EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

24 November 2020

(Technical equivalence – Similarity of hazard profiles – Right to good administration – Duties of the Agency)

Case number	A-004-2019
Language of the case	English
Appellant	ARKEMA France, France
Representatives	Eric Barbier de La Serre and Elodie Simon Jones Day, France
Contested Decision	TAP-D-1340769-21-00/F of 7 December 2018 adopted by the European Chemicals Agency (the 'Agency') under Article 54(4) of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1; the 'BPR')

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. Under Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1; the 'Biocidal Products Directive'), the European Commission ('the Commission') established and implemented a work programme for the systematic examination of all existing active substances that were on the market prior to 14 May 2000 (the 'review programme').

2. Active chlorine released from sodium hypochlorite was included in the review programme.

3. The Biocidal Products Directive was repealed and replaced by the BPR on 1 September 2013.

4. In order to facilitate a smooth transition from the Biocidal Products Directive to the BPR, the Commission is empowered, under the third subparagraph of Article 89(1) of the BPR, to adopt implementing regulations determining whether, and under which conditions, existing active substances included in the review programme can be approved.

5. Under the BPR, the review programme is implemented under the provisions set out in Commission Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in [the BPR] (OJ L 294, 10.10.2014, p. 1; the 'Review Programme Regulation').

6. On 14 July 2017, the Commission adopted Implementing Regulation (EU) 2017/1273 approving active chlorine released from sodium hypochlorite [the 'AS Reference'] as an existing active substance for use in biocidal products of product-types 1, 2, 3, 4 and 5 (OJ L 184, 15.7.2017, p. 13; 'Implementing Regulation 2017/1273'). Prior to the adoption of Implementing Regulation 2017/1273, the competent authority of Italy had prepared an assessment report on the AS Reference pursuant to Article 6 of the Review Programme Regulation (the 'assessment report of the competent authority').

7. The specifications of the AS Reference, and the conditions for placing on the market biocidal products containing the AS Reference, are set out in the Annex to Implementing Regulation 2017/1273. A maximum concentration limit of 18 % for active chlorine is defined in the Annex. However, according to the Annex '*[t]he active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance*'.

8. The Appellant manufactures active chlorine released from sodium hypochlorite (the 'AS Alternative') at a concentration higher than the maximum active chlorine concentration set for the AS Reference in Implementing Regulation 2017/1273.

9. On 18 May 2018, the Appellant submitted an application to the Agency under Article 54(1) of the BPR seeking to establish technical equivalence of the AS Alternative and the AS Reference. A technical equivalence assessment by the Agency is split into two parts. First, technical equivalence between a reference source and an alternative source can be established on the basis of the similarity of their chemical compositions (the 'Tier I assessment'). Second, if the chemical compositions of a reference source and an alternative source are not sufficiently similar, technical

equivalence can be established on the basis of the similarity of their hazard profiles (the 'Tier II assessment').

10. In its application the Appellant indicated that the maximum active chlorine concentration of the AS Alternative is 26.4 %. The Appellant considered that the chemical composition of the AS Reference and the AS Alternative are not similar and sought to establish the technical equivalence in a Tier II assessment based on the similarity of their hazard profiles.

11. The Appellant argued that Annex VI to 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; the 'CLP Regulation') sets out a harmonised classification (Skin Corrosion 1B; H314) for all sodium hypochlorite solutions containing at least 5 % of active chlorine.

12. The Appellant argued that due to these corrosive properties, as indicated by the harmonised classification as '*Skin Corrosion 1B;H314*', the human health effects of both the AS Reference and the AS Alternative are '*primarily due to [their] local mode of action*' and their systemic toxicity is secondary to the '*direct irritating reactivity*'. As a result, the hazard profiles of the AS Reference and the AS Alternative are similar and the toxicological properties shown in the studies available on the AS Reference apply also to the AS Alternative.

13. On 10 July 2018, the Agency sent to the Appellant a request for additional information (the 'additional information request') under Article 54(5) of the BPR. The Agency stated in its request that the application submitted by the Appellant did not contain all the information necessary for the Agency to assess technical equivalence. The Agency requested the Appellant to provide more information on the AS Alternative, in particular on its composition and toxicological and ecotoxicological properties. With regard to the toxicological properties, the Agency requested the Appellant to '*include also local toxicity in [its] assessment*'.

14. On 8 October 2018, the Appellant replied to the additional information request. The Appellant provided, amongst other information, a '*summary of local effects*' quoting several study reports on skin and eye irritation conducted on sodium hypochlorite solutions with 5.25 % and 5.5 % active chlorine concentrations.

15. On 14 November 2018, the Agency notified a draft decision to the Appellant. In the draft decision the Agency concluded that technical equivalence cannot be established because the Appellant *'did not provide sufficient evidence to show that the changes in the composition will not result in an unacceptable change of the hazard profile of [the AS Alternative] compared to [the AS Reference]'*. The Agency considered that '*it cannot be excluded that [the AS Alternative] will not induce more severe local and systemic toxicity effects compared to [the AS Reference]'.*

16. On 22 November 2018, the Agency and the Appellant held a teleconference. The Agency indicated that harmonised classification under the CLP Regulation is only one of the relevant aspects that have to be taken into account in the assessment of the similarity of the hazard profiles of a reference source and an alternative source in the technical equivalence assessment. The Agency indicated that '*the main reason*' in the draft decision for rejecting the application for technical equivalence was '*the absence of sufficient information regarding possible increased potency in effects related to respiratory irritation*'.

17. On 30 November 2018, the Appellant submitted its comments on the draft decision. The Appellant reiterated that the harmonised classification of sodium hypochlorite under the CLP Regulation remains the same even if the active chlorine concentration

is higher. The Appellant committed to limit the active chlorine concentration of the AS Alternative to a maximum of 25 % instead of the maximum concentration of 26.4 % indicated in its application seeking to establish technical equivalence.

18. On 7 December 2018, the Agency adopted the Contested Decision under Article 54(4) of the BPR. The Agency rejected the Appellant's application for technical equivalence.

19. The Agency found that the Appellant had not provided '*sufficient evidence to show that the changes in the composition will not result in an unacceptable change of the hazard profile of [the AS Alternative] compared to [the AS Reference]*'.

20. The Contested Decision further states:

'[*The Appellant] has not submitted any information to demonstrate that [the AS Reference] and [the AS Alternative] have a similar corrosivity/irritation hazard, apart from the argument that [the AS Reference] and [the AS Alternative] have the same classification and labelling based on the computational method of the CLP Regulation which applies the threshold concentration of 5 % that triggers classification as Skin Corr. 1B without providing information on the type, potency, and duration of corrosive effects. The absence of information provided by [the Appellant] applies also to local hazard on respiratory irritation.*

[…]

Overall, [the Agency] notes that [the AS Alternative] contains a higher amount of active chlorine than the maximum amount permitted in [the AS Reference]. Active chlorine induces local toxicity (skin corrosion, respiratory irritation). Also the latter effect was identified in [the assessment report of the competent authority] as the critical effect for setting reference values (AEC inhalation). Conclusively, it cannot be excluded that [the AS Alternative] has a different hazard profile compared to [the AS Reference] with respect to the type, potency and duration of corrosivity and the effect of local respiratory irritation.

[…]

[I]t has not been demonstrated, and it cannot be excluded that [the AS Alternative] will not induce more severe local and systemic toxicity effects compared to [the AS Reference]. It is noted that the health effects of active chlorine are primarily due to the local mode of action of hypochlorite and potential systemic effects are secondary to its direct irritating reactivity […].'

Procedure before the Board of Appeal

21. On 6 March 2019, the Appellant filed this appeal.

22. On 24 May 2019, the Agency submitted its Defence.

23. On 3 September 2019, the Appellant filed its observations on the Defence.

24. On 3 October 2019, PETA International Science Consortium Ltd. ('PISC') was granted leave to intervene in support of the Appellant.

25. On 4 November 2019, the Agency filed its observations on the Appellant's observations on the Defence.

26. On 28 November 2019, PISC informed the Board of Appeal that it no longer wished to intervene in the case.

27. On 19 March 2020, the Appellant and the Agency replied to questions from the Board of Appeal.

28. On 26 March 2020, the Board of Appeal closed the written procedure. Neither of the Parties requested a hearing to be held in the present case and the Board of Appeal considered that a hearing was not necessary.

29. On 25 May 2020, Sakari Vuorensola, alternate member of the Board of Appeal, was designated to replace Sari Haukka in this case, in accordance with the first 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).

Form of order sought

30. The Appellant requests the Board of Appeal to:

- annul the Contested Decision;
- replace the Contested Decision with a decision establishing the technical equivalence of the AS Alternative with the AS Reference; and
- refund the appeal fee.

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

Reasons

1. Relevant provisions

32. Article 3(1) ('*Definitions*') of the BPR provides:

'"[T]echnical equivalence" means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial assessment was carried out as established in Article 54'.

33. Article 19 ('*Conditions for granting an authorisation*') of the BPR provides:

'1. A biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 25 shall be authorised provided the following conditions are met:

a) the active substances are included in Annex I or approved for the relevant product-type and any conditions specified for those active substances are met;

[…]

c) the chemical identity, quantity and technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant and relevant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined according to the relevant requirements in Annexes II and III;

[…].'

34. Article 54 ('*Assessment of technical equivalence*') of the BPR provides:

'*1. Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence ("the applicant") shall submit an application to the Agency.*

2. The applicant shall submit all data that the Agency requires to assess technical equivalence.

3. The Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

4. After giving the applicant the opportunity to submit comments, the Agency shall take a decision within 90 days of receipt of the application referred to in paragraph 1 and shall communicate it to Member States and to the applicant.

5. Where, in the opinion of the Agency, additional information is necessary to carry out the assessment of technical equivalence, the Agency shall ask the applicant to submit such information within a time limit specified by the Agency. The Agency shall reject the application if the applicant fails to submit the additional information within the specified time limit. The 90-day period referred to in paragraph 4 shall be suspended from the date of issue of the request until the information is received. The suspension shall not exceed 180 days except where justified by the nature of the data requested or in exceptional circumstances.

6. Where appropriate, the Agency may consult the competent authority of the Member State which acted as the evaluating competent authority for the evaluation of the active substance.

7. An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraphs 3, 4 and 5 of this Article.

8. The Agency shall draw up technical guidance notes to facilitate the implementation of this Article.'

35. The second and third Recitals of Commission Delegated Regulation (EU) No 837/2013 amending Annex III to [the BPR] as regards the information requirements for authorisation of biocidal products (OJ L 234, 3.9.2013, p. 1; the 'Commission Delegated Regulation') provide:

'(2) A biocidal product may be authorised even if one or more of the active substances contained therein has been manufactured in a different location or according to a different process, including from different starting materials, than those of the substance evaluated for approval pursuant to Article 9 of [the BPR].

(3) In such cases, for the purpose of ensuring that the active substance contained in a biocidal product does not have significantly more hazardous properties than the substance which has been evaluated for the purpose of approval, it is necessary to establish technical equivalence pursuant to Article 54 of [the BPR].'

2. Assessment of the Appellant's pleas

36. The Appellant raises seven pleas in support of its appeal:

- the Agency breached its duty to state reasons by failing to justify why the evidence provided by the Appellant was not sufficient to demonstrate technical equivalence (first plea);
- the Agency infringed its obligation to carry out its own technical equivalence assessment by considering that the Appellant did not provide the necessary information to establish technical equivalence and by relying on a misleading extract of the Appellant's application to reject the technical equivalence (second plea);

- the Agency exceeded its powers by misinterpreting the technical equivalence criteria set out in Article 3(1)(w) of the BPR and implicitly requiring the Appellant to provide additional studies on the corrosive properties of the AS Alternative (third plea);
- the Agency breached the principle of legitimate expectations by contradicting the technical equivalence criteria set out in the Agency's Guidance on applications for technical equivalence (version 1.1, March 2017; the 'Technical Equivalence Guidance') (fourth plea);
- the Agency breached the right to good administration by acting in contradiction with the Technical Equivalence Guidance and the CLP Regulation (fifth plea);
- the Agency breached Article 62 of the BPR by implicitly requiring the Appellant to conduct additional studies on the corrosive properties of the AS Alternative (sixth plea); and
- the Agency breached the principle of proportionality by rejecting the Appellant's application for technical equivalence in the absence of any specific environmental or human health risk and thereby causing disproportionate impacts for the Appellant and the manufacturers of biocidal products containing the AS Alternative (seventh plea).

37. First, the second and fifth pleas will be examined together.

Arguments of the Parties

38. By its second plea, the Appellant argues that the Agency breached its duties under Article 54 of the BPR. By its fifth plea, the Appellant argues that the Agency breached the right to good administration.

39. The Appellant argues that if the Agency considered that the information provided by the Appellant was insufficient to carry out the assessment of technical equivalence, the Agency should have specified which additional testing could address its concerns regarding the toxicological properties of the AS Alternative. The failure to request and specify the necessary additional information qualifies as a breach of the Agency's duty of good administration.

40. The Agency argues that, under Article 54 of the BPR, an applicant for technical equivalence has to demonstrate that the hazard profile of the alternative source is equivalent to that of the reference source.

41. The Agency argues that it does not have an obligation to request the applicant for technical equivalence to provide specific tests or information. Rather, it is for the applicant '*to provide all the information necessary for [the Agency] to make its assessment in line with the requirements established in the [Technical Equivalence Guidance]*'. In the present case, the additional information request was aimed at clarifying whether the higher concentration of active chlorine could lead to a change in toxicity, '*such as a change in the potency/magnitude/severity of corrosion/irritation, which is concentration dependent*'.

42. The Agency argues that as the Appellant failed to provide sufficient information '*it could not be excluded that the AS Alternative would induce more severe local and systemic toxicity effects compared to the AS Reference*'. In particular, the Appellant failed to demonstrate why the higher active chlorine concentration '*will not lead to a higher degree of respiratory irritation*'.

Findings of the Board of Appeal

43. In essence, the Appellant argues that the Agency did not apply Article 54 of the BPR in full compliance with the requirements of the right to good administration. It is therefore necessary to determine what duties must the Agency respect to comply with the right to good administration in the exercise of its responsibilities under Article 54 of the BPR.

The right to good administration

44. The right to good administration is enshrined in Article 41 of the Charter of Fundamental Rights of the European Union.

45. The right to good administration entails, in particular, a duty for the administration to examine carefully and impartially all the relevant aspects of an individual case and the right of the person concerned to be heard and to receive an adequately reasoned decision (see judgment of 21 November 1991, *Technische Universität München*, C-269/90, EU:C:1991:438, paragraph 14).

46. The right to be heard guarantees all persons the opportunity to make known their views effectively during an administrative procedure and before the adoption of any decision liable to affect their interests adversely (see judgment of 11 December 2014, C-249/13, *Khaled Boudjlida* v *Préfet des Pyrénées-Atlantiques*, EU:C:2014:2431, paragraph 36).

47. That right pursues a twofold objective. On the one hand, it allows the administration to acquire full knowledge of the facts of a case and to correct any errors in its initial assessment. On the other hand, it ensures the effective protection of the persons concerned, allowing them to submit such information as will argue in favour of the adoption or non-adoption of a decision, or of its having a specific content (see, to this effect, judgment of 4 June 2020, *EEAS* v *De Loecker*, C-187/19 P, EU:C:2020:444, paragraph 69, and *Khaled Boudjlida* v *Préfet des Pyrénées-Atlantiques*, cited in the previous paragraph, paragraphs 37 and 59 of the judgment).

The Agency's duty to comply with the right to good administration within the framework of Article 54 of the BPR

48. Under Article 54(1) and (2) of the BPR, it is for the person seeking to establish technical equivalence – the applicant – to submit to the Agency an application containing all the information needed by the Agency to carry out its assessment of technical equivalence.

49. Under Article 54(5) of the BPR, it is for the Agency to require the applicant to submit additional information if the Agency considers that such additional information is necessary to carry out its assessment of technical equivalence.

50. Under Article 54(4) of the BPR, it is for the Agency to give the applicant the opportunity to provide comments on a draft decision before taking a decision on an application for technical equivalence submitted under Article 54(1) of the BPR.

51. Under the provisions described in the previous three paragraphs, it is for the applicant to provide evidence of the similarity of the hazard profiles of the alternative source and the reference source of an active substance. The Agency does not have to gather itself any evidence in this respect.

52. However, the Agency has the duty to ensure that any decision under Article 54(4) of the BPR is taken after having considered all relevant information. If the Agency

considers that the information contained in an application for technical equivalence submitted under Article 54(1) of the BPR is insufficient to carry out the assessment of technical equivalence it must, under Article 54(5) of the BPR, require the applicant to submit the necessary additional information.

53. In order to be able to examine carefully and impartially whether the alternative source and the reference source are technically equivalent, the Agency must ensure that its additional information request is sufficiently clear and comprehensive as to allow the applicant to gather and submit the information needed for an assessment of technical equivalence. A clear and comprehensive additional information request is necessary to place the applicant for technical equivalence in a position to submit observations that enable the Agency to effectively take into account all relevant information (see, by analogy, judgment of 18 December 2008, *Sopropé – Organizações de Calçado Lda* v *Fazenda Pública,* C-349/07, EU:C:2008:746, paragraph 49).

54. Therefore, if the Agency considers, under Article 54(5) of the BPR, that the information provided in an application for technical equivalence submitted under Article 54(1) of the BPR is insufficient to carry out the assessment of technical equivalence, the Agency must not only request additional information but also specify clearly and comprehensively what additional information is needed.

55. Finally, the Agency may take a decision rejecting or accepting an application for technical equivalence under Article 54(4) of the BPR only after giving the applicant the opportunity to submit comments on a draft decision. In order to comply with the right to be heard, a draft decision must cover the elements that lead the Agency to its draft conclusions on whether to reject or accept the application for technical equivalence. This is necessary to enable the applicant to submit comments on the draft decision that can correct an error or provide information that will argue in favour of the adoption or non-adoption of the final decision, or in favour of its having a specific content (see, to this effect, *Khaled Boudjlida* v *Préfet des Pyrénées-Atlantiques*, cited in paragraph 46 above, paragraph 37 of the judgment).

56. It is therefore necessary to examine whether the Agency complied with its duty to comply with the right to good administration within the framework of Article 54 of the BPR in the decision-making procedure leading to the Contested Decision.

The decision-making procedure leading to the Contested Decision

57. In its application for technical equivalence, the Appellant provided a summary of the toxicological and ecotoxicological data available on the AS Reference and argued that this is sufficient to demonstrate technical equivalence, through similarity of the hazard profiles, with the AS Alternative (see paragraphs 9 to 12 above).

58. In its additional information request (see paragraph 13 above) the Agency stated the following:

'*In your Tier II assessment report ("Summary of Technical equivalence", April 2018), you have stated that [the AS Alternative] contains "a higher concentration of available chlorine than [the AS Reference] so is expected to show even higher degree of local irritation/corrosion". You have justified that [the AS Alternative] does not have significantly higher systemic toxicity than [the AS Reference]. Please include also local toxicity in your assessment.*'

59. The additional information request did not contain any further explanation of the meaning of '*local toxicity*' or references to other specific additional information that would be necessary to carry out the assessment of technical equivalence.

60. Following the Appellant's reply to the additional information request, the Agency concluded that the information provided by the Appellant was insufficient to establish that the AS Reference and the AS Alternative are technically equivalent. The Agency therefore notified to the Appellant a draft decision rejecting the Appellant's application for technical equivalence for comments (see paragraphs 14 and 15 above).

61. Following the notification of the draft decision, the Agency and the Appellant held a teleconference (see paragraph 16 above). In the teleconference, the Agency indicated that '*the main reason*' for concluding, in the draft decision, that the information provided by the Appellant was insufficient to establish that the AS Reference and the AS Alternative are technically equivalent, was the lack of information on '*possible increased potency [of the AS Alternative] in effects related to respiratory irritation*'.

62. In its replies of 19 March 2020 to questions from the Board of Appeal, the Agency acknowledged that the concern relating to the lack of information on respiratory irritation was explicitly raised for the first time at the teleconference of 22 November 2018. The Agency further explained that no new information regarding respiratory irritation was included in the Appellant's comments on the draft decision that the Agency received on 30 November 2018. Subsequently, the Agency adopted the Contested Decision on 7 December 2018.

63. In the Contested Decision, the Agency stated that '*local toxicity*' in the present case referred to skin corrosion and respiratory irritation and found that the Appellant had failed to provide information both on '*the type, potency and duration of corrosive effects*' and on respiratory irritation which was necessary for the technical equivalence assessment. The Agency therefore concluded that the Appellant had not provided '*sufficient evidence to show that the changes in the composition will not result in an unacceptable change of the hazard profile of [the AS Alternative] compared to [the AS Reference]*' and rejected the Appellant's application.

Result

64. In the decision-making process leading to the Contested Decision, the Agency failed to fulfil its duty to comply with the right to good administration within the framework of Article 54 of the BPR in two respects.

(a) The Agency failed to submit a clear and comprehensive additional information request

65. The additional information request sent by the Agency to the Appellant under Article 54(5) of the BPR was unclear and incomplete. The term *'local toxicity'* was not explained by the Agency (see paragraphs 58 and 59 above). The term '*local toxicity*' is also not defined in the Technical Equivalence Guidance adopted by the Agency under Article 54(8) of the BPR. Therefore, the Appellant was not in a position to understand clearly and comprehensively what information it was expected to submit on '*local toxicity*'.

66. The Appellant based its conclusion regarding the similarity of the hazard profiles of the AS Reference and the AS Alternative on the data available on the AS Reference and on the fact that they shared the same harmonised classification (see paragraphs 9 to 12 above). As the Agency considered that this was insufficient to carry out the assessment of technical equivalence, it should have specified what additional information was needed in order for it to be able to carry out its technical equivalence assessment.

67. In order to fulfil its duty to comply with the right to good administration within the framework of Article 54 of the BPR, the Agency should have clarified, in the additional information request, what information was needed, and on which effects. The use of a term such as '*local toxicity*', which has not been explained or defined, does not satisfy the requirement that any additional information request must be sufficiently clear and comprehensive as to allow the applicant to gather and submit the information needed for the Agency's assessment of technical equivalence (see paragraphs 52 and 53 above).

68. In particular, the Agency should have clearly explained the need to submit information on respiratory irritation as the lack of such information was the main reason for the rejection of the application for technical equivalence (see paragraph 16 above).

69. The need for information on respiratory irritation was not specifically mentioned in the additional information request. Therefore, the Appellant could not know that it was expected to submit information specifically on respiratory irritation in its reply to the additional information request.

70. It follows from the reasons set out in the paragraphs 65 to 69 above that the Agency breached the right to good administration as it failed to fulfil its duties under Article 54 of the BPR to specify clearly and comprehensively the additional information necessary for the technical equivalence assessment.

(b) The Agency failed to give the Appellant the opportunity to make known its views

71. Neither the meaning of '*local toxicity*' nor an explanation of the need for information on respiratory irritation were included in the draft decision. The Agency merely concluded that, based on the evidence provided by the Appellant, '*it cannot be excluded that [the AS Alternative] will not induce more severe local and systemic toxicity effects compared to [the AS Reference]* (see paragraph 15 above).

72. The Agency referred to the need for information on respiratory irritation for the first time in the informal teleconference that took place after the draft decision had been notified to the Appellant and only eight days before the expiry of the deadline granted to the Appellant to submit comments on the draft decision (see paragraph 61 above). Such a short period of time to submit comments on an element - the need for information on respiratory irritation – that the Agency considered as being the main reason for rejecting the Appellant's technical equivalence application was clearly inadequate.

73. The Appellant was placed in a position where it effectively had no opportunity to make known its views on the need for information on respiratory irritation before the adoption of the Contested Decision. Therefore, the Agency breached the right to good administration as it failed to respect the Appellant's right to be heard.

74. An infringement of the right to be heard results in the annulment of a decision taken at the end of a procedure only if, had it not been for such an irregularity, the outcome of the procedure might have been different (order of 14 April 2016, *Dalli* v *Commission*, C-394/15 P, EU:C:2016:262, paragraph 41, and the cited case-law).

75. The procedure under Article 54 of the BPR has two possible outcomes: the Agency can either accept or reject the application for technical equivalence. If the Appellant was given an opportunity, within a reasonable deadline, to submit additional information on respiratory irritation, or to make observations on the need for such information, it might have persuaded the Agency to accept the application for technical equivalence.

76. Therefore, if the Appellant's right to be heard had been respected, the outcome of the procedure in this case might have been different. The infringement of the right to be heard therefore results in the annulment of the Contested Decision.

(c) *Conclusion*

77. In light of the reasons set out in paragraphs 65 to 76 above, the second and fifth pleas must be upheld, and the Contested Decision annulled. There is no need to examine the remaining pleas.

78. Under Article 93(3) 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), following its examination of a case, the Board of Appeal may exercise any power that lies within the competence of the Agency or remit the case to the competent body of the Agency for further action. That provision applies to the present case in accordance with Article 77(1) of the BPR.

79. The Appellant requests the Board of Appeal to replace the Contested Decision with a decision establishing the technical equivalence of the AS Alternative and the AS Reference.

80. The Contested Decision is annulled on two grounds. First, the Agency breached the right to good administration as it failed to specify clearly and comprehensively the additional information it needed to assess the application for technical equivalence submitted under Article 54(1) of the BPR (see paragraphs 65 to 70 above). Second, the Agency breached the right to good administration as it failed to respect the Appellant's right to be heard by rejecting the Appellant's application for technical equivalence partly on considerations on which the Appellant effectively did not have an opportunity to make known its views (see paragraphs 71 to 76 above).

81. It is not possible to assess whether the AS Reference and AS Alternative are technically equivalent before giving the Appellant the opportunity to submit additional information which has been clearly and comprehensively specified by the Agency. The present case must therefore be remitted to the competent body of the Agency for further action in this respect.

Refund of the appeal fee

82. In accordance with Article 4(4) of Commission Implementing Regulation (EU) No 564/2013 on the fees and charges payable to the European Chemicals Agency pursuant to the BPR (OJ L 167, 19.6.2013, p. 17), the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the appeal has been decided in favour of the Appellant, the appeal fee must be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Contested Decision.**
2. **Remits the case to the competent body of the Agency for further action.**
3. **Decides that the appeal fee is refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal