

**DECISION OF THE BOARD OF APPEAL  
OF THE EUROPEAN CHEMICALS AGENCY**

**8 August 2018**

*(Substance evaluation – Right to be heard)*

<b>Case number</b>	A-009-2016
<b>Language of the case</b>	English
<b>Appellant</b>	Symrise AG, Germany
<b>Representatives</b>	Ruxandra Cana, Eléonore Mullier and Michel Michaux Steptoe & Johnson LLP, Belgium
<b>Interveners</b>	(I) European Coalition to End Animal Experiments, United Kingdom  (II) The Member State Competent Authority of the United Kingdom  Represented by:  Health and Safety Executive, United Kingdom  (III) PETA International Science Consortium Ltd, United Kingdom
<b>Contested Decision</b>	Decision of 30 June 2016 on the substance evaluation of climbazole, adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation')

**THE BOARD OF APPEAL**

composed of Mercedes Ortuño (Chairman and Rapporteur), Andrew Fasey (Technically Qualified Member) and Sari Haukka (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

## Decision

### Background to the dispute

1. The Appellant is the only registrant of the substance climbazole (EC No 253-775-4, CAS No 38083-17-9).
2. The Appellant registered climbazole at the 100 to 1000 tonnes per year tonnage band and exclusively for use as an ingredient in cosmetic products.
3. Climbazole was included in the Community Rolling Action Plan ('CoRAP') for substance evaluation due to initial grounds for concern relating to its potential reproductive toxicity and potential human exposure.
4. The Health and Safety Executive ('HSE') was appointed to carry out the substance evaluation of climbazole as Member State Competent Authority of the United Kingdom.
5. On 22 October 2014, HSE obtained further data concerning the methodology of a study on climbazole (E. Richter *et al.*, *Ecotoxicity of climbazole, a fungicide contained in anti-dandruff shampoo*, (2013) *Env. Tox. and Chem.* 32(12), 2816-2825; the 'Richter *et al.* (2013) study'), by email, from one of the authors of that study.
6. On 2 February 2015, HSE sent a draft substance evaluation report to the Appellant for information.
7. On 6 May 2015, a draft decision prepared by HSE requesting further information pursuant to Article 46(1) of the REACH Regulation (the 'Draft Decision') was notified to the Appellant in accordance with Article 50(1) of that Regulation (all references to Articles hereinafter concern the REACH Regulation unless stated otherwise).
8. The Draft Decision required the Appellant to provide, amongst other information:
  - a combined repeated-dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422; the 'OECD TG 422 study'),
  - an aerobic sludge treatment simulation test,
  - *in vitro* endocrine disruption screening studies, and
  - further information on worker exposure.
9. By 18 June 2015, the Appellant commented on the Draft Decision. In those comments the Appellant stated:

*'[W]ith regards to the uncertainties and concerns on reproductive/fertility [sic] and on self-mutilation, the registrant agree[s] to perform an extended OECD TG 422 study in a sufficient number of animals and [to] include examinations on possible neurobehavioural changes as functional observation battery in non-pregnant animals.'*
10. In September 2015, climbazole was discussed at a meeting of the Agency's Endocrine Disruptor Expert Group. Representatives of the Appellant and HSE were present at that meeting.
11. By 22 January 2016, HSE revised the Draft Decision (the 'Revised Draft Decision').
12. On 22 January 2016, HSE notified the Revised Draft Decision to the competent authorities of the other Member States and to the Agency.

