adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 42(1) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; the 'REACH Regulation')

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. This appeal concerns the follow-up of a decision on the compliance check of the Appellant's registration dossier for substance esterification products of 1,3-dioxo-2-benzofuran-5-carboxylic acid with nonan-1-ol (EC Number 941-303-6; the 'Substance').

2. On 15 December 2014, the Appellant registered the Substance as the lead registrant at the tonnage band of 1000 tonnes or more per year.

3. In its registration dossier the Appellant sought to fulfil several standard information requirements set out in Annexes VII to X of the REACH Regulation (the 'testing Annexes') by means of adaptations (all references to Articles or Annexes hereinafter concern the REACH Regulation unless stated otherwise). Amongst other adaptations the Appellant sought to fulfil the standard information requirement for a sub-chronic toxicity study (Section 8.6.2. of Annex IX) by means of a read-across adaptation under Section 1.5. of Annex XI.

4. On 18 December 2017, the Agency adopted a decision on the compliance check of the Appellant's registration dossier under Article 41 (the 'initial compliance check decision'). In the initial compliance check decision the Agency rejected the Appellant's adaptations and requested the Appellant to complete its dossier by submitting information on several standard information requirements set out in the testing Annexes.

5. The initial compliance check decision required the Appellant to submit information on a sub-chronic toxicity study (90-day), oral route (Section 8.6.2. of Annex IX, test method: OECD test guideline ('TG') 408) by 3 January 2019.

6. On 3 January 2019, in response to the initial compliance check decision, the Appellant updated its registration dossier. The Appellant sought to fulfil the information requirement for the sub-chronic toxicity study by an updated read-across adaptation.

7. On 28 February 2019, the Agency sent a letter to the Appellant stating that the updated read-across adaptation for the sub-chronic toxicity study was not adequately justified and that the Agency intended to issue a follow-up decision under Article 42(1).

8. On 3 May 2019, the Appellant informed the Agency via the REACH-IT system that it had ceased the manufacture of the Substance.

9. On 19 July 2019, the Agency notified a draft decision to the Appellant under Article 50(1) (the 'draft follow-up decision'). In the draft follow-up decision, the Agency stated that the Appellant's registration dossier '*still does not comply with*' the information requirement for a sub-chronic toxicity study set out in Section 8.6.2. of Annex IX.

10. On 27 August 2019, the Appellant sent a letter to the Agency in which it reiterated that it had ceased the manufacture of the Substance. The Appellant stated that the supplier of the raw material used by the Appellant to manufacture the Substance had stopped producing that raw material following a fire at its production site. The Appellant also stated that the use of any of the alternative raw materials available on the market would result in the production of a different substance than the one registered by the Appellant. The Appellant further stated that it therefore had no other choice but to cease the manufacture of the Substance.

11. On 6 September 2019, the Appellant submitted comments on the draft follow-up decision. In its comments the Appellant stated that, as it had informed the Agency about the cessation of manufacture before receiving the draft follow-up decision, the Agency should not have requested the Appellant to submit further information on the Substance.

The Appellant also explained that it had entered into negotiations on the transfer of the lead registrant role to another registrant of the Substance (the 'other registrant').

12. On 18 October 2019, the Agency sent a letter to the Appellant explaining that the draft follow-up decision did not contain a request for further information but only concluded that the registration dossier of the Appellant was still non-compliant. The Agency stated that the Appellant continued to be bound to provide the information requested in the initial compliance check decision regardless of the cessation of manufacture and of the transfer of the lead registrant role.

13. On 4 November 2019, the Appellant sent to a letter to the Agency in which it stated that the Agency had misinterpreted Articles 41, 42 and 50. The Appellant stated that in adopting a follow-up decision under Article 42(1) the Agency is required to follow the procedure set out in Article 50 and that the Appellant cannot be subject to any information requests as it had informed the Agency of the cessation of manufacture before the receipt of the draft follow-up decision in accordance with Article 50(2).

14. The Agency did not modify the draft follow-up decision and notified it to the competent authorities of the Member States under Article 51(1).

15. On 30 June 2020, as no proposals for amendments were submitted by the competent authorities of the Member States, the Agency adopted the Contested Decision under Article 51(3).

16. The Contested Decision states:

'*Your registration still does not comply with the following information requirement:*

> *Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats with the registered substance*

You are therefore still required to provide the information requested in the original decision.

[…]

The respective Member State competent authority (MSCA) and National enforcement authority (NEA) will be informed of this decision. They may consider enforcement actions to secure the implementation of the original decision and exercise the powers reserved to them under Article 126 […] (penalties for non-compliance) for the period during which the registration dossier was not compliant.'

Procedure before the Board of Appeal

17. On 28 September 2020, the Appellant filed this appeal.

18. On 7 December 2020, the Agency filed its Defence.

19. On 8 February 2021, the Appellant submitted its observations on the Defence.

20. On 12 March 2021, Ekaterina Georgieva 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').

21. On 15 March 2021, the Agency submitted its observations on the Appellant's observations on the Defence.

22. On 10 June 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 Parties made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

23. The Appellant requests the Board of Appeal to:
    - annul the Contested Decision, and
    - order the Agency to pay the costs of these appeal proceedings.
24. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

25. The Appellant raises the following pleas in law:
    - The Agency breached Articles 42(1) and 50 by addressing the Contested Decision to the Appellant although it had lawfully ceased the manufacture of the Substance in accordance with Article 50(2) (first plea);
    - The Agency breached the principle of legal certainty and the principle of legitimate expectations by interpreting and applying Article 50(2) in contradiction with the REACH Regulation and the Agency's guidance documents, and by notifying the Appellant of this interpretation only after the Appellant had received the draft follow-up decision (second plea);
    - The Agency breached, first, the principle of proportionality as the Contested Decision exceeded the limits of what is appropriate and necessary in order to achieve the objectives pursued by the REACH Regulation, and, second, the principle of good administration as the Appellant was not given a possibility to express its views on the Agency's interpretation of Article 50(2) (third plea);
    - The Agency made an error in the assessment of the Appellant's read-across adaptation (fourth plea); and
    - The Agency breached Articles 5 and 6 by requiring the Appellant to generate and submit data on the Substance that could no more be manufactured due to the unavailability of the relevant raw material, and by declaring the Appellant in a situation of non-compliance for not submitting that data (fifth plea).
26. The first, second, third and fifth plea, which all relate to the consequences of the Appellant's cessation of the manufacture of the Substance, will be examined first.

1. First plea: Breach of Articles 42 and 50

Relevant legislation

27. Article 42 ('*Check of information submitted and follow-up to dossier evaluation*') provides:

    '*1. The Agency shall examine any information submitted in consequence of a decision taken under Articles 40 or 41, and draft any appropriate decisions in accordance with these Articles, if necessary.*

    2. Once the dossier evaluation is completed, the Agency shall notify the Commission and the competent authorities of the Member States of the information obtained and any conclusions made. The competent authorities shall use the information obtained from this evaluation for the purposes of Article 45(5), Article 59(3) and Article 69(4).

The Agency shall use the information obtained from this evaluation for the purposes of Article 44.'

28. 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.

4. Notwithstanding paragraphs 2 and 3, further information may be required in accordance with Article 46 in either or both of the following cases:

(a) where the competent authority prepares a dossier in accordance with Annex XV concluding that there is a potential long-term risk to human health or the environment justifying the need for further information;

(b) where the exposure to the substance manufactured or imported by the registrant(s), or to the substance in the article produced or imported by the registrant(s), or to the substance used by the downstream user(s) contributes significantly to that risk.

The procedure in Articles 69 to 73 shall apply mutatis mutandis.'

Arguments of the Parties

29. The Appellant argues that the Agency breached Articles 42(1) and 50 by adopting the Contested Decision and declaring the Appellant in a situation of non-compliance despite the fact that the Appellant had lawfully ceased the manufacture of the Substance in accordance with Article 50(2).

30. The Appellant argues that the Agency was required to respect the procedural safeguards set out in Article 50 in the follow-up process which the Agency started under Article 42(1) following the examination of the information submitted by the Appellant in response to the initial compliance check decision.

31. The Appellant argues that it could not be required to provide any information on the Substance as it had informed the Agency of the cessation of manufacture of the Substance before receiving the draft follow-up decision, in accordance with Article 50(2).

32. The Appellant argues that the Agency erred in considering that the Contested Decision did not contain a request for further information and that the Appellant continued to be bound to provide the information requested in the initial compliance check decision.

33. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

1.1. Cessation of manufacture or import of a substance under the REACH Regulation

34. The consequences of a cessation of manufacture or import of a substance are regulated by Article 50(2) and (3). Those provisions establish a right for any registrant not to be subject to a request for further information after a cessation of manufacture or import.

35. Article 50(2) establishes a rule of general application, regardless of the moment when the cessation of manufacture or import occurs. Article 50(3) establishes a specific rule which is applicable at a certain moment of the evaluation process, upon receipt by the registrant concerned of a draft decision on testing proposal under Article 40, on compliance check under Article 41 or on substance evaluation under Article 46.

36. Article 50(2) and (3) both make use of the same expression to define the consequences of a cessation of manufacture or import on requests for information. Those provisions state that if a registrant ceases the manufacture or import of a substance '*no further information may be requested with respect to that substance*'.

37. Article 50(4) sets out an exception to the rules established in Article 50(2) and (3). Under Article 50(4) further information may be requested in a substance evaluation process under Article 46 regardless of the cessation of manufacture or import if the substance poses a potential long-term risk to human health or the environment, or if the exposure to the substance contributes significantly to that risk.

38. Therefore a registrant that has ceased the manufacture or import of a substance in accordance with Article 50(2) or (3) cannot be requested to provide further information, unless the specific conditions set out in Article 50(4) are fulfilled.

1.2. The objectives of a follow-up process under Article 42(1)

39. The Appellant ceased the manufacture of the Substance after the adoption of the initial compliance check decision under Article 41 but before the receipt of the draft follow-up decision under Article 42(1).

40. The Parties agree that in the present case Article 50(2) is applicable and that the registration of the Appellant is inactive since it has ceased the manufacture of the Substance. However, the Parties disagree about the consequences of the application of Article 50(2) in the follow-up process under Article 42(1) as regards the Appellant's obligation to provide the information requested in the initial compliance check decision.

41. The Appellant argues that following the cessation of manufacture under Article 50(2) it could not be required to provide any information, including the information requested in the initial compliance check decision.

42. The Agency argues that, following the cessation of manufacture, the Appellant continued to be bound to provide the information requested in the initial compliance check decision but cannot be requested to provide any other additional information.

43. In order to decide on this plea, it is therefore necessary to examine what impact a cessation of manufacture or import of a substance under Article 50(2) has on a follow-up process under Article 42(1).

44. An initial compliance check decision adopted under Article 41 identifies one or more data-gaps in the registration dossier concerned, that is to say the information missing from the registration dossier in question, and requires the registrant to submit information to fill those data-gaps. For each data-gap identified in an initial compliance check decision, the registrant concerned must submit information on the study requested or, alternatively, an acceptable adaptation (see, by analogy, Case A-011-2018, *Clariant Plastics & Coatings,* decision of the Board of Appeal of 4 May 2020, paragraph 95).

45. The examination carried out by the Agency under Article 42(1) following an initial compliance check decision that requires a registrant to bring its dossier into compliance is merely the continuation of the same, single procedure. When the Agency prepares a follow-up compliance check decision under Article 42(1), it does not identify data-gaps because the relevant data-gaps have already been identified in the initial compliance check decision. The Agency does not identify again '*further information*' within the meaning of Article 41(3) in a follow-up compliance check decision under Article 42(1) (see Case A-001-2019, *Solvay Fluor*, decision of the Board of Appeal of 21 October 2020, paragraphs 55, 56 and 58).

46. A follow-up compliance check decision under Article 42(1) is therefore intended to determine whether the information provided by the registrant either corresponds to the information requested in an initial compliance check decision, or constitutes compliant adaptations in accordance with the rules laid down in the relevant annexes to the REACH Regulation (see *Solvay Fluor*, cited in the previous paragraph, paragraph 56 of the decision; see also judgment of 8 May 2018, *Esso Raffinage* v *ECHA*, T-283/15, EU:T:2018:263, paragraphs 62 and 63 and judgment of 21 January 2021, *Germany* v *Esso Raffinage,* C-471/18, EU:C:2021:48, paragraphs 135 and 136).

47. The registrant whose dossier has been subject to an initial compliance check decision continues to be bound by all the other relevant information requirements set out in the REACH Regulation (*Germany* v *Esso Raffinage*, cited in the previous paragraph, paragraph 83 of the judgment). The adoption of an initial compliance check decision does not prevent the Agency from identifying, at a later stage, in the same registration dossier, other data-gaps that are different from the data-gaps identified in the initial compliance check decision. However, in such a case, the Agency must start a new compliance check process under Article 41, and cannot base its examination of those potential new data-gaps on Article 42(1).

48. Consequently, the follow-up process under Article 42(1) is strictly limited to an assessment of whether the data-gaps identified in the initial compliance check decision have been filled. The Agency cannot request further information in a follow-up compliance check decision adopted under Article 42(1). Any request for further information, after the adoption of an initial compliance check decision, must be based on a new compliance check process under Article 41.

1.3. Consequences of the cessation of the manufacture after the initial compliance check decision

49. It follows from the reasons set out in paragraphs 34 to 48 above that if a registrant ceases the manufacture or import of a substance, the Agency cannot start, or must discontinue if it has already started, a compliance check process under Article 41, as such a process could lead to a request for further information from that registrant.

Conversely, a registrant continues to be bound by any compliance check decision addressed to it which was adopted before the cessation of the manufacture or import of the substance at issue and the Agency must check under Article 42(1) whether that registrant has complied with that decision.

50. In the present case, the initial compliance check decision identified several data-gaps in the Appellant's registration dossier. One of those data-gaps concerned the requirement to provide information on a sub-chronic toxicity study under Section 8.6.2. of Annex IX. The Appellant sought to fill that data-gap by an updated read-across adaptation and subsequently ceased the manufacture of the Substance before the receipt of the draft follow-up decision.

51. In the follow-up compliance check decision, which is the Contested Decision in the present case, the Agency found that the Appellant's updated read-across adaptation did not meet the requirements of the REACH Regulation and consequently that the Appellant's registration dossier still did not comply with the information requirement set out in Section 8.6.2. of Annex IX.

