EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

17 January 2023

(Substance evaluation – Article 47(1) – Legal certainty – Misuse of powers – Proportionality – Error of assessment)

Case number	A-009-2021
Language of the case	English
Appellant	SCAS Europe S.A./N.V., Belgium
Representatives	Ruxandra Cana, Eléonore Mullier and Lukasz Gorywoda Steptoe & Johnson LLP, Belgium
Intervener	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), France
Contested Decision	Decision of 12 March 2021 on the substance evaluation of resorcinol adopted by the European Chemicals Agency under Article 46 of the REACH Regulation The Contested Decision was notified to the Appellant under annotation number SEV-D-2114545856-36-01/F

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

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1. Background to the dispute

1. This appeal concerns the substance evaluation of resorcinol[1] as regards its potential endocrine disrupting properties for the environment.

2. The Appellant is the lead registrant for resorcinol and registered resorcinol as an only representative on behalf of non-EU manufacturers.

1.1. The first substance evaluation of resorcinol

3. On 29 February 2012, the Agency included resorcinol in the Community rolling action plan (CoRAP) for substance evaluation. The Competent Authority of Finland (TUKES) was appointed as the evaluating Member State Competent Authority for the substance evaluation.

4. On 24 October 2017, TUKES issued a document entitled: 'Substance evaluation conclusion as required by REACH[2] Article 48 and evaluation report for resorcinol' (the conclusion document). TUKES concluded that whilst the available data is not conclusive, resorcinol '*is likely an ED [endocrine disruptor] substance for the thyroid with a TPO (thyroid peroxidase) inhibitor mode of action*'.[3] However, TUKES stated that the population level adversity in the environment had not been studied and could not be proven by using the study methods available in the test guidelines (TG) of the OECD[4].

5. In particular, TUKES held that by conducting an Amphibian Metamorphosis Assay (AMA) or a Larval Amphibian Growth and Development Assay (LAGDA) it may not be possible to gain such new information '*that would significantly change or improve the conclusion on thyroid disrupting properties of resorcinol*'. As a result, TUKES did not suggest requesting further information from the registrants of resorcinol and therefore did not prepare a draft decision under Article 46(1).[5]

6. On 7 May 2018, TUKES issued a risk management option analysis (RMOA) on resorcinol. In this document, TUKES proposed that resorcinol would, in addition to the existing harmonised classifications under Annex VI of the CLP Regulation[6], be classified as harmful to aquatic life with long-lasting effects and as a skin sensitiser. Besides, TUKES considered that based on the available evidence resorcinol does not fulfil the conditions under Article 57(f) for identifying it as a substance of very high concern for an equivalent level of concern as an endocrine disruptor.[7]

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1 EC No 203-585-2, CAS No 108-46-3.

2 Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1). All references to Articles, Titles and Annexes concern the REACH Regulation unless stated otherwise.

3 TUKES, Substance evaluation conclusion as required by REACH Article 48 and evaluation report for resorcinol, 24 October 2017, p. 66.

4 Organisation for Economic Co-operation and Development.

5 TUKES' Substance evaluation conclusion document cited in footnote 3, pp. 2 and 66-67.

6 Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

7 TUKES, Risk management option analysis conclusion document, substance name: resorcinol, 7 May 2018, pp. 5-6 and 8.

1.2. The second substance evaluation of resorcinol

7. On 19 March 2019, following a proposal of the Competent Authority of France (ANSES) and an opinion of the Member State Committee (MSC)[8], the Agency reinserted resorcinol in the CoRAP. ANSES was appointed as the evaluating Member State Competent Authority for the substance evaluation.

8. The reinsertion of resorcinol in the CoRAP was based on a justification document issued by ANSES (the CoRAP justification document). In the CoRAP justification document, ANSES held that in light of two guidance documents[9, 10] which had been published after the first substance evaluation process was concluded, further testing, for example LAGDA, could provide sufficient information on whether resorcinol has endocrine disrupting properties for the environment.

1.3. The Contested Decision

9. On 18 March 2020, ANSES submitted to the Agency a draft decision in accordance with Articles 46(1) and 52(1).

10. On 16 April 2020, in accordance with Article 50(1), the Agency notified the draft decision to the Appellant and invited it to provide comments. The draft decision requested the Appellant to provide information on a LAGDA according to OECD TG 241.

11. On 19 June 2020, the Appellant submitted comments on the draft decision in accordance with Article 50(1).

12. On 29 October 2020, ANSES notified a revised draft decision to the competent authorities of the other Member States and the Agency in accordance with Article 52(1). TUKES and the Competent Authority of the Netherlands made proposals for amendment in accordance with Article 51(2) but did not oppose the request for LAGDA.

13. On 4 December 2020, the Agency notified the revised draft decision and the proposals for amendment to the Appellant.

14. On 14 December 2020, the Agency referred the revised draft decision to the MSC.

15. On 4 January 2021, the Appellant submitted comments on the proposals for amendment.

16. In its meeting of 9 to 11 February 2021, the MSC reached unanimous agreement on the draft decision.

17. On 12 March 2021, the Agency adopted the Contested Decision.

18. The Contested Decision requires the Appellant to update their registration dossier by 19 September 2022 with information on a LAGDA.

2. Procedure before the Board of Appeal

19. On 11 June 2021, the Appellant filed this appeal.

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[8] ECHA, Minutes of the 63rd Meeting of the Member State Committee, 5-7 February 2019, p. 10-11.

[9] Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption, 3 September 2018.

[10] Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, 7 June 2018.

20. On 6 September 2021, the Agency submitted its Defence.

21. On 5 November 2021, the Appellant submitted observations on the Defence.

22. On 7 December 2021, ANSES was granted leave to intervene in support of the Agency.

23. On 24 January 2022, the Agency submitted its observations on the Appellant's observations on the Defence.

24. On 31 January 2022, ANSES filed its statement in intervention.

25. On 3 March 2022, the Appellant and the Agency submitted their observations on the statement in intervention.

26. On 13 September 2022, a hearing was held at the Appellant's request. At the hearing, the Appellant and the Agency made oral submissions and responded to questions from the Board of Appeal.

3. Form of order sought

27. The Appellant requests the Board of Appeal to:

- annul the Contested Decision,
- order the refund of the appeal fee, and
- take such other or further measures as justice may require.

28. The Agency, supported by ANSES, requests the Board of Appeal to dismiss the appeal as unfounded.

4. Assessment of the case

29. The Appellant raises the following pleas in law, alleging that the Agency:

- breached Article 47(1) and the principle of legal certainty and misused its powers in adopting the Contested Decision (first plea); and
- breached the principle of proportionality, committed errors of assessment, and failed to take all information into account in requesting the LAGDA (second plea).

4.1. First plea: Breach of Article 47(1), breach of the principle of legal certainty and misuse of powers

30. By the first plea, the Appellant argues that the Agency:

- breached Article 47(1) (first part of the first plea),
- breached the principle of legal certainty (second part of the first plea), and
- misused its powers (third part of the first plea).

4.1.1. First part of the first plea: Breach of Article 47(1)

Arguments of the Parties

31. By the first part of the first plea, the Appellant argues that the Agency breached Article 47(1) in adopting the Contested Decision.

32. The Appellant argues that the conclusion document issued by TUKES constituted a decision, which triggered the application of the conditions set out in the third

sentence of Article 47(1), under which the re-opening of a substance evaluation may be justified only by a change of circumstances or acquired knowledge.

33. According to the Appellant the conditions set out in the third sentence of Article 47(1) were not fulfilled in the present case. There was no such change of circumstances or acquired knowledge that could have justified the adoption of the Contested Decision.

34. The Agency, supported by ANSES, disputes the Appellant's arguments.

Findings of the Board of Appeal

35. Article 46 provides:

'1. If the competent authority considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission. A draft decision shall be prepared within 12 months of the publication of the Community rolling action plan on the Agency's website for substances to be evaluated that year. The decision shall be taken in accordance with the procedure laid down in Articles 50 and 52.

[…]

4. The competent authority shall finish its evaluation activities within 12 months of the start of the evaluation of the substance or within 12 months of the information being submitted under paragraph 2, and notify the Agency accordingly. If this deadline is exceeded, the evaluation shall be deemed to be finished.'

36. The third sentence of Article 47(1) provides:

'*In cases where a decision on an evaluation has been previously taken in accordance with Article 51 or Article 52, any draft decision requiring further information under Article 46 may be justified only by a change of circumstances or acquired knowledge.'*

37. The third sentence of Article 47(1) sets out a specific threshold for the evaluation of a substance which has previously been subject either to a decision on a testing proposal or on dossier evaluation under Article 51 or to a decision on substance evaluation under Article 52. In other terms, as regards substance evaluation, it is only in cases where a decision under Article 52 has been previously taken on a substance that the conditions set out in the third sentence of Article 47(1) apply to a potential new evaluation of the same substance.

38. The evaluating Member State Competent Authority of the first substance evaluation, TUKES, concluded its evaluation under Article 46(4) without preparing a draft decision in accordance with Article 46(1).

39. As the first substance evaluation process did not lead to a decision under Article 52, the conditions set out in the third sentence of Article 47(1) do not apply in the present case and do not need to be assessed.

40. The first part of the Appellant's first plea is therefore unfounded and must be rejected.

4.1.2. Second part of the first plea: Breach of the principle of legitimate expectations as a corollary of the principle of legal certainty

Arguments of the Parties

41. By the second part of the first plea, the Appellant argues that the Agency breached the principle of legitimate expectations which is a '*corollary of the principle of legal certainty*'.

42. The Appellant argues that it could not reasonably have expected a new substance evaluation to be conducted on resorcinol a few years after the conclusion of the first substance evaluation process where (i) the properties investigated were the same, (ii) the circumstances in terms of the test were essentially unchanged and (iii) the opposite conclusion was reached.

43. The Agency, supported by ANSES, disputes the Appellant's arguments.

Findings of the Board of Appeal

44. The principle of legal certainty requires that rules of law must be clear and precise, and that their application must be foreseeable by those subject to them.[11]

45. The principle of the protection of legitimate expectations presupposes that the administration gave the person concerned precise assurances, leading that person to entertain justified expectations. Information which is precise, unconditional and consistent, in whatever form it is given, constitutes such assurances.[12]

46. In the present case, the Agency did not adopt any decision nor take any position on the basis of the outcome of the first substance evaluation process.

47. The Appellant was explicitly made aware of the absence of position of the Agency in the disclaimer contained in the conclusion document issued by TUKES at the end of the first substance evaluation process. The disclaimer stated: '*The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. […] Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage'*.[13]

48. Moreover, in the conclusion document TUKES did not set aside the potential risk for endocrine disrupting properties for the environment with a thyroid peroxidase inhibitor mode of action. To the contrary, TUKES held that resorcinol likely has endocrine disrupting properties, but considered that it may not be possible to obtain such new information with an AMA or a LAGDA that would significantly change or improve the conclusion on thyroid disrupting properties of resorcinol, due to the lack of apical endpoints in the test methods that would indicate clear (population level) adversity mediated by the hypothalamic-pituitary-thyroid (HPT) axis.[14]

49. The issuance of the conclusion document after the first substance evaluation process did not give rise to any legitimate expectations that resorcinol could not in

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[11] Judgment of 11 September 2019, *Călin*, C-676/17, EU:C:2019:700, paragraph 50; decision of the Board of Appeal of 31 October 2022, *Croda EU*, A-011-2021, paragraph 63.

[12] Judgment of 16 September 2021, *FVE Holýšov I and Others* v *Commission*, C-850/19 P, EU:C:2021:740, paragraph 34; *Croda EU*, cited in footnote 11, paragraph 26 of the decision.

[13] TUKES' Substance evaluation conclusion document cited in footnote 3 above, p. 3.

[14] TUKES' Substance evaluation conclusion document cited in footnote 3 above, p. 62.

the future be subject to another substance evaluation concerning its potential endocrine disrupting properties for the environment.

50. The second part of the Appellant's first plea is therefore unfounded and must be rejected.

4.1.3. Third part of the first plea: Misuse of powers

Arguments of the Parties

51. By the third part of the first plea, the Appellant argues that the Agency misused its powers since diverging national priorities do not constitute a potential risk that would allow requesting further information in a substance evaluation process under Article 46.

52. The Appellant argues that the Agency misused its powers as it made use of the second substance evaluation process to pursue an objective of a national nature, as resorcinol is the subject of a national priority plan in France. The Appellant's argument is based on the following statement in the CoRAP justification document issued by ANSES: *'[R]esorcinol has been included in 2018 into the French National Strategy for Endocrine Disruptor and its evaluation and regulation if relevant are considered a national priority for [ANSES]'.*

53. The Agency, supported by ANSES, argues that the third part of the first plea is inadmissible and, in any event, unfounded.

Findings of the Board of Appeal

(a) Admissibility

54. The Agency argues that by the third part of the first plea the Appellant is challenging the decision taken by the Agency in 2019 to reinsert resorcinol in the CoRAP, instead of challenging the Contested Decision.

55. According to the Agency, the third part of the first plea is therefore inadmissible as the Board of Appeal is not competent to decide on appeals against the Agency's decision to include a substance in the CoRAP.

56. By the third part of the first plea, the Appellant argues, in essence, that the reason for initiating the second substance evaluation process leading to the Contested Decision was the fact that resorcinol is part of a national priority plan in France.

57. Whilst the Appellant's argumentation on the misuse of powers is based on the CoRAP justification document, the Appellant uses this argumentation to challenge the adoption of the Contested Decision.

58. The Agency's inadmissibility claim must therefore be rejected.

(b) Substance

59. When an appellant claims that the Agency misused its powers, it is necessary to examine whether the Agency adopted a measure with the exclusive or main purpose of achieving an end other than that stated or evading a procedure specifically prescribed by the REACH Regulation for dealing with the circumstances of the case. A decision amounts to a misuse of powers if it appears, on the basis of objective,

relevant and consistent factors, to have been taken to achieve an end other than that stated.[15]

60. The reasons for adopting the Contested Decision were set out in its Appendix entitled '*Reasons to request information to clarify the risk related to Endocrine disruption*'.

61. In those reasons, the Agency stated that resorcinol may pose a risk to the environment due to its potential endocrine disrupting properties and further information is needed to clarify that potential risk.

62. Therefore, the reason for adopting the Contested Decision was the identification of the potential risk that resorcinol poses and not the existence of a national priority plan concerning the same substance. Consequently, the Agency did not misuse its powers.

63. The third part of the Appellant's first plea is therefore unfounded and must be rejected.

4.1.4. Conclusion on the first plea

64. As all its three parts are rejected, the first plea must be rejected in its entirety.

4.2. Second plea: Breach of the principle of proportionality, errors of assessment and failure to take all relevant information into account

Arguments of the Parties

65. By the second plea, the Appellant argues that the Agency breached the principle of proportionality, erred in its assessment and failed to take all relevant information into account in requesting the LAGDA.

66. According to the Appellant, the Agency failed to establish that resorcinol poses a potential risk to human health or the environment based on a combination of available information on hazard and exposure. Therefore, in the absence of a potential risk, there is no need to investigate the endocrine disrupting properties of resorcinol further and therefore the requested LAGDA is unnecessary.

67. First, the Appellant argues that the Agency erred in the assessment of the available data as regards the potential hazard. The Appellant argues specifically that:

- the available *in vitro* studies on thyroid peroxidase inhibition are not sufficient to establish that resorcinol may have endocrine disrupting properties for the environment;
- the Agency's conclusion on the potential endocrine disrupting properties is based on the wrong assertion that resorcinol would have a high potency to induce thyroid peroxidase inhibition and would therefore lead to adverse effects even at low concentrations;
- based on the available toxicokinetic studies on resorcinol and other phenolic compounds it is highly unlikely that resorcinol would, '*at environmentally relevant concentrations*', enter the thyroid glands of amphibians at sufficient levels to induce thyroid function disruption;

[15] Judgment of 20 September 2017, *Tilly-Sabco SAS* v *Commission*, C-183/16 P, EU:C:2017:704, paragraph 64; decision of the Board of Appeal of 13 December 2017, *Akzo Nobel Chemicals and Others*, A-023-2015, paragraph 158.

- the thyroid effects detected in the available mammalian studies are not consistent or statistically not significant and therefore do not support the Agency's conclusion on the potential endocrine disrupting properties;
- the available aquatic toxicity studies are irrelevant as none of them was specifically designed to assess potential endocrine disrupting effects;
- the Thienpont *et al.* (2011)[16] and Jarque *et al.* (2018)[17] studies on fish are unreliable as they are subject to several limitations and uncertainties.

68. Second, the Appellant argues that the Agency erred in its conclusion on the potential exposure.

69. According to the Appellant, the Agency failed to take into account the available information related to potential exposure to resorcinol in the environment. More specifically, the Agency erred by requiring the Appellant to demonstrate that the potential exposure to the environment originating from the use of resorcinol is excluded and by failing to assess if a potential risk can occur in reality.

70. According to the Appellant, the emissions of resorcinol to the aquatic and terrestrial environments are minor, firstly because sufficient risk management measures are already applied, and secondly because industrial and consumer uses do not increase the presence of resorcinol in the environment beyond the baseline presence due to natural sources.

71. Third, the Appellant argues that:

- the LAGDA could lead to false positive results or to uncertainties as regards the interpretation of the results as the LAGDA test guideline is insufficiently validated, the historical data is limited, and the testing laboratories do not have enough experience with the test; and
- the results of the LAGDA would not be reliable, because the physico-chemical properties of resorcinol make it difficult to maintain the concentration of resorcinol in the course of the study.

72. Fourth, the Appellant argues that conducting the LAGDA does not have a realistic possibility of leading to improved risk management measures as the current risk management measures are already adequate.

73. The Agency, supported by ANSES, disputes the Appellant's arguments.

Findings of the Board of Appeal

74. To comply with the principle of proportionality, measures adopted by the Agency must not exceed the limits of what is appropriate and necessary to attain the objectives legitimately pursued by that measure; 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.[18]

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[16] B. Thienpont *et al.*, Zebrafish Eleutheroembryos Provide a Suitable Vertebrate Model for Screening Chemicals that Impair Thyroid Hormone Synthesis. Environmental Science & Technology 45(17) (2011), pp. 7525-32.

[17] S. Jarque *et al.*, An automated screening method for detecting compounds with goitrogenic activity using transgenic zebrafish embryos. PLoS One 13 (8):e0203087 (2018). doi:10.1371/journal.pone.0203087.

[18] Decision of the Board of Appeal of 10 May 2022, *LANXESS Deutschland,* Case A-002-2021, paragraph 88.

75. To demonstrate the necessity of a request for information under substance evaluation, the Agency must establish that:

- there are grounds for considering that, based on a combination of information on potential hazard and potential exposure, a substance constitutes a potential risk to human health or the environment;
- the potential risk needs to be clarified; and
- the requested information, needed to clarify the concern, has a realistic possibility of leading to improved risk management measures.[19]

76. To request information under substance evaluation, it is not necessary for the Agency to demonstrate an actual risk, only a potential risk. The aim of requesting additional information under substance evaluation is to clarify the risk.[20]

77. This is consistent with the different types of risk that must be taken into account at different stages of the processes established by the REACH Regulation.

78. This is also consistent with the European Union Courts' interpretation of the precautionary principle according to which '*a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time the measure was taken*'.[21]

79. A request for further information under substance evaluation cannot be triggered by a purely hypothetical risk[22] or by a failure to prove the lack of any risk[23].

80. It is the Agency's responsibility to justify a request for further information under substance evaluation by demonstrating that the three conditions of the necessity test referred to in paragraph 75 above are met.

81. When an appellant challenges such information request it must show that the Agency erred in its conclusions on one or more of those three conditions.

82. In assessing the Appellant's pleas that the Agency committed errors of assessment, it must therefore be examined whether the arguments put forward by the Appellant demonstrate that the Agency made errors and failed to take all relevant information into account in concluding that those three conditions are met in the present case.[24]

83. The principle of proportionality also requires that the requested information must be capable of achieving its objective. Therefore, in order to demonstrate the appropriateness of an information request in the context of substance evaluation,

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[19] Judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638, paragraph 276, and *LANXESS Deutschland*, cited in footnote 18, paragraph 89 of the decision.

[20] *BASF Grenzach* v *ECHA*, cited in footnote 19, paragraphs 269 to 273 of the judgment; decision of the Board of Appeal of 22 March 2022, *Campine*, Case A-003-2020, paragraph 110.

[21] Judgment of 11 September 2002*, Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 144; decision of the Board of Appeal of 17 December 2019, *BASF and Kemira*, Joined Cases A-003-2018, A-004-2018, and A-005-2018, paragraphs 84 to 87.

[22] See, to that effect, judgment of 5 February 2004, *Commission* v *France*, C-24/00, EU:C:2004:70, paragraph 56.

[23] See, to that effect, judgment of 21 October 2003, *Solvay* v *Council,* T-392/02, EU:T:2003:277, paragraph 130.

[24] Decision of the Board of Appeal of 12 January 2021, *Chemours Netherlands*, A-007-2019, paragraph 40.

the Agency must be able to establish that the potential risk posed by the substance can be clarified by the requested information.[25]

4.2.1. Potential risk

84. When requesting further information in a substance evaluation process under Article 46, it is the Agency's responsibility to demonstrate that there is a potential risk. Potential risk is a combination of potential hazard and potential exposure. The Agency must take into account all the available evidence as a whole before deciding that the respective substance poses a potential risk which requires further investigation.[26]

- Potential hazard

85. An appellant who is challenging the Agency's conclusion on a potential hazard, must establish that the Agency's conclusion is erroneous. It is therefore necessary to examine whether the arguments put forward by the Appellant are capable of demonstrating that the Agency erred in concluding that resorcinol may have endocrine disrupting properties relevant for the environment.[27]

86. The Appellant argues that the Agency erred in the assessment of the available data in finding that resorcinol may have endocrine disrupting properties for the environment.

87. In the Contested Decision, the Agency listed several *in vitro* studies in which resorcinol was found to inhibit thyroid peroxidase.

88. The Agency further listed mammalian studies on resorcinol which indicate several thyroid effects, including increased thyroid weight, histopathological findings and changes in thyroid hormone levels. The Agency stated that whilst the available mammalian data is not fully consistent, it however supports together with the findings of the *in vitro* studies the conclusion that resorcinol may be a thyroid disruptor in the environment.

89. The Agency further stated that the available studies on aquatic toxicity, in particular the Thienpont *et al.* (2011) and Jarque *et al.* (2018) studies, indicate that resorcinol may impact the thyroid gland function in fish.

90. The Appellant raises the following arguments against the findings of the Agency.

91. First, although the Appellant contests the thyroid disrupting potency of resorcinol in general, it does not contest the findings of the *in vitro* studies on the thyroid peroxidase inhibition potential. The Appellant argues that the *in vitro* studies are not sufficient to establish that resorcinol may have endocrine disrupting properties for the environment. According to the Appellant, the Agency's conclusion on the potential endocrine disrupting properties is based on a wrong assertion that resorcinol would have a high potency to induce thyroid peroxidase inhibition and would therefore lead to adverse effects even at low concentrations.

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[25] Decision of the Board of Appeal of 15 January 2019, *3v Sigma,* A-004-2017, paragraph 88.

[26] Decision of the Board of Appeal of 22 February 2022, *S. Goldmann & Co. Germany*, A-005-2020, paragraph 128.

[27] See *BASF Grenzach* v *ECHA*, cited in footnote 19, paragraph 89 of the judgment.

92. The Appellant argues that it is highly unlikely that resorcinol would '*at environmentally relevant concentrations*' enter the thyroid gland at sufficient levels to induce thyroid peroxidase inhibition.

93. Second, the Appellant argues that the Agency erred in considering that the thyroid effects detected in the available mammalian studies, the developmental neurotoxicity study (OECD TG 426) and the two-generation reproductive toxicity study (OECD TG 416), would support the conclusion on the potential endocrine disrupting properties of resorcinol. According to the Appellant those studies cannot be relied on as their results are not consistent or statistically significant.

94. Third, the Appellant argues that the available mammalian and amphibian toxicokinetic studies on resorcinol and other related phenolic compounds show that due to rapid metabolism and excretion, resorcinol will not be present in the thyroid glands of amphibians at concentrations that would induce thyroid function disruption.

95. Fourth, the Appellant argues that the available aquatic toxicity studies are irrelevant as none of them was specifically designed to assess potential endocrine disrupting effects. In particular, the Thienpont *et al.* and Jarque *et al.* studies are not relevant and reliable as they are short-term screening studies which were not specifically designed to assess the endocrine disrupting effects and as the conduct of those studies was subject to several limitations and uncertainties.

96. The arguments of the Appellant must be rejected for the following reasons.

97. The potential hazard relates to the intrinsic toxicological or ecotoxicological properties that the substance at issue may have.

98. The available studies, on which the Agency relied in the Contested Decision, are not sufficient on their own or together to establish that resorcinol is an endocrine disruptor for the environment; however, they are adequate to indicate that resorcinol may have potential endocrine disrupting properties and that it needs to be investigated further.

99. The Agency, with the support of the Intervener, demonstrated that the available toxicokinetic data cannot dispel the concern. It is correctly highlighted in the Contested Decision that the thyroid peroxidase inhibition *in vitro* is not sufficient to demonstrate a hazard, but a potential hazard cannot be excluded based only on toxicokinetic data. The Appellant's arguments on the rapid metabolism and excretion do not suffice to establish that the Agency erred in demonstrating that resorcinol could potentially enter the thyroid glands of amphibians at sufficient levels to induce thyroid function disruption. Rapid metabolism is acknowledged by the Agency in the Contested Decision, but it must be considered together with the results of the *in vitro* studies on the thyroid peroxidase inhibition of resorcinol. Therefore, even low systemic concentrations of resorcinol may induce potential adverse thyroid effects.

100. Moreover, the *in vivo* studies referred to in paragraphs 93 and 95 above provide additional indications that it is not hypothetical that resorcinol could have endocrine disrupting properties to the aquatic environment and therefore, together with the other evidence, justifies the need to clarify the potential hazard for the environment.

101. It follows that the Appellant has not demonstrated that the Agency committed an error of assessment in finding that resorcinol may have endocrine disrupting properties relevant for the environment.

- Potential exposure

102. The examination of exposure for the purposes of demonstrating a potential risk[28] is not the same as the examination of exposure for the purposes of demonstrating a realistic possibility of improved risk management measures[29].

103. The Appellant's arguments that the exposure is sufficiently controlled and therefore not relevant will be examined, where necessary, under the part of the Appellant's plea related to improved risk management measures.

104. The arguments of the Appellant described in paragraphs 68 to 70 above must be rejected for the following reasons.

105. In the Contested Decision, the Agency found that resorcinol may be released into the aquatic environment via wastewaters originating from its downstream uses in tyre manufacturing, phenolic resin production and flame retardant production. The Agency also found that the exposure of the environment through the service life of articles containing resorcinol is likely.

106. Whilst the Appellant challenges some of the Agency's findings in the Contested Decision on the potential emissions from the industrial sites in which resorcinol is used under the existing operational conditions, it has not established that the Agency committed an error of assessment in finding that resorcinol may be released into the aquatic environment. Although the Appellant may consider the exceeding releases as exceptional, the potential releases have been identified by the Agency in the Contested Decision. Moreover, the Appellant has also not established that the Agency committed an error of assessment in considering that the potential release of resorcinol in the aquatic environment might have a potential impact to the manifestation of environmental hazard effects which are related to the presence of resorcinol.

107. That conclusion is not called into question by the Appellant's argument that resorcinol is released also from natural sources. The release of resorcinol from natural sources does not make the need to investigate the potential risk posed by additional release from industrial sources less important.

108. Therefore, the Agency did not err in considering that resorcinol may potentially be released into the environment as wastewater emissions and eventually enter the aquatic environment, resulting in the exposure of aquatic wildlife to resorcinol.

109. It follows that the Appellant has not demonstrated that the Agency committed an error of assessment in finding that there is a potential exposure to resorcinol.

- Conclusion on the potential risk

110. In view of paragraphs 84 to 109 above, the available data on potential hazard and the potential exposure shows that the Agency did not make an error of assessment in considering that resorcinol may pose a potential risk to the aquatic environment. The Agency's evaluation was based on the existence of a potential risk and not on the Appellant's failure to prove the lack of any risk.[30]

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[28] The first condition referred to in paragraph 75 above.

[29] The third condition referred to in paragraph 75 above.

[30] See paragraphs 76 to 79 above.

4.2.2. Appropriateness of the information request

111. By the arguments described in paragraph 71 above the Appellant contests the appropriateness of the LAGDA. These arguments must be rejected for the following reasons.

112. First, LAGDA is a validated method for examining endocrine disrupting concern related to the thyroid mode of action.[31]

113. The limited historical control data or the limited experience of testing laboratories do not, as such, call into question the suitability of the LAGDA to examine the potential endocrine disrupting properties of resorcinol.

114. Second, in the Contested Decision, the Agency addressed the Appellant's concern related to the technical difficulties in conducting the LAGDA on resorcinol by providing guidance on how to maintain the biological conditions and the chemical exposure under flow-through conditions. The Agency also referred to a specific OECD Guidance Document which provides further information on the toxicity testing of difficult test chemicals.[32]

115. Whilst the Appellant argues that the guidance given by the Agency is not sufficient for addressing the difficulties in conducting the study, it has not demonstrated that the LAGDA could not be successfully performed on resorcinol.

116. Moreover, it is not for the Agency but instead for the Appellant together with its contract research organisation to define the details of the test protocol for the LAGDA to be conducted on resorcinol. The Contested Decision does not prevent the Appellant from mitigating or coming up with innovative solutions to address the technical challenges of the testing.

4.2.3. Realistic possibility of leading to improved risk management measures

117. Whether or not the requested information has a realistic possibility of leading to improved risk management measures must be assessed taking into account the potential risk.

118. In the Contested Decision, the Agency stated that if resorcinol is found to have endocrine disrupting properties for the environment it may be identified as a substance of very high concern (SVHC). The Agency explained that the SVHC identification could result in stricter operational conditions and risk management measures compared to those currently in place. Following the SVHC identification resorcinol could eventually also become subject to authorisation under Title VII.

119. The Appellant argues that the current risk management measures applied in the industrial plants using resorcinol are already adequate and that therefore conducting the LAGDA does not have a realistic possibility of leading to improved risk management measures.

120. The argument of the Appellant must be rejected for the following reasons.

121. First, the Agency did not err in finding that conclusions on the adequacy of the already applied operational conditions and risk management measures can only be made when the potential endocrine disrupting properties of resorcinol for the environment have been examined further. The fact that operational conditions and

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[31] *LANXESS Deutschland*, cited in footnote 18, paragraphs 78 to 80 of the decision.

[32] OECD Guidance Document 23 on Aqueous Phase Aquatic Toxicity Testing of Difficult Test Chemicals.

risk management measures are currently applied in industrial plants to minimise the releases of resorcinol into the aquatic environment does not mean that other or further risk management measures could not be necessary to address the risk posed by the potential endocrine disrupting properties of resorcinol.

122. Second, if the potential concern is confirmed by the outcome of the requested information (LAGDA), this could realistically lead to the introduction of several other improved risk management measures in addition to the ones applied in the industrial plants. Such improved risk management measures may, amongst others, include revised waste-water discharge conditions, identification of resorcinol as a substance of very high concern (SVHC) with the obligation to notify the SVHC to the Agency under Article 7(2) and communicate about it in the supply chain under Articles 31 and 33. Such identification could in turn, amongst others, lead to revised classification and labelling, introducing a restriction on the use of resorcinol under Title VIII or an authorisation requirement under Title VII.

123. New or additional risk management measures may be realistically introduced irrespective of whether or not resorcinol is also identified as an endocrine disruptor for human health. The consequences of identifying a substance as an endocrine disruptor for the environment are independent from the consequences of identifying a substance as an endocrine disruptor for human health. In particular, under Article 56(5), the cosmetics uses of resorcinol would be exempted from the authorisation process if the authorisation requirement was based on endocrine disrupting properties for human health only.

124. Therefore, the conclusion that conducting the LAGDA has a realistic possibility of leading to improved risk management measures is not called into question by the fact that identifying resorcinol as an SVCH due to its endocrine disrupting properties for human health is currently under consideration.

4.2.4. Conclusion on the second plea

125. It follows from the reasons set out in sections 4.2.1. to 4.2.3. above that the Agency was correct in finding that resorcinol may pose a risk to the environment and that this potential risk needs to be clarified. The Agency did not err in concluding that the potential risk must be clarified by conducting the LAGDA and that this information request has a realistic possibility of leading to improved risk management measures.

126. The second plea must therefore be rejected.

4.3. Result

127. As all the pleas have been rejected, the appeal must be dismissed.

5. Effects of the Contested Decision

128. The Contested Decision, upheld in the present appeal proceedings, required the Appellant to submit information on a LAGDA by 19 September 2022, which is 1 year 6 months and 7 days from the date of that decision.

129. Under Article 91(2), an appeal has suspensive effect. The deadline set in the Contested Decision must therefore be calculated starting from the date of notification of the present decision of the Board of Appeal to the Parties.

130. The Appellant must consequently provide the information requested in the Contested Decision by 24 July 2024.

6. Refund of the appeal fee

131. Under Article 10(4) of the Fee Regulation[33], the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the appeal is dismissed, the appeal fee is not refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the information on a LAGDA required by the Contested Decision must be provided by 24 July 2024.**
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

[33] 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).