13. Two competent authorities and the Agency submitted proposals for amendment pursuant to Article 51(2) in conjunction with Article 52(2). The competent authority of Denmark proposed, amongst other things, that the Appellant should be required to perform an extended one-generation reproductive toxicity study ('EOGRTS') to clarify a potential concern related to endocrine disruption, rather than an OECD TG 422 study to clarify a potential concern related to reproductive toxicity.
14. On 26 February 2016, the Revised Draft Decision was notified to the Appellant together with the proposals for amendment. The Appellant was invited to comment on the proposals for amendment by 29 March 2016.
15. By 7 March 2016, HSE examined the proposals for amendment and amended the Revised Draft Decision (the 'Amended Draft Decision').
16. On 7 March 2016, the Amended Draft Decision was referred to the Member State Committee ('MSC').
17. On 29 March 2016, the deadline for the Appellant's comments on the proposals for amendment expired without the Appellant submitting any comments.
18. On 1 April 2016, the Appellant requested the Agency to extend the deadline for commenting on the proposals for amendment. The Appellant explained that:  
*'Unfortunately, we couldn't finish our commenting process in time. This happened due to an internal organisation change (the responsible substance coordinator left the team) and because of the Easter holiday period here in Germany and because some member states referred [sic] to literature articles that were not cited before and that we have to order and evaluate in order to provide well-founded comments.'*
19. On 4 April 2016, the Agency rejected the Appellant's request to extend the deadline for commenting on the proposals for amendment. In the communication rejecting the request, the Agency stated:  
*'[I]f the MSC decides to discuss [climbazole] in a plenary session, you will be invited to attend the MSC meeting where the proposals for amendment will be discussed. This will allow you to understand the proposals for amendment better. However, at this meeting you will not be requested to present your comments on the proposals for amendment as they were not submitted on time. Nevertheless, your presence is welcome as some members may however seek some clarifications from you regarding the properties of [climbazole] and information already contained in your registration dossier.'*
20. The Amended Draft Decision was discussed at the MSC meeting of 25 to 29 April 2016. In a part of the meeting that was closed to the public, the MSC further modified the Amended Draft Decision and reached unanimous agreement on the Contested Decision. In the Contested Decision, the MSC agreed that an EOGRTS should be required in order to clarify a potential concern related to reproductive toxicity.
21. On 30 June 2016, the Agency adopted the Contested Decision.

### **Contested Decision**

22. The Contested Decision requires the Appellant to submit further information on climbazole by 9 July 2018.
23. Section II of the Contested Decision, entitled '*Information required*', states:

*'Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods/instructions (in accordance with Article 13(3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:*

1. *[EOGRTS] (test method: OECD TG 443) in rats, oral route, with the registered substance, specified as follows:*

- *Dose level setting shall aim to induce some toxicity at the highest dose level;*
- *Cohort 1A (Reproductive toxicity); and*
- *Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to product the F2 generation;*

*and*

2. *Simulation test – aerobic sludge treatment, A: activated sludge units, B: biofilms (test method OECD 303 A or B);*

*The Registrant shall select, with justification, the most appropriate methodology (OECD 303 A or B).*

3. *In vitro endocrine disruption screening studies;*

*H29SR Steroidogenesis assay (test method OECD 456) with additional measurement of progesterone*

*and either*

*Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals (Draft OECD Test Guideline due for finalisation in 2016), if adopted by the time of testing*

*Or*

*Androgen Receptor Binding Assay (test method US EPA OPPTS 890.1150).*

*Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall also submit the following information regarding the registered substance subject to the present decision:*

4. *Further information on worker exposure addressing the following aspects:*

- a. *Descriptive text for each process/task within each exposure scenario shall be provided. This shall include: an explanation of the processes that are covered by each scenario and PROC code; the form in which the substance is present at each stage of the process; a justification for the choice of modelling parameters, including the choice of a non-default refinement factor applied to PROC 5 in exposure scenario 2; and*
- b. *For those scenarios where climbazole is used as a solid dissolved in a liquid, the Registrant shall re-calculate the exposures with a tool that has the ability to model this condition of use or, alternatively, provide measured data. For modelled exposure estimates, a copy of the model output reports and a justification for each of the parameters selected shall be provided.'*

### **Procedure before the Board of Appeal**

24. On 29 September 2016, the Appellant filed this appeal.

25. On 30 November 2016, the Agency submitted its Defence.

26. On 7 March 2017, the Appellant submitted its observations on the Defence.
27. On 5 April 2017, HSE was granted leave to intervene in this case in support of the Agency. On the same day, the European Coalition to End Animal Experiments (ECEAE) and PETA International Science Consortium (PISC) were granted leave to intervene in support of the Appellant.
28. On 27 April 2017, the Agency submitted its observations on the Appellant's observations on the Defence.
29. On 15, 16 and 19 June 2017 respectively, ECEAE, HSE and PISC submitted their statements in intervention. In their statements in intervention ECEAE and PISC raised arguments concerning the use of climbazole as an ingredient in cosmetic products.
30. On 13 and 14 September 2017 respectively, the Appellant and the Agency submitted their observations on the statements in intervention. Both objected to the admissibility of the arguments raised by ECEAE and PISC concerning the use of climbazole as an ingredient in cosmetic products.
31. On 30 October and 13 November 2017 respectively, the Appellant and the Agency replied to written questions from the Board of Appeal.
32. On 18 January 2018, a hearing was held at the Appellant's request. At the hearing, the Parties and the Interveners made oral submissions and responded to questions from the Board of Appeal.

### **Form of order sought**

33. The Appellant, supported by ECEAE and PISC, requests the Board of Appeal to:
  - declare the appeal admissible,
  - annul the Contested Decision in its entirety,
  - order the refund of the appeal fee, and
  - take such other or further measures as justice may require.
34. In the alternative, if the appeal should be dismissed, the Appellant requests the Board of Appeal to extend the deadline for submitting the required information to the Agency in light of the suspensive effect of an appeal.
35. The Agency, supported by HSE, requests the Board of Appeal to dismiss the appeal as unfounded.

### **Reasons**

36. In the Notice of Appeal, the Appellant raises several pleas in law. With regard to the whole of the Contested Decision, it alleges breaches of Articles 50 to 52 and the principle of the protection of legitimate expectations. With regard to the individual information requirements, it alleges breaches of the right to be heard, the duty to state reasons, the principle of proportionality, Article 25, and the principle of legal certainty, as well as various errors of assessment.
37. In addition, at the hearing, the Appellant raised new pleas in law alleging that the Agency had failed to take into account the exclusive use of climbazole as an ingredient in cosmetic products and address the implications of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 342, 22.12.2009, p. 59; the 'Cosmetics Regulation'). The Appellant also requested the Board

of Appeal to consider, of its own motion, a possible breach of the duty to state reasons in this regard.

38. The Board of Appeal will first examine whether the Agency breached Articles 50 to 52 and the principle of the protection of legitimate expectations (Section 1 below).
39. Second, the Board of Appeal will examine whether, in the circumstances of the present case, the Appellant's right to be heard was respected as regards the individual information requirements (Section 2 below).

### **1. Alleged breaches of Articles 50 to 52**

#### **Arguments of the Appellant**

40. The Appellant claims that the Agency breached Articles 50 to 52 in three ways:
  - first, the Agency should have given the Appellant an opportunity to comment on the Revised Draft Decision,
  - second, the Agency should have given the Appellant an opportunity to speak at the MSC meeting, and
  - third, the Agency should have extended the deadline for commenting on the proposals for amendment.
41. The Appellant further claims that it had legitimate expectations that it would be given an opportunity to speak at the MSC meeting.
42. PISC and ECEAE do not raise any arguments concerning the alleged breach of Articles 50 to 52.

#### **Arguments of the Agency**

43. The Agency disputes the Appellant's arguments.
44. HSE does not raise any arguments concerning the alleged breach of Articles 50 to 52.

#### **Findings of the Board of Appeal**

45. Articles 50 to 52 set out the procedure for the adoption of decisions requiring further information pursuant to substance evaluation.
46. In the present case, the Agency gave the Appellant all the opportunities to comment that are expressly foreseen in Articles 50 to 52, namely the opportunity to comment on the Draft Decision and on the proposals for amendment (see paragraphs 7 to 9 and 14 to 17 above).
47. The Board of Appeal will next examine the three ways in which the Appellant claims the Agency breached Articles 50 to 52.
48. First, contrary to the Appellant's argument, Articles 50 to 52 do not give concerned registrants a right to comment on a revised draft decision (see, to this effect, Case A-009-2014, *Albemarle Europe and Others*, Decision of the Board of Appeal of 12 July 2016, paragraphs 221 and 222, and Case A-004-2015, *Polynt*, Decision of the Board of Appeal of 19 October 2016, paragraphs 58 to 62).

49. Second, neither Articles 50 to 52 nor the rules of procedure of the MSC give registrants a right to speak at MSC meetings (see, to this effect, Case A-006-2012, *Momentive Specialty Chemicals*, Decision of 13 February 2014, paragraph 127, and Case A-023-2015, *Akzo Nobel Chemicals*, Decision of the Board of Appeal of 13 December 2017, paragraph 324).
50. Third, the Agency was not obliged to grant the Appellant's request for an extension of the deadline for commenting on the proposals for amendment as the Appellant submitted its extension request after the expiry of the deadline (see paragraphs 17 to 19 above).
51. Finally, with regard to the Appellant's claim that it had legitimate expectations that it would be given an opportunity to speak at the MSC meeting, it is clear from the Agency's communication of 4 April 2016 (see paragraph 19 above) that the Appellant was not given a precise, unconditional assurance that it would be allowed to speak in the MSC meeting. Therefore, the Appellant cannot rely on legitimate expectations in this regard (see, to this effect, judgment of 21 June 2018, *Poland v Parliament and Council*, C-5/16, EU:C:2018:483, paragraph 110).
52. The Appellant's arguments alleging breaches of Articles 50 to 52 and of the principle of the protection of legitimate expectations must therefore be rejected.
53. However, there are circumstances in which, in order to comply with the right to be heard, registrants must be given an opportunity to make known their views beyond the procedural rules set out in Articles 50 to 52 (*Albemarle Europe and Others*, cited in paragraph 48 above, paragraphs 224 and 225, and *Polynt*, cited in paragraph 48 above, paragraph 65).
54. The Board of Appeal will therefore examine whether, despite the fact that the Appellant had all the opportunities to comment expressly foreseen in Articles 50 to 52, its right to be heard was nevertheless breached.

## **2. Alleged breaches of the right to be heard**

### **Arguments of the Appellant**

55. The Appellant claims that the Agency breached its right to be heard in three additional ways.
56. First, concerning information requirement 1 (EOGRTS), the Appellant claims that it should have been given an opportunity to speak at the MSC meeting in order to comment on the changes made by the MSC to the Amended Draft Decision, namely that an EOGRTS was required instead of an OECD TG 422 study to clarify whether climbazole is a reproductive toxicant (see paragraph 20 above).
57. Second, concerning information requirement 2 (aerobic sludge treatment simulation study), the Appellant claims that HSE assessed the reliability of the Richter *et al.* (2013) study by obtaining further data directly from one of the authors of that study (see paragraph 5 above). The Appellant claims that HSE did not share all the data it received with the Appellant. The Appellant was therefore unable to comment on these new data.
58. In addition, the Appellant argues that the Contested Decision states that the reliability score of the Richter *et al.* (2013) study is Klimisch 2 without explaining the details of the assessment behind this score. This constitutes a breach of the duty to state reasons.
59. Third, concerning information requirement 3 (*in vitro* endocrine disruption screening studies), the Appellant claims that HSE included in the Revised Draft Decision references to information on which the Appellant did not have the opportunity to comment, namely:

- information derived from an assessment of climbazole carried out in the United States of America ('Tox21 data'),
  - information on oestrogen receptor bioactivity from the Endocrine Disruptor Screening Program carried out by the Environmental Protection Agency of the United States of America ('EPA EDSP information'),
  - environmental data on a structural analogue to climbazole which were discussed in a meeting of the Agency's Risk Assessment Committee in December 2015 ('RAC data'),
  - S. Chen *et al.*, *Cell-Based High-Throughput Screening for Aromatase Inhibitors in the Tox21 10K Library*, (2015) *Tox. Sci.* 147(2), 446-457 (the 'Chen *et al.* (2015) study'), and
  - P. Matthiessen and L. Weltje, *A review of the effects of azole compounds in fish and their possible involvement in masculinization of wild fish populations*, (2015) *Crit. Rev. Tox.* 45(5), 453-467 (the 'Matthiessen and Weltje (2015) review').
60. PISC and ECEAE do not raise any arguments concerning the alleged breaches of the right to be heard.

#### **Arguments of the Agency and HSE**

61. Concerning information requirement 1 (EOGRTS), the Agency argues that the Appellant had no right to speak at the MSC meeting. However, the Appellant had the opportunity to comment on the proposal for amendment submitted by the competent authority of Denmark proposing an EOGRTS (see paragraphs 13 and 14 above).
62. Concerning information requirement 2 (aerobic sludge treatment simulation study), the Agency, supported by HSE, argues that all information on the Richter *et al.* (2013) study that was known to HSE was available to the Appellant in the draft substance evaluation report which was shared with the Appellant. Consequently, the Appellant could comment on all the relevant information when commenting on the Draft Decision and was aware of the reasons why the reliability score attributed to the Richter *et al.* (2013) study was Klimisch 2.
63. Concerning information requirement 3 (*in vitro* endocrine disruption screening studies), the Agency, supported by HSE, argues that the information included in the Revised Draft Decision was discussed with the Appellant at a meeting of the Agency's Endocrine Disruptor Expert Group (see paragraph 10 above). That meeting of the Endocrine Disruptor Expert Group was referred to expressly in the proposal for amendment submitted by the Agency.
64. In addition, the Agency claims that the Appellant's arguments on information requirement 3 (*in vitro* endocrine disruption screening studies) are ineffective because, even if upheld, they would not lead to the annulment of the information requirement. According to the Agency, the reasoning in the Draft Decision was sufficient to support information requirement 3 even without reference to the information identified in paragraph 59 above.



### **Findings of the Board of Appeal**

65. The right to be heard is enshrined in Article 41 of the Charter of Fundamental Rights as part of the right to good administration.
66. In the context of substance evaluation, the right to be heard requires that concerned registrants are placed in a position in which they can effectively make known their views on all the information on which a decision is based as well as the information requirements that the decision will impose (see, to this effect and by analogy, judgments of 23 October 1974, *Transocean Marine Paint Association v Commission*, C-17/74, EU:C:1974:106, paragraph 15, and of 22 October 2002, *Schneider Electric v Commission*, T-310/01, EU:T:2002:254, paragraphs 453 to 460).
67. The right to be heard is not a mere procedural formality. It is a fundamental right and serves a twofold purpose.
68. First, the right to be heard allows the addressees of decisions that significantly affect their interests to defend themselves by influencing the decision-making process (see, to this effect, judgment of 3 July 2014, *Kamino International Logistics and Datema Hellmann Worldwide Logistics*, C-129/13 and C-130/13, EU:C:2014:2041, paragraphs 28, 30 and 38).
69. Second, the right to be heard ensures that decisions are taken with all due care and prudence, so that all relevant factors and circumstances are taken into account and the decision is substantively correct (see, to this effect, *Kamino International Logistics and Datema Hellmann Worldwide Logistics*, cited in the previous paragraph, paragraph 38).
70. In the present case, the Agency gave the Appellant all the opportunities to comment that are expressly foreseen in Articles 50 to 52 (see Section 1 above).
71. If the relevant procedural rules have been followed, the right to be heard is normally deemed to have been respected (*Polynt*, cited in paragraph 48 above, paragraph 63).
72. However, Articles 50 to 52 do not make provision for the three specific situations that, according to the Appellant, are at issue in the present case, namely:
  - first, the MSC modified the Amended Draft Decision to require an EOGRTS to clarify a reproductive toxicity concern; the Appellant was not given an opportunity to comment on this particular combination of study and concern,
  - second, some of the data on which the request for an aerobic sludge treatment simulation study is based were not shared with the Appellant; the Appellant therefore could not comment on the correctness and relevance of these data, and
  - third, the Revised Draft Decision referred to new information in support of the request for *in vitro* endocrine disruption screening studies; the Appellant was not given the opportunity to comment on the correctness and relevance of this new information.
73. The Board of Appeal will therefore examine whether the Appellant's right to be heard was breached in any of these three situations.

#### **2.1. Information requirement 1 (EOGRTS)**

74. The Appellant claims that it should have been given an opportunity to comment on the changes that occurred when the MSC modified the Amended Draft Decision to require an EOGRTS instead of an OECD TG 422 study to address a reproductive toxicity concern.

75. The Draft Decision required an OECD TG 422 study to clarify whether climbazole is a reproductive toxicant. When commenting on the Draft Decision, the Appellant therefore had the opportunity to comment on whether an OECD TG 422 study should be requested in order to clarify whether climbazole is a reproductive toxicant. The Appellant agreed in principle to conduct such a study (see paragraphs 8 and 9 above).
76. The competent authority of Denmark subsequently proposed an EOGRTS to clarify whether climbazole is an endocrine disruptor. When the Appellant had the opportunity to comment on this proposal for amendment it therefore had the opportunity to comment on whether an EOGRTS should be requested in order to clarify whether climbazole is an endocrine disruptor (see paragraphs 13 and 14 above).
77. However, the MSC finally agreed to request an EOGRTS in order to clarify whether climbazole is a reproductive toxicant, not whether climbazole is an endocrine disruptor. This change was made in the very last stage of the decision-making procedure (see paragraph 20 above), namely in the closed session of the MSC meeting to which the Appellant was not invited. The Appellant therefore did not have the opportunity to comment on whether an EOGRTS should be requested in order to clarify whether climbazole is a reproductive toxicant.
78. In these circumstances, the Appellant's right to be heard was breached because it did not have an opportunity to comment on the specific combination of the requested study (EOGRTS) and the potential concern (reproductive toxicity).
79. Moreover, as regards information requirement 1 (EOGRTS), the Contested Decision states:

*'The relative merits of the [OECD TG 422 study] and the [EOGRTS] were discussed at the [MSC meeting] and it was concluded that in using a similar number of animals, the [EOGRTS] would provide more information on endpoints leading to a more comprehensive assessment of reproductive toxicity which can contribute to regulatory risk management. This was highlighted as being important due to the severe reproductive hazard identified in a close structural analogue, triadimenol (EC 259-537-6).'*
80. It is therefore clear that the relative merits of the EOGRTS and OECD TG 422 constituted an important issue in deciding how the reproductive toxicity concern identified should be addressed.
81. The available information on climbazole also gives rise to a considerable degree of scientific uncertainty. Depending on its interpretation, the available information might indicate a potential concern for reproductive toxicity and/or neurotoxicity and/or endocrine disruption. Depending on how the available information is interpreted, therefore, an EOGRTS or an OECD TG 422 study might be required.
82. This context of scientific uncertainty regarding the potential concern or concerns to be clarified and the different tests available to do so, coupled with the broad margin of discretion available to the Agency under the substance evaluation process, makes it all the more important that the right to be heard should be respected (see, to this effect and by analogy, judgment of 21 November 1991, *Technische Universität München*, C-269/90, EU:C:1991:438, paragraphs 13 and 14).
83. In these circumstances, it is clear that, if the Appellant had been heard on whether an EOGRTS should be requested in order to clarify whether climbazole is a reproductive toxicant, the outcome of the decision-making procedure might have been different.
84. The Appellant's plea alleging a breach of the right to be heard must therefore be upheld with regard to information requirement 1 (EOGRTS).

**2.2. Information requirement 2 (aerobic sludge treatment simulation study)**

85. The Appellant claims that its right to be heard was breached because the Contested Decision requires an aerobic sludge treatment simulation study on the basis of information which was not disclosed to it, namely information that HSE obtained directly from one of the authors of the Richter *et al.* (2013) study.
86. The Appellant also claims that the Agency breached the duty to state reasons by failing to explain, in the Contested Decision, the reasons why it assigned a Klimisch 2 score to the Richter *et al.* (2013) study.
87. First, as regards the alleged breach of the right to be heard, HSE examined in the draft substance evaluation report the Richter *et al.* (2013) study using information obtained directly, by email, from one of the authors of that study (see paragraph 5 above).
88. The Appellant was not given this email. However, the Appellant was given a copy of the draft substance evaluation report before being given the opportunity to comment on the Draft Decision (see paragraph 6 above).
89. A comparison of the draft substance evaluation report with the email sent to HSE by one of the authors of the Richter *et al.* (2013) study shows that the draft substance evaluation report correctly and completely reflected the information contained in that email.
90. The Appellant could therefore comment on all the information available to HSE and the Agency concerning the Richter *et al.* (2013) study when it commented on the Draft Decision.
91. It follows that the Agency did not breach the Appellant's right to be heard with regard to the Richter *et al.* (2013) study.
92. Second, as regards the alleged breach of the duty to state reasons, the draft substance evaluation report explained, succinctly but clearly, why HSE assigned a Klimisch 2 score to the Richter *et al.* (2013) study. The Appellant therefore knew the reasons underlying the Klimisch 2 score assigned to that study.
93. It follows that the Agency did not breach the duty to state reasons with regard to the Klimisch score assigned to the Richter *et al.* (2013) study.
94. The Appellant's pleas alleging breaches of the right to be heard and the duty to state reasons with regard to information requirement 2 (aerobic sludge treatment simulation study) must therefore be rejected.

**2.3. Information requirement 3 (*in vitro* endocrine disruption screening studies)**

95. The Appellant claims that it did not have the opportunity to comment on the information supporting the request for *in vitro* endocrine disruption screening studies that was included for the first time in the Revised Draft Decision, namely the Tox21 data, the EPA EDSP information, the RAC data, the Chen *et al.* (2015) study, and the Matthiessen and Weltje (2015) review.
96. The Appellant had the opportunity to comment on the Draft Decision and on the proposals for amendment (see paragraphs 7, 9 and 14 above).
97. The EPA EDSP information was expressly mentioned in the proposal for amendment submitted by the Agency. The Appellant therefore had the opportunity to make known its views on the correctness and relevance of this information.

98. The Tox21 data, the RAC data, the Chen *et al.* (2015) study, and the Matthiessen and Weltje (2015) review, however, were not mentioned expressly in the Draft Decision or in any of the proposals for amendment. They were also not included in the Appellant's registration dossier or mentioned in its comments on the Draft Decision.
99. The Appellant therefore did not have the opportunity to make its views known on the correctness and relevance of the Tox21 data, the RAC data, the Chen *et al.* (2015) study, and the Matthiessen and Weltje (2015) review during the decision-making procedure.
100. The Agency argues that this information was discussed in another forum, namely a meeting of the Endocrine Disruptor Expert Group, in the presence of the Appellant (see paragraphs 10 and 63 above).
101. However, the Endocrine Disruptor Expert Group is neither part of the substance evaluation decision-making procedure, nor the broader substance evaluation process. Although the Endocrine Disruptor Expert Group provides informal scientific advice on the identification of endocrine disrupting properties of substances, decision-making under the substance evaluation process remains the responsibility of the competent authorities of the Member States and the Agency. The discussions at this meeting were therefore insufficient to ensure that the right to be heard was respected.
102. It follows that the Appellant was not given an opportunity to put forward its views effectively on the correctness and relevance of the Tox21 data, the RAC data, the Chen *et al.* (2015) study, and the Matthiessen and Weltje (2015) review to support information requirement 3 (*in vitro* endocrine disruption screening studies).
103. In these circumstances, the Appellant's right to be heard was breached because it did not have an opportunity to make its views known effectively on the Tox21 data, the RAC data, the Chen *et al.* (2015) study, and the Matthiessen and Weltje (2015) review, which were used to support information requirement 3 (*in vitro* endocrine disruption screening studies).
104. Moreover, as regards information requirement 3 (*in vitro* endocrine disruption screening tests), the Draft Decision states:

*'Several azole-containing pesticides and pharmaceuticals can disturb the endocrine system in fish. A literature search did not identify any information on the endocrine-disrupting potential of climbazole, but given its widespread detection and persistence in the environment, it is considered prudent to request some evidence to inform on this possibility. In vitro screening tests provide results quickly and do not involve the use of vertebrates.'*
105. This reasoning is couched in such generic terms that it was insufficient to justify information requirement 3 (*in vitro* endocrine disruption screening studies).
106. Contrary to the Agency's argument, therefore, the references to the Tox21 data, the RAC data, the Chen *et al.* (2015) study, and the Matthiessen and Weltje (2015) review were not simply additions to strengthen a justification that was already sufficient in itself.
107. Had the Appellant been heard on this information, the outcome of the decision-making procedure might consequently have been different.
108. The Appellant's plea alleging breaches of the right to be heard must therefore be upheld with regard to information requirement 3 (*in vitro* endocrine disruption screening tests).

### **3. Conclusion**

109. The Board of Appeal has rejected the Appellant's pleas and arguments alleging breaches of Articles 50 to 52 and the protection of legitimate expectations related to the whole of the Contested Decision (see Section 1 above).
110. As the Appellant raises no further arguments with regard to information requirement 4 (further information on worker exposure) the appeal must be dismissed with regard to this information requirement.
111. The Board of Appeal has rejected the Appellant's pleas and arguments alleging breaches of the right to be heard and the duty to state reasons as regards information requirement 2 (aerobic sludge treatment simulation study; see Section 2.2 above). As the Appellant raises no further arguments contesting information requirement 2 (aerobic sludge treatment simulation study) the appeal must be dismissed with regard to this information requirement.
112. The Board of Appeal has found that the Agency breached the Appellant's right to be heard as regards information requirements 1 (EOGRTS; see Section 2.1 above) and 3 (*in vitro* endocrine disruption screening studies; see Section 2.3 above). These information requirements must therefore be annulled and the case remitted to the competent body of the Agency for further action in accordance with Article 93(3).
113. There is therefore no need to examine any other of the Appellant's pleas and arguments with regard to information requirements 1 and 3 (EOGRTS and *in vitro* endocrine disruption screening studies).
114. Finally, as information requirement 1 (EOGRTS) is the only test on vertebrate animals required by the Contested Decision, and this information requirement is annulled, there is no need to decide on the admissibility or substance of the pleas and arguments concerning vertebrate animal testing under the Cosmetics Regulation raised by ECEAE, PISC and the Appellant (see paragraphs 29, 30 and 37 above).

### **Refund of the appeal fee**

115. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to REACH (OJ L 107, 17.4.2008, p. 6), the appeal fee shall be refunded if the appeal is decided in favour of an appellant.
116. As the appeal has been partially decided in favour of the Appellant, the appeal fee must be refunded.

### **Effects of the Contested Decision**

117. According to Article 91(2), an appeal has suspensive effect.
118. The Contested Decision required the Appellant to provide the information at issue by 9 July 2018, which is 24 months and 9 days from the date of its adoption.
119. The deadline set in the Contested Decision corresponds to the time required for performing an EOGRTS, which is the most time-consuming of the information requirements set out in the Contested Decision.

120. As the Agency explained at the hearing, and the Appellant did not dispute, performing the aerobic sludge simulation study will take approximately 12 months, whilst collecting and submitting the required information on worker exposure will require approximately 6 months. The two information requirements can be complied with simultaneously.
121. In the light of the Parties' positions, as expressed at the hearing, the Board of Appeal considers that the Appellant should be given 12 months to perform the aerobic sludge simulation study and collect the required information on worker exposure, and an additional three months for preparatory work.
122. It is therefore appropriate that the Board of Appeal should set a new deadline for providing the aerobic sludge simulation study and the information on worker exposure, namely 15 months from the date of notification of the present decision.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Annuls the Contested Decision insofar as it requires the Appellant to submit an EOGRTS and *in vitro* endocrine disruption screening studies (information requirements 1 and 3).**
- 2. Remits the case to the competent body of the Agency for further action in relation to information requirements 1 and 3.**
- 3. Dismisses the appeal for the remainder.**
- 4. Decides that the information on an aerobic sludge simulation study and further information on worker exposure (information requirements 2 and 4) must be submitted to the Agency by 8 November 2019.**
- 5. Decides that the appeal fee must be refunded.**

Sari HAUKKA

On behalf of the Chairman of the Board of Appeal

Marc GOODACRE

On behalf of the Registrar of the Board of Appeal