52. The Contested Decision does not contain any request for further information within the meaning of Article 50(2) but merely concludes that the data-gap regarding the information on a sub-chronic toxicity study that was identified in the initial compliance check decision still has not been filled.

53. The cessation of manufacture did not remove this data-gap from the Appellant's registration dossier and consequently could not relieve the Appellant from the obligation to provide the information requested in the initial compliance check decision.

54. The Appellant continued to be bound to provide the information requested in the initial compliance check decision regardless of the fact that it ceased the manufacture of the Substance after the receipt of that decision. Such a cessation of manufacture only prevents the Appellant from being subject to a new request concerning other information that was not requested in the initial compliance check decision.

55. The initial compliance check decision has not been appealed and is therefore final. The Agency has not withdrawn, rectified nor amended the initial compliance check decision. The initial compliance check decision is therefore valid and enforceable.

1.4. Conclusion on the first plea

56. It follows from the reasons set out in paragraphs 49 to 55 above that the Agency did not breach Article 42(1) or Article 50 by adopting the Contested Decision. The first plea must therefore be rejected as unfounded.

2. Second plea: Breach of the principles of legal certainty and the protection of legitimate expectations

Arguments of the Parties

57. First, the Appellant argues that the Agency breached the principle of legal certainty by construing Article 50(2) as if that provision only applied to the initial compliance check process under Article 41 and not to the follow-up process under Article 42(1), such as the process leading to the Contested Decision.

58. According to the Appellant, both the wording of Article 50(2) and the applicable guidance documents of the Agency, that is to say the practical guide '*How to act in dossier evaluation*' (the 'practical guide') and the document entitled '*Questions and Answers'*, indicate that a registrant can rely on Article 50(2) if it ceases the manufacture or import

before any draft decision, including a draft decision under Article 42(1). The Appellant argues that the Agency breached the principle of legal certainty by interpreting and applying Article 50(2) in contradiction with the Agency's guidance documents and by informing the Appellant of this interpretation only after the Appellant had received the draft follow-up decision.

59. Second, the Appellant argues that it had a legitimate expectation that it would not be required to provide the information requested in the initial compliance check decision after having ceased the manufacture of the Substance. The Appellant argues that neither the REACH Regulation nor the guidance documents of the Agency indicate that Article 50(2) could not be relied on after the initial compliance check decision.

60. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

61. The principle of legal certainty requires that every act of the administration which produces legal effects should be clear and precise so that the person concerned is able to know without ambiguity what his rights and obligations are and to take steps accordingly. As part of the principle of legal certainty, registrants must be able to rely on the most recent instruction issued by the Agency being up-to-date and correct (see Case A-001-2018, *BrüggemannChemical, L. Brüggemann*, decision of the Board of Appeal of 9 April 2019, paragraphs 44 and 50).

62. The right to rely on the principle of the protection of legitimate expectations presupposes that precise, unconditional and consistent assurances originating from authorised, reliable sources have been given to the person concerned by the competent authorities of the European Union ('EU'). In accordance with the Court of Justice's settled case-law, that right applies to any individual in a situation in which an EU institution, body or agency, by giving that person precise assurances, has led that individual to entertain well-founded expectations. Precise, unconditional and consistent information, in whatever form it is given, constitutes such an assurance (*Solvay Fluor,* cited in paragraph 45 above, paragraph 89 of the decision).

63. First, the Appellant argues that it could not foresee the Agency's interpretation of Article 50(2) and take steps accordingly as that interpretation was in contradiction with both the wording of Article 50(2) and the advice given in the applicable guidance documents of the Agency. The Appellant argues that it was therefore placed in a position of legal uncertainty.

64. Second, the Appellant argues that the Agency also breached the principle of the protection of legitimate expectations as based on the wording of the REACH Regulation and the advice given in the guidance documents of the Agency the Appellant had a legitimate expectation that it would not be required to provide any information after the cessation of manufacture of the Substance.

65. The Appellant's arguments must be rejected for the following reasons.

66. The version of the practical guide issued by the Agency in January 2019, which was applicable when the Appellant ceased the manufacture of the Substance, explicitly indicated that a registrant continues to be bound to provide the information requested in an initial compliance check decision if it ceases the manufacture or import of the substance at issue after the receipt of that decision.

67. That part of the practical guide remains unchanged in the most recent version of the practical guide to which the Appellant referred in these appeal proceedings. Section 5.4. of the practical guide states: *'If you cease manufacture or import upon receipt of the adopted decision, being an addressee of the adopted decision, you will still have to*

comply with the information requested' (practical guide '*How to act in dossier evaluation',* January 2019, version 1.0., p. 22; April 2020, version 1.2., p. 23). The same information, in identical terms, appears also in section 6 of the practical guide (p. 24 of version 1.0. and p. 25 of version 1.2.).

68. Similar guidance is given to registrants under the entry number 1580 in the Agency's document entitled '*Questions and Answers',* which the Appellant cited in its submissions in these appeal proceedings. The relevant extract of that document reads as follows: *'If upon receipt of the adopted decision, you cease the manufacture or import of your substance […] you will have to comply with the decision, regardless.'*

69. Therefore, the Agency's interpretation was clearly communicated in the applicable guidance documents, which both stated that a registrant that ceases the manufacture or import of a substance still continues to be bound to provide the information requested in an initial compliance check decision adopted before the cessation of manufacture or import of that substance.

70. The guidance provided by the Agency was clear and precise and enabled the Appellant to know without ambiguity what its rights and obligations are and to take steps accordingly. The Appellant was able to rely on the most recent instruction issued by the Agency. The Appellant's argument that the Agency breached the principle of legal certainty must therefore be rejected.

71. For the same reasons, the applicable guidance documents did not give any assurances that following the cessation of manufacture of the Substance the Appellant would not continue to be bound to provide the information requested in the initial compliance check decision. It follows that the applicable guidance documents gave the Appellant the exact opposite assurances, that is to say that following the cessation of manufacture of the Substance the Appellant would continue to be bound to provide the information requested in the initial compliance check decision. The Appellant's argument that the Agency breached the principle of the protection of legitimate expectations must therefore also be rejected.

72. It follows from the reasons set out in paragraphs 61 to 71 above, that the second plea must be rejected as unfounded.

3. Third plea: Breach of the principles of proportionality and good administration

Arguments of the Parties

73. The Appellant argues that the Agency breached the principle of proportionality for the following reasons.

74. First, the Appellant argues that, by addressing the Contested Decision to the Appellant, the Agency exceeded the limits of what was appropriate and necessary in order to achieve the objectives pursued. According to the Appellant, the Agency could have achieved the objective of ensuring a high level of protection of human health and the environment by addressing the Contested Decision to the other registrant that had not ceased the manufacture of the Substance.

75. Second, the Appellant argues that the disadvantages caused by the Contested Decision are disproportionate to the objectives pursued as the national authorities of the relevant Member State will start enforcement actions following the Contested Decision although the Appellant does not manufacture the Substance anymore.

76. The Appellant argues that the Agency breached the principle of good administration as it failed to take into account in the Contested Decision the Appellant's arguments on the

cessation of manufacture and on the transfer of the lead registrant role. As the Agency addressed those comments only in a separate letter and neither in the draft follow-up decision nor in the Contested Decision, the Appellant considers that its rights to be heard and to have an adequately reasoned decision were breached.

77. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

3.1. Principle of proportionality

78. In order to respect the principle of proportionality, measures adopted by the EU institutions and agencies must not exceed the limits of what is appropriate and necessary in order to achieve the objectives legitimately pursued by the measure in question. When there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see Case A-014-2019, *LG Chem Europe*, decision of the Board of Appeal of 29 April 2021, paragraph 107).

79. First, the Appellant argues that the Agency breached the principle of proportionality as it addressed the Contested Decision to the Appellant instead of addressing it to the other registrant. This argument must be rejected for the following reasons.

80. A follow-up process under Article 42(1) is the continuation of the same, single compliance check process that has started under Article 41 (see paragraph 45 above).

81. In the present case, the compliance check process under Article 41 only involved the Appellant and the initial compliance check decision was addressed only to the Appellant. That decision has not been appealed and is therefore final.

82. The other registrant was not involved in the compliance check process and was not an addressee of the initial compliance check decision. It was therefore legally impossible for the Agency to involve the other registrant in the follow-up process that led to the Contested Decision.

83. Second, the Appellant argues that the Agency breached the principle of proportionality as the Contested Decision may lead to enforcement actions by the national authorities of the relevant Member State and such enforcement actions would be disproportionate as the Appellant has ceased the manufacture of the Substance. This argument must be rejected for the following reasons.

84. Under Article 42(1), it is the exclusive role of the Agency to assess the information provided by a registrant to comply with the initial compliance check decision. If the Agency concludes that the registration dossier remains non-compliant, it must inform the national authorities of the Member States. It is then the exclusive role of the national authorities of the Member States to impose sanctions that are effective, proportionate and dissuasive, having regard to the facts of the case (see *Esso Raffinage* v *ECHA*, cited in paragraph 46 above, paragraphs 61 and 93 of the judgment).

85. In the Contested Decision, the Agency found, without committing an error (see Section 1 above), that the Appellant continued to be bound to provide the information requested in the initial compliance check decision regardless of the fact that it had ceased the manufacture of the Substance after the adoption of that decision. The fact that there is another registrant of the Substance that still manufactures the Substance does not have any bearing on this finding.

86. The consequences of this finding, as regards the potential sanctions that the national authorities of the Member States might take, flow directly from the REACH Regulation.

The Agency was neither required nor empowered to assess the need or the proportionality of such potential sanctions.

3.2. Right to good administration

87. The right to good administration, which is codified in Article 41 of the Charter of the Fundamental Rights of the European Union, requires the administration to examine carefully and impartially all the relevant facts of the individual case, to gather all the factual and legal material necessary for the exercise of its discretion, and to ensure the proper conduct and the efficiency of the procedures it was implementing (see judgment of 3 October 2019, *BASF* v *ECHA*, T-805/17, EU:T:2019:723, paragraph 57; judgment of 3 October 2019, *BASF* and *REACH & colours* v *ECHA*, T-806/17, EU:T:2019:724, paragraph 75).

88. The right to good administration entails the right of the person concerned to be heard and to receive an adequately reasoned decision (see Case A-004-2019, *Arkema*, decision of the Board of Appeal of 24 November 2020, paragraph 45).

89. Under Article 130, the Agency must state reasons for all decisions it takes under the REACH Regulation. The duty to state reasons is an essential procedural requirement which is enshrined in the second paragraph of Article 296 of the Treaty on the Functioning of the European Union and is included in Article 41(2)(c) of the Charter of Fundamental Rights of the European Union as part of the right to good administration (see Case A-001-2020, *SNF*, decision of the Board of Appeal of 29 June 2021, paragraph 134).

90. In its comments on the draft follow-up decision, the Appellant argued that following the cessation of manufacture it was no longer responsible for complying with the request for information on a sub-chronic toxicity study set out in the initial compliance check decision. The Appellant also stated that it was negotiating about the transfer of the lead registrant's role with the other registrant. Similar arguments were raised by the Appellant in the additional letters it sent to the Agency (see paragraphs 10, 11 and 13 above).

91. Those arguments of the Appellant were addressed by the Agency in its letter of 18 October 2019 (see paragraph 12 above). The Agency stated in this letter that the draft follow-up decision does not contain a request for further information and explained that the Appellant was required to comply with the initial compliance check decision regardless of the cessation of manufacture and the transfer of the lead registrant role.

92. In the Contested Decision, the Agency did not directly address the Appellant's comments relating to the cessation of manufacture and the transfer of the lead registrant role. However, in Appendix 2 to the Contested Decision, the Agency stated that *'comments of procedural nature (referring to a cease of manufacture and transfer of the lead registrant role) which do not relate to the content of this decision, have been addressed in a separate communication to you'*.

93. In the present case, the letter of 18 October 2019, to which the Contested Decision referred in its Appendix 2, enabled the Appellant to understand why it continued to be bound to provide the information requested in the initial compliance check decision.

94. The Appellant's involvement in the follow-up process which led to the Contested Decision, coupled with the reasoning in the Contested Decision, enabled the Appellant to understand how the Agency arrived at its conclusions (see, to this effect, Case A-018-2014, *BASF Grenzach*, decision of the Board of Appeal of 19 December 2016, paragraph 217).

95. Therefore, the Agency neither failed to take the cessation of manufacture into account in the Contested Decision nor breached the Appellant's right to be heard and to receive an adequately reasoned decision. The Appellant's arguments that the Agency breached the right to good administration must consequently be rejected.

3.3. Conclusion on the third plea

96. It follows from the reasons set out in paragraphs 78 to 95 above that the Agency did not breach the principle of proportionality or the right to good administration. The third plea must therefore be rejected as unfounded.

4. Fifth plea: Breach of Articles 5 and 6

Relevant legislation

97. Article 5 ('*No data, no market*') provides:

'*Subject to Articles 6, 7, 21 and 23, substances on their own, in mixtures or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.*'

98. Article 6 ('*General obligation to register substances on their own or in mixtures*'), paragraph 1, provides:

'*Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to the Agency.*'

Arguments of the Parties

99. The Appellant argues that the Agency breached Articles 5 and 6 for two reasons.

100. First, the Appellant argues that, following a fire at the production site of its supplier, a raw material that is necessary for the manufacture of the Substance is no longer available. The Appellant argues that it had no other choice but to cease the manufacture of the Substance. Therefore, the Appellant argues that the Agency breached Articles 5 and 6 when it requested the Appellant to generate and submit data on a substance that the Appellant could no longer manufacture.

101. Second, the Appellant argues that the use of any of the alternative raw materials available on the EU market would result in manufacturing a different substance than the one registered by the Appellant. Therefore, according to the Appellant, the Agency also breached Articles 5 and 6 by requesting the Appellant to generate and submit data on a substance that is technically impossible to be manufactured in the EU and by declaring the Appellant in a situation of non-compliance for not submitting that data.

102. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

103. In the support of its fifth plea the Appellant raises, in essence, two different arguments based on *force majeure*.

104. The Appellant argues, first, that it can no longer manufacture the Substance as no suitable raw material is available and, in accordance with Articles 5 and 6, it is therefore not required to provide any further information on the Substance.

105. This argument must be rejected for the following reasons.

106. Article 6 provides a general obligation for manufacturers and 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. Article 5 sets out a generic rule which prohibits placing on the EU market substances which have not been registered.

107. Registrants must submit a registration dossier containing all the information required by the REACH Regulation for the respective tonnage band. Under Article 10(a)(vi) and (vii), this includes information on the intrinsic properties of a substance in accordance with the requirements of the testing Annexes.

108. 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).

109. It is undisputed that at the time of the initial compliance check decision the Appellant was subject to the obligation to register the Substance and to fulfil the standard information requirements of the relevant testing Annexes in accordance with Articles 5 and 6.

110. The Agency did not err in finding in the Contested Decision that the Appellant continued to be bound to provide the information requested in the initial compliance check decision regardless of the cessation of the manufacture of the Substance (see Section 1 above). Therefore, as part of its obligations under Articles 5 and 6, the Appellant continued to be required to provide information on the sub-chronic toxicity study or an acceptable adaptation under Column 2 of Section 8.6.2. of Annex IX or under Annex XI.

111. These findings are independent from the Appellant's reasons for ceasing the manufacture of the Substance. The Appellant's obligation to submit information on the Substance flow directly from the provisions of the REACH Regulation, which were correctly interpreted by the Agency, in particular as regards the consequences of the cessation of manufacture of the Substance after the adoption of the initial compliance check decision.

112. Therefore, the fact that the Appellant ceased the manufacture of the Substance due to *force majeure*, or to any other circumstances, and the fact that the Appellant can no longer manufacture the Substance, do not relieve the Appellant from the obligation to provide the information requested in the initial compliance check decision, which was adopted before the cessation of manufacture of the Substance.

113. The Appellant argues, second, that no one else can manufacture the Substance due to the lack of suitable raw material. According to the Appellant, there are differences in the compositions of the raw material used by the Appellant to manufacture the Substance and the alternative raw materials that are currently available on the market. The Appellant argues that it is therefore impossible to obtain a sample of suitable test material for the requested sub-chronic toxicity study.

114. This argument must be rejected for the following reasons.

115. As the Agency stated in Section 4 of Appendix 3 to the initial compliance check decision, it is the responsibility of the registrants that jointly register a substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

116. In the present case, the Appellant has not established that it would be impossible to perform the sub-chronic toxicity study due to the unavailability of a suitable sample of relevant test material. The Appellant's argument that the raw materials differ in their

composition (see paragraph 113 above) does not suffice to demonstrate that a sub-chronic toxicity study performed on test material supplied by the other registrant, or by any other potential manufacturer of the Substance, would not provide relevant data for the registration dossier of the Appellant.

117. In addition, this argument contradicts an argument which the Appellant raised to support its plea concerning the breach of the principle of proportionality (see Section 3 above). In support of that plea, the Appellant argues that the Agency should have addressed the Contested Decision to the other registrant which has not ceased the manufacture of the Substance (see paragraph 74 above). Therefore, the Appellant itself argues that the other registrant is able to provide information on the sub-chronic toxicity study as it is requested in the initial compliance check decision. Consequently, the Appellant also acknowledges that the other registrant is able to provide a sample of suitable test material for the requested sub-chronic toxicity study.

118. It follows from the reasons set out in paragraphs 103 to 117 above that the Agency did not breach Articles 5 and 6 in adopting the Contested Decision. The fifth plea must therefore be rejected as unfounded.

119. As all the pleas related to the consequences of the Appellant's cessation of manufacture of the Substance are rejected, it is necessary to also examine the Appellant's fourth plea by which the Appellant claims that the Agency made an error of assessment in rejecting the read-across adaptation for a sub-chronic toxicity study under Section 8.6.2. of Annex IX.

5. Fourth plea: Error of assessment

Arguments of the Parties

120. The Appellant argues that the Agency failed to examine, carefully and impartially, all the relevant information submitted by the Appellant, and in particular the updated read-across adaptation that the Appellant submitted in response to the initial compliance check decision.

121. The Appellant argues that the sub-chronic toxicity properties of the Substance (the 'target substance') can be predicted from the data available on three structurally related chemical compounds (the 'three source substances') by means of read-across under Section 1.5. of Annex XI. According to the Appellant, the Substance and the three source substances belong to the same pool of structurally related chemical compounds which are metabolised into structurally similar breakdown products. The Appellant argues that it adequately justified the read-across adaptation by establishing sufficient similarity between the Substance and the three source substances.

122. The Appellant argues that, contrary to the Agency's conclusion in the Contested Decision, the sub-chronic toxicity properties of the Substance can therefore be predicted from the information available on the three source substances.

123. The Agency disputes Appellant's arguments.

Findings of the Board of Appeal

124. In its registration for the Substance, the Appellant did not submit information on the study required under Column 1 of Section 8.6.2. of Annex IX. Instead, the Appellant sought to fulfil the information requirement of Section 8.6.2. of Annex IX by means of a read-across adaptation under Section 1.5. of Annex XI.

125. Under 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 source substance(s) when the physicochemical, toxicological and ecotoxicological properties of the target substance and the source substance(s) are likely to be similar or follow a regular pattern as a result of structural similarity.

126. When relying on a read-across adaptation, it is for the registrant to provide evidence establishing that the adaptation complies with the requirements set out in Section 1.5. of Annex XI. The task of the Agency 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 (see Case A-006-2018, *Emerald Kalama Chemical and Others*, decision of the Board of Appeal of 24 March 2020, paragraphs 61 and 62).

127. Section 1.5. of Annex XI therefore allows for an adaptation if it is established that (i) the substances in a group or category are structurally similar, (ii) the properties of the substances are likely to be similar or follow a regular pattern, and (iii) the similarity of properties or their regular pattern is the result of structural similarity (see joined Cases A-016-2019 to A-029-2019, *Lubrizol France and Others*, decision of the Board of Appeal of 23 February 2021, paragraph 100).

128. In the present case, the structural similarity of the Substance and the three source substances is not disputed. It is therefore not disputed that the first of the three cumulative conditions referred to in the previous paragraph is fulfilled.

129. However, in the Contested Decision, the Agency found that the Appellant had not provided relevant, reliable and adequate information that would allow to compare the toxicological effects caused by repeated exposure to the Substance and the three source substances, such as studies of comparable design and duration (bridging studies) on both the Substance and the three source substances.

130. The Agency found that the predictions from computational methods on which the Appellant's read-across adaptation was based were not sufficient to support the hypothesis that the toxicological properties of the Substance and the three source substances are likely to be similar or follow a regular pattern. Therefore, the Agency concluded that the second of the three cumulative conditions referred to in paragraph 127 above was not fulfilled.

131. Three reasons support this conclusion in the Contested Decision.

132. In the first place, the Agency found that the information provided by the Appellant was not sufficient to predict the impact of all the constituents of the Substance and the three source substances on their respective toxicological properties.

133. In the second place, the Agency found that the Appellant had not provided the necessary information on the rate of metabolism of each step of the predicted three-step metabolic pathway of the Substance and the three source substances.

134. In the third place, the Agency found that according to the data provided by the Appellant the Substance may form potentially hepatotoxic metabolites which are not predicted to be formed from the three source substances. The Agency pointed out that as a result of this difference in the metabolism the Substance may have different toxicological properties than the three source substances.

135. The Appellant argues that the predictions from computational methods that it has provided are sufficient to demonstrate that the toxicological properties of the Substance and the three source substances are likely to be similar. Therefore, according to the Appellant, the Agency made an error of assessment when it rejected the Appellant's read-across adaptation. This argument must be rejected for the following reasons.

136. First, whilst the Appellant provided computational predictions on the properties of some of the contituents of the Substance and the three source substances, those computational predictions did not cover all the constituents of the Substance and the three source substances. Some of the constituents that were not covered may lead to differences in the toxicogical properties of the Substance and the three source substances. Therefore, the information provided by the Appellant remains incomplete in this respect.

137. Second, the Appellant did not provide any evidence to refute the Agency's findings concerning the lack of sufficient data on the rate of metabolism of each step of the predicted three-step metabolic pathway of the Substance and the three source substances.

138. Third, the Appellant did not provide any evidence to refute the Agency's findings concerning the fact that the Substance may cause more severe toxicological effects than the three source substances as a result of its potential hepatotoxic metabolites.

139. As a consequence, the Appellant has not established that the toxicological properties of the Substance and the three source substances would be likely to be similar or follow a regular pattern and that therefore the sub-chronic toxicity properties of the Substance could be predicted from the data avaible on the three source substances.

140. Consequently, the Agency did not make an error of assessment when it considered that the Appellant had failed to provide adequate evidence to support its read-across hypothesis as required by Section 1.5. of Annex XI and rejected the Appellant's read-across adaptation.

141. It follows from the reasons set out in paragraphs 124 to 140 above that the fourth plea must be rejected as unfounded.

Conclusion on the appeal

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

Claim for the reimbursement of costs

143. In the Notice of Appeal, the Appellant requests the Board of Appeal to order the Agency to pay the costs of these proceedings.

144. The Rules of Procedure do not provide for the reimbursement of costs that are not, as provided in Articles 17 and 21(1)(h) thereof, related to the taking of evidence. Furthermore, Article 17a of the Rules of Procedure provides that the parties shall bear their own costs.

145. Consequently, and as in the present case no costs arose in relation to the taking of evidence, the Appellant's request for reimbursement of costs is rejected.

Refund of the appeal fee

146. Pursuant to 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 is refunded if the appeal is decided in favour of an appellant. As this appeal is dismissed, the appeal fee is not refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**

2. **Rejects the claim for the reimbursement of costs incurred in these proceedings.**

3. **Decides that the appeal fee is not refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal